

**Framing the Issue – How the Medical Device Industry’s Arguments
Translated into Political Tools and Action**

Megan Elizabeth Baker

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Gabriel Blouin-Genest, Chair
Karen M. Hult
Jason P. Kelly

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ABSTRACT

The Medical Device Excise Tax (MDET) was developed as a funding source to help cover the cost of expanded health care coverage through the Affordable Care Act (ACA). The excise tax is a 2.3% tax on sales of certain medical devices and is paid by the manufacturer of the device (Bolka, 2014). This thesis reflects on the theoretical and conceptual framework that the analysis is based on, including concepts such as success/failure, policy actors, and efficiency/equity. It underlines the importance of framing the argument in the policy making process by analyzing the four main arguments that are developed by the medical device industry including: innovation, jobs, patient care, and loss of global leadership. It also looks at the arguments that were translated into the actions, which were followed by the medical device industry: campaign contributions, lobbying, and interest groups. In conclusion, the importance of unofficial actors, their framing of the issues, and how that framing develops into action are recognized and understood.

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GENERAL AUDIENCE ABSTRACT

The Medical Device Excise Tax (MDET) was developed as a funding source to help cover the cost of expanded health care coverage through the Affordable Care Act (ACA). The excise tax is a 2.3% tax on sales of certain medical devices and is paid by the manufacturer of the device (Bolka, 2014). This thesis reflects on concepts such as (1) success and failure, (2) individuals and organizations involved, as well as (3) efficiency and equity. It underlines the importance of framing the argument in the policy making process by analyzing the four main arguments that are developed by the medical device industry including: innovation (development of new medical devices), jobs, patient care, and loss of global leadership. It also looks at the arguments that were translated into the actions, which were followed by the medical device industry: campaign contributions, lobbying, and interest groups. In conclusion, the importance of industry actors, their framing of the issues, and how that framing develops into action are recognized and understood.

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Acronym list

ACA	Patient Protection and Affordable Care Act
AdvaMed	Advanced Medical Technology Association
CRS	Congressional Research Service
MDET	Medical Device Excise Tax
MDMA	Medical Device Manufacturers Association
MITA	Medical Imaging & Technology Alliance
R&D	Research and Development

INTRODUCTION: THE REPEAL OF THE MEDICAL DEVICE TAX AS A POLICY SUCCESS

The Patient Protection and Affordable Care Act (ACA) has been a point of contention since it was signed into law by President Barack Obama on March 23, 2010. The ACA is a law concerned with increasing the affordability and quality of health insurance, lowering the rate of those that are uninsured, and reducing the cost of healthcare for individuals (U.S. Department of Health & Human Services, 2015). ACA raised important and highly politicized debates when it was being introduced. Conservatives believe that the law is meddling in private business affairs because it requires employers to offer healthcare, while liberals find that all human beings should have access to quality and affordable health care. The main point of dispute in regards to this law is how it is funded through new and different tax policies (Bolka, 2014: 3). This thesis looks at what was one of the main funding contributors, the medical device industry, through the Medical Device Excise Tax (MDET).

The MDET was developed as a funding source to help cover the cost of expanded health care coverage. The excise tax is a 2.3% tax on sales of certain medical devices¹ and is paid by the manufacturer of the device (Bolka, 2014). The tax went into effect on January 1, 2013, and was expected to gross \$29 billion dollars over a ten-year time span. According to the Congressional Research Service's (CRS) report on the MDET, the tax was defensible by the Congress due to its expected revenue. As the tax was developed it was said that "the tax was justified partly because the medical device industry was among the commercial interests that stood to benefit from

¹ As pointed out by Bolka, "[t]he 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" (Bolka, 2014: 1697).

unanticipated profits as more individuals, enroll in health care insurance, post-ACA” (Gravelle and Lowry, 2015: 2). Although the tax is reasonable to Congress, the medical device industry does not believe that the tax is acceptable. Even if the industry would benefit from ACA, the medical device industry agrees with Gravelle and Lowry who say “[v]iewed from the perspective of traditional economic and tax theory, however, the tax is challenging to justify” (Gravelle and Lowry, 2015: 2). Gravelle and Lowry explain that tax policy is more efficient when differential excise taxes are not imposed, and find it more efficient to raise revenue from a broad tax base (Gravelle and Lowry, 2015:2). Therefore excise taxes are usually based on specific objectives such as discouraging undesirable activities or funding closely related government spending - these justifications do not resonate with the MDET (Gravelle and Lowry, 2015: 2).

The MDET is so current and fluid that in December of 2015 news broke that the MDET would have a two-year suspension. The Medical Device and Diagnostic Industry website released a news bulletin titled, “Congress [g]ives [d]evice [m]akers a [b]reak from [e]xcise [t]ax” with a story following that said “[b]oth the House and Senate have passed a tax deal that includes a two-year suspension of the controversial medical device tax” (Thibault, 2016).

According to HIT Consultant the MDET’s recent suspension “could rejuvenate [the] market” (Pennic, 2016). Analysts find the temporary repeal to be a positive development, and the medical device industry has considered it a success. However, can the temporary repeal be considered a success by the industry if the repeal is not yet permanent? Is it possible for this repeal to be considered a policy process success and policy process failure at once? This thesis looks at the actors involved with the tax, the ways in which they frame the issue, and what ultimately resulted in the actions taken by the medical device industry to temporarily suspend the tax.

Since the MDET was created the medical device industry has made it one of their missions to get the MDET permanently repealed. The industry's main arguments against the MDET are (1) reduction of R&D as well as (2) job budgets, (3) impacts on patient care, and the (4) loss of global leadership within the industry. Most recently in January 2016 the MDET was repealed for two years. The tax was only put into effect three short years ago, and now is going through a temporary repeal, this raises questions about the legitimacy of the tax.

The timeline that the MDET follows, first being passed into law, then shortly after that being temporarily repealed, and with continuing efforts to have it definitively repealed by the medical device industry brings some questions that need more attention:

- (1) How exactly does the medical device industry frame the MDET?
- (2) Why is the medical device industry first unsuccessful in stopping the tax from becoming law, and then partly successful with a temporary repeal?
- (3) What exactly did the medical device industry do?
- (4) What does it tell us about the policy process?
- (5) What can we learn regarding the politics behind the MDET and the overall healthcare reform?

One of the main objectives of this thesis is to dissect the different arguments that the medical device industry has against the MDET, their viewpoints of fairness and efficiency, and their actions regarding lobbying and political support. Another is to explain how the medical device industry has both failed and succeeded in regards to the MDET and does it say anything about the policy process in the United States. The emphasis is placed on the way that the medical

device industry frames the issue and how their arguments shape political and policy actions by the actors within this policy process.

I.1 The context: situating the researcher

The overall objective of this thesis is linked to my personal experience. This personal experience is necessary to underline for methodological reasons, in order to first, underline my relationship with my research object, and second, to explain where my interest in this topic comes from and to justify my research questions. Currently, I work within the Corporate Communications department at the Stryker Headquarters in Kalamazoo MI and have been with Stryker since 2014. Stryker is a global medical device company that started in 1941 and today is a leader in the medical technology industry with over 30,000 employees around the world.

Although my current profession is not directly tied to the legal or government relations side of Stryker, I still have a sincere interest in what is going on within Congress as well as the international relations functions of Stryker. Also, within the corporate function that I am housed, we are a part of a larger team that has a Government Affairs department. Topics surrounding the MDET arise frequently. I was very aware of the Affordable Care Act when I started working at Stryker. However, in all honesty, I did not know much about the Medical Device Tax. Once I began working for a Medical Device Company, I learned a lot about this specific tax and realized that it was a large topic of conversation amongst the business. On a daily basis, this subject is discussed in emails, newsletters, and even CEO Town halls. I rapidly realized that it is a significant and sensitive issue for businesses in the medical device industry. Of course, within the medical device industry, the comments behind the MDET were negative, the tax always being considered unfair.

Being involved in this environment as an employee of a major medical device company, I found myself questioning the tax more, and started to do additional research. My research led me to start questioning how fair and efficient this tax is and how this framing of the issue shapes the medical device industry practices, actions, and arguments about the tax. How did the medical device industry frame the issue of MDET as a payment method for ACA? What the medical device industry wanted to do to get the tax permanently repealed, and what have they already done that gave them success? It made me wonder what kinds of arguments are put into action within a business to make real policy change.

Throughout this work, my interest particularly peaked when looking at what was being done by not just Stryker, but the rest of the industry as well to try and have this tax repealed. It made me curious to think of this case study and what other companies are seeking to do to become active in laws related to their business and successful in impacting regulation related to taxation. The medical device industry as a whole has spent much of its time building coalitions, lobbying, and involving its top executives in trying to have the tax repealed. It brings me to the question of how the framing of issues translates into actions in the policy process and how it shapes the result of the policy process. Then how are these actions translated into a policy success or failure?

This topic deserves to be researched. It is exciting and relevant in the current health debate and warrants more discussion and analysis. Asking what caused the medical device industry to “fail” in its attempt to stop the MDET from becoming an ACA funding source, and what has caused them to “succeed” in the temporary repeal of the MDET will help to better understand the role of different actors in the policy process. The debate is still taking place for the medical device industry, there are still actors lobbying for its permanent repeal, and as this continues more insight into how these issues are framed should take place. The research object of this thesis is

consequently still changing, but this research will help shed new light on policy processes and the role of framing the issue in policy action.

I.2 Questioning the research object: main and secondary research questions

Although the MDET is repealed temporarily for the next two years, medical device companies are still asking for the permanent repeal of the tax. Therefore not only success but also failure is seen in regards to the medical device industries actions towards the MDET. This thesis will ask and answer the following questions:

I.2.1 Main research questions

1. How and why did the medical device industry fail by allowing the MDET be passed into law and then having a temporary repeal rather than a permanent repeal?
2. How and why did the medical device industry partly succeed by having the MDET repealed temporarily?

I.2.2 Secondary research questions

Secondary research questions that arise from the main research questions include:

1. How does the medical device industry frame the issue of the MDET and how does this framing translate into arguments used by the medical device industry against the MDET?
2. Does the medical device industry view the MDET as a fair and efficient way to fund and spread the cost of the ACA across the health industry?
3. What types of actions are the medical device industry taking to have the tax repealed and how are these actions shaped by the medical device industry's framing of the issue?

4. What other policy alternatives are suggested by the medical device industry and why have the medical device industry's efforts failed in getting Congress to select another form of financial delivery for ACA?

The main hypothesis that is developed tested through qualitative analysis² is that the medical device industry failed to stop Congress from passing a law allowing the MDET to be its main funding source because of the medical device industry's failure to provide an alternative option for the funding that was appealing to Congress. This failure is a link to the fact that the medical device industry found the tax to be by nature unfair and inefficient, thus limiting its ability to think about other policy options.

I hypothesize that the medical device industry succeeded in having the tax repealed temporarily due to (1) the coalitions that have developed throughout the industry and (2) because of the medical device industry's consistency in their arguments since the tax came into existence. Notably, the use of arguments based on innovation, jobs, patient care, and the loss of global leadership seemed also to play a central role in the failure and success of the medical device industry, strengthening the arguments that the tax is unfair and/or inefficient to the medical device industry. Finally, I hypothesize that both Congress and the medical device industry's viewpoint is that the MDET did not fund ACA as it was intended to when it was first written into law, bringing force to the main arguments of the industry, and leading to this mix of success and failure.

I.3 Topic and research question justification:

I.3.1 Literature on the MDET

² See section I.4 for more details.

The Medical Device Excise Tax is a research subject that does not currently have much scholarly analysis. Characteristically the work that is done surrounding ACA covers some information about the MDET, but the MDET is often not considered the main research object or topic. The lack of investigation and analysis may be because this is a relatively new topic and also because it is a piece of a much larger policy, that being the ACA. During the research phase, there were four major pieces found and considered to be scholarly work that considered the MDET their main research object.

Elizabeth M. Bolka in her article “The Medical Device Excise Tax: An Unfair Burden” gives an in-depth look at the MDET tax itself, the path that is taken to the MDET, and describes who and what is taxed. She goes into further detail discussing the economic impacts, arguments for the tax, and the political uproar that has ensued surrounding the tax. She finds that the tax is “an unfair burden based on flawed assumptions” (Bolka, 2014: 1716). In her conversation, she gives some ways to “reduce the burden” of the tax without having a complete repeal (Bolka, 2014: 1719).

Kramer and Kesselheim analyze the Medical Device Excise Tax in *The New England Journal of Medicine*. They question “where did the excise tax come from? Why is it now in danger of appeal? Moreover, what would repeal mean for the ACA?” Through their piece, both scholars look at the arguments against the tax as well as arguments disproving or questioning those of the medical device industry. The conclusion that they come to is that this tax has “uncertainty surrounding” it and that there are “unsettling questions about other future efforts to tackle rising health care costs in the context of the ACA’s expansion of health insurance” (Kramer and Kesselheim, 2013: 1768).

In Paul Van de Water's writing on the Medical Device Excise Tax, his analysis finds that the "industry lobbyists distort [the] tax's impact" (Van de Water, 2013: 1). He makes three main points: (1) the tax does not single out the medical device industry, or cause unfair treatment (2) the tax will not impact manufacturer's decisions to shift production overseas (3) the tax will have little to no effect on innovation in the industry (Van de Water, 2013: 1). He also concludes that the tax will have little impact on consumers (Van de Water, 2013: 6).

Kensington Wolgamott cleverly titles his article, "No Longer Left to their Own Devices: Evaluating the Non-Traditional Medical Device Excise Tax" (Wolgamott, 2015: 497). The first part of his writing defines what an excise tax is, and provides information around the MDET. The second part of the writing looks at the structure of the tax, and lastly in part three looks at factors that should be watched and are necessary to include in discussions about the future of the MDET. Wolgamott concludes that although there are strong arguments from both Congress and the medical device industry, "the fate of the MDET is best left for future discussions" (Wolgamott, 2015: 26). He says that "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 (Wolgamott, 2015: 26). Wolgamott argues even further that more time must be spent researching the Medical Device Excise Tax and that it is a new object of research. He believes that is a topic that is of high interest, is fascinating, and deserves to be analyzed.

After looking at these four scholarly pieces of work directly studying the MDET, we come to a few conclusions in regards to research regarding the MDET. The clearest conclusion being that more research must be done on this topic. Both authors Kramer/Kesselheim and Wolgamott have main findings within their work, and they are stating that more research must be done on this

subject. Kramer and Kesselheim find that there is too much uncertainty and conclude that it is unsettling, while Wolgamott says that there must be more research and analysis. Although Bolka and Van de Water have very clear points of view, it is fair to say that since all four articles were only written between 2013 and 2015, and the MDET was temporarily repealed in late 2015 that there is more research to be done. It is too early even to have scholarly sources reflecting on the results of the temporary repeal.

I.3.2 Analytical background and timeline

This thesis is written containing information about the tax after and while it was functioning. It is a policy story as well as a policy analysis, meaning that it looks at what went into the evolution of the legislation as well as what worked and didn't work during the few years that it was in place. Answers are offered as to what the medical device industry was fighting for before the policy was functional as well as during, and what their suggestions were to fund ACA besides the MDET. This thesis is an analysis of what was done by the medical device industry, what mistakes were made, and what their inabilities were before the tax was put into place, but also what did work for them, and how they were able to get the tax suspended for a short period of two years. It looks at the coalitions that developed amongst hospitals, doctors, and the medical device industry. An analysis of this information will help determine what the main causes for the tax to be implemented, and why the efforts of the medical device industry failed before, and then succeeded shortly after.

Government actors (policy makers) are offered as an important piece to dissect. A closer look is taken at the officials that contributed to the authorship of ACA and the MDET mechanism. Not only are specifics in regards to each politician are analyzed, but also what roles that they play in their committees, and the representation of medical device companies within their districts. This

information was readily available through AdvaMed provides insight into why and how these policy makers were able to create this tax, and not have it be repealed. The research was also done to look at these actors not only before the tax but also after it was activated to see what their role was in its suspension.

By looking at how the medical device industry succeeded in the temporary tax repeal, there is a better overall understanding of how important coalitions, officials, and lobbying efforts are to policy adoption within the medical industry. Although this thesis is looking at the medical industry, ultimately it is offering the political science discipline research on the policy making process, and what impacts that process. It also provides information on how tax policy can be altered, why it is altered, and the impact that different coalitions can have on legislative decisions.

Although this case study focuses on the medical device industry, it will be helpful in explaining how actors affected by policy can intervene and shape the policy process in any industry. It also explains how these changes are produced through the interaction between ideas, framing, and actions. This thesis thus seeks to better explain policy process in complex settings involving actors and other types of relationships.

The research in this thesis is valuable to the Political Science discipline and the sub-field of public policy. This analysis will help not only the overall policy process, as understood with the traditional “stage model” (Kraft and Furlong, 2012; Cochran et al., 2015; Jann and Wegrich, 2006: 45) where unofficial³ and/or private actors are not directly involved, but also to explore how these actors impact the agenda setting process. The agenda setting process understood as “[t]he

³ Throughout this thesis many terms/concepts are used to talk about this type of actor (“unofficial, informal, non-traditional, non-governmental, etc.”) we will use the term “unofficial actor” to refer to actors that do not fit into the “formal government institutions involved in making public policy” (Kraft & Furlong, 2012: 59).

process by which problems and alternative solutions gain or lose public and elite attention” (Birkland, 2014: 106), can thus be better understood and added with non-tradition factors such as framing.

The hypothesis stressing that the medical device industry failed in getting the permanent repeal because they were unable to propose credible alternatives, exemplifies Schattschneider’s statement that “the definition of the alternatives is the supreme instrument of power.” (Schattschneider, 1960: 68). Our analysis of the role and framing ideas of the medical device industry allows us to respond to two of the biggest problems of public policy analysis, 1) the lack of attention given to unofficial actors (Birkland, 2014: 31) and 2) the role of framing in the policy process (Cochran et al., 2015).

This research provides Political Science with the understanding of strategy that is used by businesses (in this case the medical device industry) that are involved in matters targeted by policies, and the efforts that they put forth to have taxes repealed, and what does and does not work. Although this thesis directly looks at the medical device case study, it also can use this information for other businesses and how they can develop their strategies for changing legislation related to taxes. This research also helps us to understand the coalitions that are developed and the research that is done by businesses to develop these coalitions.

On the other hand, this works also helps us to understand legislative officials, the impact they have on business through tax, and ways that both the business and policy actors can collaborate to develop better solutions. A major piece of this research is understanding the alternatives that could have been executed to satisfy both ACA as well as the medical device industry.

Overall the answers to these questions provide us insight into the involvement of businesses in legislative decision-making and the broader policy processes. This thesis gives us two perspectives, first helping us understand the framing of issues by the medical device industry, but also how this framing influences their strategies and decision-making processes. Secondly, it helps us understand Congress, how individual policy maker's perceptions are influenced, and translate into actions that develop legislation and taxes related to the medical device industry

I.4 The MDET as a research object: Methods, methodology

In order to answer the research questions and test the hypothesis, a mixed method research approach was used when analyzing how the medical device industry succeeded and failed in their efforts to have the MDET repealed. A mixed methodology is said to “involve[s] the collection, analysis, and integration of quantitative and qualitative data in a single or multiphase study” which is exactly the type of method used in this MDET study (Creswell et al., 2005: 1). Qualitative methods were used in a comparative theoretical analysis of primary and secondary sources for background information. Both the primary and secondary sources contained quantitative as well as qualitative data and were both analyzed through qualitative analysis. The quantitative data was looked at and analyzed, but not collected during this research. According to Hesse-Biber, “[m]ixed methods research holds greater potential to address these complex questions by acknowledging the dynamic interconnections that traditional research methods have not adequately addressed,” therefore by utilizing both methods and data it is easier to analyze the failures and successes of the medical device industry and how they came into existence (Hesse-Biber, 2010: 2).

Qualitative methods were used in analyzing the arguments and political tools that the medical device industry utilized in trying to stop the MDET from passing through legislation and then in being repealed. To get a true understanding of the framing that was done by the medical

device industry, primary resources were analyzed that came from coalitions of the medical device industry including AdvaMed, MITA, and the MDMA. Senate and House of Representatives' websites were also used to pull many of the primary resources that were analyzed. Documents such as advertisements, testimonies from hearings, letters to congress, memos that were written to congress and the IRS, press releases, reports that were written by the coalitions, survey data that was taken and reported as well as educational workshop materials were all used.

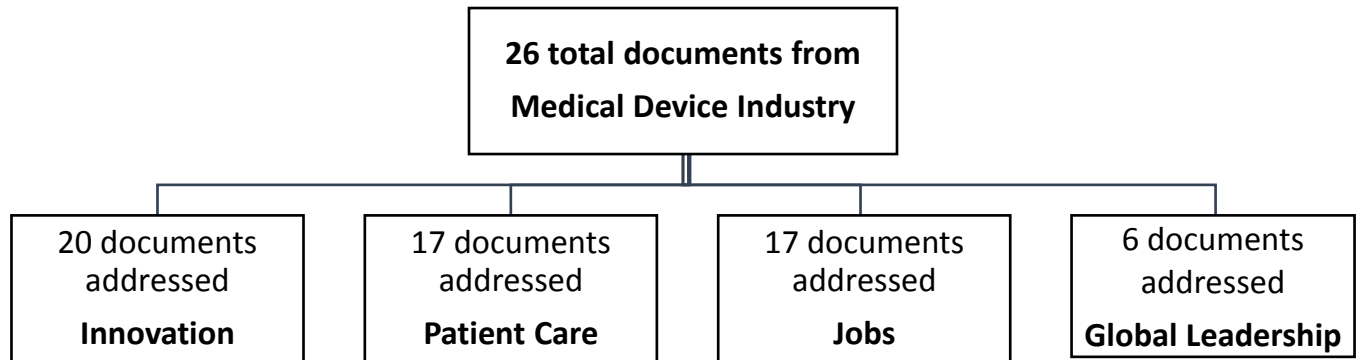
To analyze these materials, the information was put into an excel table that asked questions of each resource. This excel table is referred to as an analysis grid. The questions included:

- A. Title (name of the resource)
- B. Type of Source (i.e. advertisement, letter, report, survey, etc.)
- C. Author (who wrote the resource)
- D. Type of Actor (type of actor who wrote the resource)
- E. Time Period (when it was written/published)
- F. Goals/objectives/policy target (what was the objective of the source)
- G. Main argument
- H. Other perceptions
- I. Alternatives offered (alternatives to the MDET that were mentioned in the source)
- J. Keywords (major arguments or terminology that was mentioned)
- K. Relationship/arguments related to fairness
- L. Relationship/arguments related to efficiency

26 sources were input in the analysis grid that were then quantitatively analyzed.

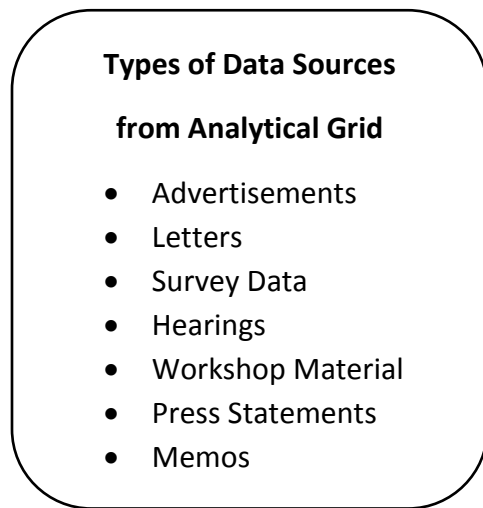
Each sheet then only contained sources that spoke directly about that keyword, in Figure 1 the number of resources for each keyword is shared. In the new sheets the resources could be looked at more deeply, they were filtered through, and qualitatively analyzed. This step provided even deeper understanding by providing insight into similarities through each of the arguments.

Figure 1 – Number of Documents Per Keyword



The analysis grid was helpful in doing a study like this because all of the sources and their arguments can be seen and compared in one place. It gives the opportunity to compare the verbiage that was used and the way in which the issue was framed by each actor. The difficulties would arise in working on this table because not every question could be answered – each source was different and required different attention. There was no major solution to this problem but caused added time in the analysis piece of reading each document individually and noting the differences. It was also problematic putting so many different types of sources into the same table because this table had letters, reports, surveys, and news releases included. To help with this, an additional column was added to indicate what type of source that it was, the types of sources are list in Figure 2.

Figure 2 – Types of Data Sources from Analysis Grid



The most difficult columns to complete for each resource were the efficiency and fairness column (questions K and L above). The other columns were able to be directly answered by the content of the document. However, these questions were often not as direct or clear. The resource wouldn't necessarily say that the tax was unfair because of a certain thing, or that it was inefficient because of a certain thing, there had to be a bit more analysis and thought behind the way in which it was framed how it would impact the industry and the specific author of that data source.

CHAPTER 1: THEORETICAL AND CONCEPTUAL FRAMEWORK

1.1 Public Policy: theoretical and conceptual framework

This chapter provides background information surrounding the concepts that are used throughout the analysis of this thesis. It also delivers an understanding of issue framing and ideas in the policy making process and how this framing of MDET influences the process around its

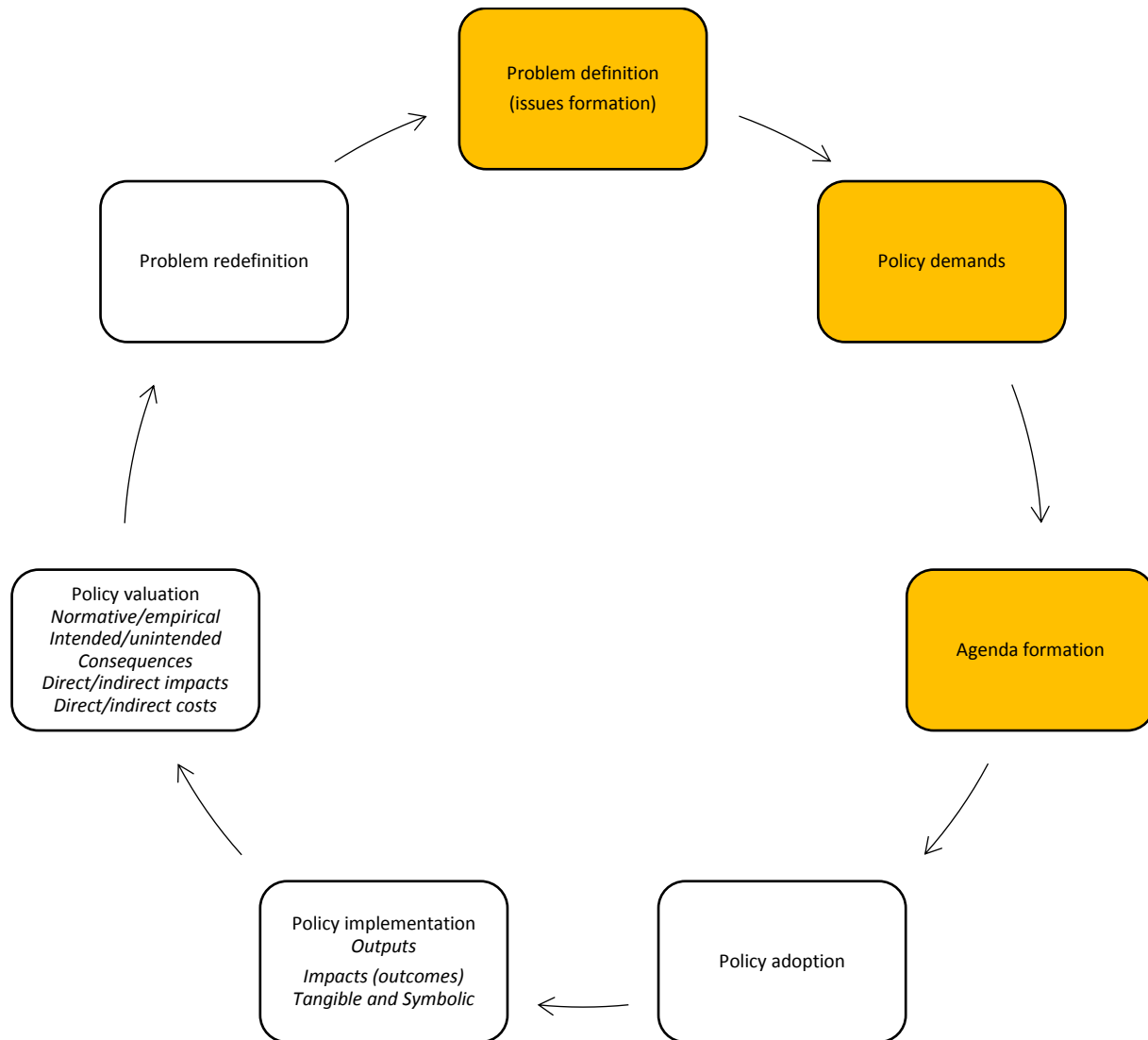
development. Also, it looks at the actors that affect the policy process and how actors are essential to these processes. Success and failure are consistently used terms throughout this study so their definition must be explored to understand what is meant by success and failure within the story of the MDET. Finally, the definitions of equity and efficiency related to the MDET and ACA are also addressed in this chapter to understand further the way the actors framed the issues throughout.

1.1.1 The Policy Process: framing, ideas and policy failure/success

There are three phases typically used to describe the policy process: design, implementation, and evaluation. This simple conceptualization known as the “simple model” (Kraft and Furlong, 2012) seeks to simplify the understanding of the policy process. However, this simple model has shown many limitations including inconsistency with the complexity of the policy process, its inability to include unofficial actors and its lack of flexibility (Birkland, 2014).

To address this limitation issue with the “simple model” other more complex and sophisticated models have been developed. The most cited would be the “stage model” (Kraft and Furlong, 2012; Cochran et al., 2015; Jann and Wegrich, 2006: 45) seen here:

Figure 3 – Stages of the Policy Process (Cochran, et al., 2015:9) – Gold blocks represent Pre-Policy Stage



This model shows the different steps of the policy process. The Stage Model is part of the rational approach to the policy process (Cochran et al., 2015: 7; Andrew, 2006: 161). The rational approach focuses on individualized behaviors (even when groups are analyzed), rationality, self-interest, gain maximization, etc. (Birkland, 2014: 254-255; Kraft and Furlong, 2012: 81-82; Howlett, Ramesh, and Perl, 2009: 32).

The main concern with the rational approach is that it usually takes into account official actors to the policy process but does not take into account the ways in which ideas are framed and the link with policy action is not directly addressed (Stone, 2012; Birkland, 2014), and not to mention that human and organizations are not always rational (Kraft and Furlong, 2012: 82-83) and/or that we don't always have the complete information to act rationally (Howlett, Ramesh, and Perl, 2009: 23)

To summarize, the Stage model and the rational process are too rigid; they underestimate the importance of collective action, and they do not take into account non-material/economic aspects. Therefore what is missing from the rational approach to the policy process and the stage model is the absence of ideas and framing of issues in the policy process. This thesis will contribute to and help respond to this problem by exploring how the framing of ideas by actors influence the policy process.

There are several scholars who have shown that ideas, viewpoints and framing play a very central role in the policy process (Cochran et al., 2015). For Birkland, perception and ideas are considered the driving factor behind the policy process (Birkland, 2014). Ideas can be used to position concerns and interests by policy makers and the general population. While on the other hand, perceptions play a very central role at different stages of the policy process, defining the problem, but also identifying the target population, and understanding responses to the policy problems, legitimate or not (Jann and Wegrich, 2006: 47).

Without different viewpoints and ideas, there are no thoughts or arguments to be had by individuals, groups or policy-makers. Few studies have however been able to incorporate ideas in the analysis of a specific policy object (such as the MDET) and the contribution of its different actors (including the unofficial ones). Throughout the arguments in this thesis, ideas and framing

are utilized because they are the building blocks for the medical device industry's arguments. The medical device industry, by sharing their viewpoints educate and influence political actors (problem definition), developing their knowledge base surrounding the issue of the MDET (agenda formation), and ultimately guiding the change in policy (policy adoption).

In Schuck's discussion of policy success and failure he very clearly touches on the ways in which policy are interpreted and perceived. He states that "reasonable people will disagree about how to assess a policy" which shows how important perception and interpretation are to policy development and process (Schuck, 2014: 43). Ideas and the way in which they are framed are relevant to this thesis because of the way in which the medical device industry is assessing the MDET and how they try to modify the overall viewpoint of this tax mechanism (legislators and the population). Schuck says:

"Unanimity is not to be expected or even desired. People differ among things, in their predictions about what the likely effects of a policy will be; how they evaluate those effects; what relative weights they attach to them; how they discount the flow of the beneficial and costly effects over time; whether they optimize or merely "satisfice"; and the values that they ascribe to the particular decision process by which a policy is determined and implemented" (Schuck, 2014 :43).

This is particularly relevant for this thesis as it provides an understanding of the complexity of the policy process by including the impact of the rationale/views of the different actors. Perceptions vary according to Schuck depending on 5 things: (1) how they evaluate, (2) the weights they use, (3) how they discount the flow of costs, (4) their interpretation of optimization, and (5) their thoughts on decision process (Schuck, 2014: 43). What this means to this analysis is that ideas, viewpoints, and the way in which they are framed are different amongst individuals but also actors. The way that Schuck describes the analysis of policy, I describe the viewpoint of an actor and the ways that they frame the policy at hand.

This thesis offers an understanding as to how the medical device industry frames certain issues surround the MDET, and how those ideas assist in the development of the arguments against the MDET. This will then show us the ways in which the framing of ideas can build an argument, and become the backbone for change within the policy process. Groups that have the ability to aggregate their ideas and frame them with different narratives have more power than thought possible. Utilizing ideas to develop arguments and take action, as this thesis stresses, can be a successful process. Fischer and Miller argue that “discourse approaches emphasize the role of language and political symbolism in the definition and perception of a policy problem. It is a constructivist approach that emphasizes intersubjective knowledge – common understandings and shared identities—as the dynamic for change” (Fischer, Miller, and Sidney, 2007:156). According to this thought, there is a direct connection between “common understandings and shared identities” through the medical device industry. When there are common thoughts and understandings the dynamic for change is created. Now for an understanding of success and failure within the policy process.

1.1.2 Success and failure as concepts of public policy analysis

The last set of concepts to understand are success and failure; they play a large part in this discussion. Through this thesis, we analyze (1) the ways in which framing impacts the arguments of the medical device industry, (2) caused the medical device industry to act, and then (3) resulted in both success and failures. Definitions are based on Peter Schuck’s work called “Success, Failure, and In Between” and Allan McConnell’s work “Policy Success, Policy Failure and Grey Areas In-Between” (Schuck, 2014: 41; McConnell, 2010: 345). According to Schuck “a policy may fail for many reasons: a flawed theory or design, costs that exceed benefits, erratic enforcement, muddled implementation, unforeseen consequences, or political compromises that

undermine its efficacy either at its inception or as it plays out in the real world.” (Schuck, 2014: 41) Meanwhile, McConnell says “policy is successful if it achieves the goals that proponents set out to achieve and attracts no criticism of any significance and/or support is virtually universal” (McConnell, 2010: 351). Schuck’s analysis not only looks at the success and failure of the actions taken by the medical device industry to have the MDET changed, but also looks at the framing that was done by the medical device industry and how that influences the failures and success of this policy. Schuck says, “all policies succeed in some respects and fail in others” (Schuck, 2014: 42). The reality of this to Schuck’s point is that not all policies must be perfect, “imperfect policies should suffice” but this is only true if Congress and the government has done the best that it can do under the circumstances (Schuck, 2014: 42). Shuck finds that individual citizens have the right to ask that policies work, he says, “[w]e citizens have a right to demand that our policies work in this pragmatic sense” (Schuck, 2014: 42). Although this thesis does not analyze the effectiveness of the MDET, it does analyze the way the medical device industry frames ideas of the MDET, and how the industry’s work was successful in getting the policy changed temporarily. Like McConnell says, “success is in the eye of the beholder, depending on factors such as a protagonist’s values, beliefs and extent to which they are affected by the policy” this argues the exact point that strategically framing is so important to not only agenda development, but also the viewpoint of success and/or failure (McConnell, 2010: 351). This thesis uses success and failure as “relative terms” (as done by Schuck) and will use them as shorthand to describe when there are wins and losses from the medical device industry’s actions (Schuck, 2014: 42). McConnell also has an interesting look into policy success and failure. He says that success and failure are not mutually exclusive (McConnell, 2010: 359). Diving into the successes and failures of the MDET we realize that this is an excellent example to exam along with McConnell findings because the success and

failures of the MDET are not black and white, rather “grey” just like McConnell titles his writing “Grey Areas In-Between” (McConnell, 2010: 345).

1.1.3 Policy actors and processes

The discussion of shared identities and framing leads us directly into the conversation surrounding actors. Actors are crucial to the development, support, and execution of the policy process (Birkland, 2014: 7). Throughout this policy story an understanding will develop of the medical device industry through campaign contribution, lobbying, and interest groups (what we previously termed “unofficial actors” (Birkland, 2014)). All three are actions that involve groups or collaborations. According to Birkland that without groups and lobbyists our democratic system of policy formation and implementation could not function (Birkland, 2014: 1).

Through this thesis, understanding is developed around the failures and successes of the medical device industry in having the MDET repealed. Due to the involvement of the actors, their framing of the issues, arguments, and actions analysis is done on the concept of pluralism, neo-pluralism, and actor-centered institutionalism. All of these theories look at the impact that actors have in the policy process.

First we begin with pluralism, “[p]luralism is based on the assumption that interest groups are the political actors that matter most in shaping public policy” this definition is clearly defended by the actions that were taken by the medical device industry in attempting to have a permanent repeal of the MDET (Howlett, Ramesh, and Perl, 2009: 38). The medical device industry’s interest groups and collaborations, as well as the political actors that were involved, were who mattered the most in shaping the policy. Bentley argues that society finds their social interests in different groups that have similar concerns and that results in society itself being no more than the “complex

of the groups that compose it” (Howlett, Ramesh, and Perl, 2009: 38). This suggests that the interest groups that argue most for the repeal of the MDET are those that will make the biggest difference across these policy concerns.

The biggest issue that can be seen in regards to pluralism and the argument with the MDET is the fact that pluralists tend to believe that all groups with “legitimate voices can and will be heard” and they do not see any difference from group to group (Howlett, Ramesh, and Perl, 2009: 39). Whereas the neo-pluralists “modified the idea of approximate equality among groups and explicitly acknowledged that some groups are more powerful than others” (Howlett, Ramesh, and Perl, 2009: 39). There is truth to this when it comes to groups like MDMA, MITA, and Advamed. There is no way that smaller groups can compete with the clout that these organizations bring to the table in regards to a policy story.

Next neo-institutionalism, which may be the closest of all the theories that were analyzed, especially that of “actor-centered institutionalism” which seems to be exactly what is found with the involvement of interest groups and unofficial actors in the involvement of policy (Howlett, Ramesh, and Perl, 2009: 27). Actor-centered institutionalism states the importance of the independence of political institutions from the society in which they exist. Similar to public choice theory, actor-centered institutionalism starts with the idea of assessing human behavior. However, “unlike these more focused perspectives, neo- or actor-centered institutionalism assumes that a greater influence on human behavior comes from the socio-political environment surrounding people and organizations than from within an individual or from group-based interactions” (Howlett, Ramesh, and Perl, 2009: 44).

Now by understanding these theories the importance of actors in the policy process can be seen and a look at theories behind the types of groups that were active in the MDET policy. Interest

groups are essential to the policy process and according to Birkland they may be central “because the power of the individual is greatly magnified when they form groups.” (Birkland, 2014: 3). Interest groups have been a part of politics in America since the founding, and since the 1960s the number of interest groups has rapidly expanded. According to Birkland, one of the most important resources for interest groups is knowledge (Birkland, 2014: 4). This can be seen when analyzing the policy process of the MDET through the interest groups involved. The interest groups provide knowledge and resources to the political actors that otherwise wouldn’t have been known. Because they are involved in the policy every day these groups often times bring information to the table that would never have been thought of. Also because they are within collaborative groups, they are able to compare the actions and events that take place daily which give these interest groups metrics and data to pull together for their fight against the policy. Along with knowledge, interest groups also bring money to the table, because they can come together with their resources they are able to make a much bigger bang for their buck. Through this thesis, it is seen that different actors use their resources through their actions to make an impact on the policy design, and process.

When looking at the medical device industry, it becomes clear that this interest group would be considered an “economic group” by Birkland (Birkland, 2014: 6). According to Birkland, industry groups are clearly economic groups. Birkland argues that these groups tend to be smaller groups in regards to the actual number of members, but that they are powerful because they are collections of powerful economic interest that most often receive support from local, regional, or national political support (Birkland, 2014: 7). There is some disagreement in regards to these groups being small, mostly because this thesis focuses on the medical device industry and they are currently a vast group of organizations and corporations that have come together to argue against the MDET. However, there is agreement that these groups are powerful due to their

collections of powerful economic interest. Therefore the actor that being studied at this point in time, the medical device industry, has two very powerful attributes its economic approach, and its size.

Now looking at the theory behind the main actions that are taken by the medical device industry in this thesis. The main actions discussed are lobbying and campaign contributions. Lobbying is defined by Birkland as “the organized, continuous act of communicating with the government” (Birkland, 2014: 8). Lobbying is and has been applied to the process behind the MDET and is used in persuading the legislative and or executive branches to enact policies that promote the group’s interest. Not only does lobbying work to prevent, change, or stop a policy but it can be used to change policies which have already been executed. That would be the type of impact that medical device industry was and is looking for, although they lobbied well before the MDET went into place, they continue to lobby against the tax hoping to have it repealed completely. Campaign contributions will be touched on later in this thesis, but it is important to remember that campaign contributions are not the only form of lobbying. Lobbying is also the practice of getting the ear of legislative and executive branches, and influencing political actors.

In regards to the theory behind groups, the final conclusion is that their activity within policy is that it is very important to process. These actors are more influential than many might think and have large impacts on the policy creation, maintenance, and possibly permanent repeal process. The actors that are discussed in this section have viewpoints about efficiency. In the next section, we will understand what both efficiency and equity mean as policy concepts.

1.2 Introduction to efficiency and fairness

Equity and efficiency are two major concepts that help to define this research. By looking at the viewpoint of both of these concepts, there is a better understanding of how the different actors interpret the MDET and how they communicate their views of the tax as efficient or fair. The medical device companies that are being taxed certainly view the efficiency and equity of the MDET much differently than the legislative officials that created this tax policy, reinforcing the contested nature of the policy process (Birkland, 2014). This leads us also to look at the theory of constructivism in public policy and how it impacted the policy design of the MDET. Information is taken from Ingram, Schneider, Deleon's writing "Social Construction and Policy Design" to help understand if when the MDET was created that the legislative officials made this decision off of socially constructed populations. Ingram et al. asks "[h]ow is it that, while every citizen is nominally equal before the law, policy design tends to distribute mainly benefits to some people while almost always punishing others?" (Ingram, Schneider, and Deleon, 2006: 1). Through different viewpoints of efficiency and equity this thesis helps to determine if the MDET is actually punishing one actor, while benefitting the other, or how it constructs and defines specifically some policy targets (Ingram, Schneider, and Deleon, 2006: 1). Ingram et al. also asks "[w]hy is it that some policies are perpetuated and even enlarged, despite their failure to achieve policy goals?" this is an interesting question for us to look at because there is some indication through research on the MDET that it is not producing the amount of funding that was expected (Ingram, Schneider, and Deleon, 2006: 1). Possibly leading to actions taken by policy makers to have the tax temporarily repealed.

1.2.1 Efficiency as a policy concept

For purposes of this thesis to define efficiency, the definition of Pareto Efficiency is used and taken from Reinhardt. Reinhardt says that Pareto Efficiency is when "an efficient allocation

of resources is one from which no person can be made to feel better off without making another person feel worse off” (Reinhardt, 1992: 7). As Reinhardt describes in this definition “efficiency is meant to reflect social welfare, because the concept is based on the way people “feel” about different allocations” (Reinhardt, 1992: 7). Efficiency is a hard term to define because it means so many different things for many different actors, however, by using “pareto-efficiency” we can be “absolute in the sense that a resource allocation either is or is not Pareto-efficient” (Reinhardt, 1992: 7). Therefore is the MDET efficient? Is it an “efficient allocation of resources” in “which no person can be made to feel better off without making another person feel worse off?”

According to the Congressional Research Service and traditional economic and tax theories, excise taxes are typically “based on specific objectives such as discouraging undesirable activities (e.g. tobacco taxes) or funding closely related government spending (e.g. gasoline taxes to finance highway construction)” (Gravelle and Lowry, 2015: 2). An example of an excise tax that was developed to discourage undesirable activities is the soft drink tax described by Williams and Christ. Williams and Christ out of George Mason University ask if excise taxes are efficient throughout. Within their article Williams and Christ bring up valid points in regards to excise taxes, their efficiency and whether they advance public interest (Williams and Christ, 2009). Williams and Christ’s study looks at tax on soft drinks, which has an end goal of decreasing the amount of obesity in the United States. Although two very different types of excise taxes are being compared, the ideas within this study were able to give insight into a wide variety of excise taxes and how the MDET is and is not efficient.

1.2.2 Fairness as a policy concept

Before going any further, a definition must be defined around fairness. Fairness has so many definitions, and the viewpoint of fairness can be so different from one actor to another. As

Lynch and Gollust state, “little is known about ordinary Americans’ beliefs about fairness” and therefore they utilize surveys to determine how the typical American would define fairness (Lynch and Gollust, 2010: 851). According to their article “Playing Fair” Lynch and Gollust explain that “research suggests that for a plurality of Americans, the idea of fairness, in general, is most closely linked to the notion of equal opportunity or equal treatment, rather than to equal outcomes” (Lynch and Gollust, 2010: 853). There are so many individuals trying to truly understand what equity means in regards to health policy and another one of those authors is Paula Braveman, she compares many definitions of fairness including the following:

- “Equity in health means that all persons have fair opportunities to attain their full health potential, to the extent possible.”
- “Equity means that people’s needs, rather than their social privileges, guide the distribution of opportunities for well-being. In virtually every society in the world, social privilege is reflected by differences in socioeconomic status, gender, geographical location, racial/ethnic/religious differences and age. Pursuing equity in health means trying to reduce avoidable gaps in health status and health services between groups with different levels of social privilege.”
- “Equity in health is operationally defined as minimizing avoidable disparities in health and its determinants—including but not limited to health care—between groups of people who have different levels of underlying social advantage” (Braveman, 2006: 173)

Head says there are two basic principles of tax fairness, the “Benefits Principle” and “The Ability to Pay Principle” (Head, 1992: 2). The “Benefits Principle” states that those who benefit

the most from the tax should pay more to support the expenditure. This principle relates closely to the MDET because according to the policy design those that are benefitting from ACA (Medical Device Companies) are paying for the tax. Ultimately the increase in purchases of medical devices, due to availability/affordability of health insurance thanks to ACA should result in an increase in revenue for Medical Device companies, giving them the chance to afford the tax.

The second basic principle of tax fairness is “The Ability to Pay Principle” which says that those who have more wealth should pay more taxes. This does seem to correlate with the MDET because ultimately the medical device industry is paying for this tax and they are not an industry that is doing poorly at this time (EmergoGroup, 2015: 2). The question is whether the medical device industry will continue to take on the tax, or if they will pass the expense of the tax on to the consumer.

Another concrete point within the Williams and Christ study was their interest in the fairness of excise taxes. They look at whom the weight of the tax falls on, and whether is it disproportionate to the number of people being provided assistance. In the case of soft drink excise tax Williams and Christ find that the soft drink excise tax is a regressive tax “because the weight of these taxes often falls disproportionately on the poor” (Williams and Christ, 2009: 2).

According to the IRS, an excise tax is a tax that is “paid when purchases are made on a specific good, such as gasoline. Excise taxes are often included in the price of the product. There are also excise taxes on activities, such as on wagering or on highway usage by trucks.” (IRS, 2015). The MDET is an interesting case when it comes to fairness, because most excise taxes are paid when a particular commodity is purchased by a large, diverse audience, however, with the MDET they are charging a sole target audience, medical device companies, this is another piece that could question the MDET’s fairness and contribute to their arguments.

In Chapter 2 there is a deep dive into the arguments most frequently used by the medical device industry. Throughout these arguments efficiency and fairness appear, by understanding the above theories and concepts, a better understanding is developed around the viewpoint of fairness and efficiency related to the MDET.

CHAPTER 2: BUDGET ARGUMENTS AS POLITICAL TOOLS

2.1 Introduction

Even before the MDET went into effect, the medical device industry framed the tax as unfair and has strived to rid the industry of the tax by having it permanently repealed. The medical device industry consistently identifies four main arguments against the MDET:

- (1) The reduction of research and development (R&D) budgets (innovation)
- (2) The reduction of job budgets
- (3) The impacts on patient care
- (4) The loss of global leadership within the industry

The first two arguments will be analyzed in this chapter, while the second two arguments related to patient care and global leadership will be analyzed in more depth in Chapter 3. The arguments based on innovation, jobs, patient care, and the loss of global leadership play a central role in the failure and success of the medical device industry, further strengthening the arguments that the tax is viewed as unfair and/or inefficient to the industry. The top four arguments analyzed through this chapter and the next were identified through the analytical grid described in Chapter 1. These chapters will analyze each argument through details discovered through the grid, and offer details, including:

What is the argument?

Why is the argument important to the medical device industry?

What sources defend and explain the argument?

What actors are interested in the argument?

Goals and objectives surrounding the argument.

Viewpoint of fairness in relation to the argument.

Viewpoint of efficiency in connection with the argument.

These arguments are the main reasons that the medical device industry succeeded in having the MDET repealed even if only temporarily. They provide sound reasoning for their viewpoint on the unfairness and inequity of the MDET and lead to explanations of why the medical device industry succeeded in its efforts. The arguments also provide insight into the framing of the MDET by the medical device industry and explains why the MDET is not viewed as a fair and efficient way to spread the cost of ACA across the health industry.

This chapter looks at the framing of the arguments behind the medical device industry, specifically, the impact the MDET has on innovation and job budgets within the medical device industry. The information was extracted from the analysis grid, and once the keywords “innovation” and “jobs” were identified amongst all the sources there were sheets made for each argument. The sort and filter functions were used to determine which concepts were most used amongst the keywords. This showed what the most common arguments against the MDET were according to the medical device industry. A word cloud is displayed below in Figure 4 showing many of the keywords that appeared throughout these resources.

Figure 4 – Word Cloud of Keywords



The most commonly used keywords were innovation, jobs, patient care, and [loss of] global leadership. After these keywords had been identified different excel sheets were created for each of the four most commonly used keyword. Once those sheets were made, the information was looked at specific to each source, actor, and keyword (the grid can be seen in the appendix). The questions were part of the analytical grid, and each source was reviewed using these questions. Figure 5 and 6 display the lists of resources by keyword, all documents that referenced innovation are listed in Figure 5, while all documents referencing jobs are in Figure 6.

Figure 5 – Documents with Keyword Innovation

Documents with Keyword Innovation			
Title	Type of Source	Author	Date
Innovation isn't all that suffers from a tax on medical devices.	Advertisement	MDMA	2009
Behind every medical device breakthrough stand the people who make it possible	Advertisement	MDMA	2009
MDMA Survey on Impact of MDET	Survey Data	MDMA	2013
Letter to Senate Finance Committee	Letter	MDMA	10/6/2009
Coalition Letter to Congress Against MDET	Letter	Trade Assoc., Companies,	10/13/2009
MDMA Letter to IRS	Letter	MDMA	3/28/2011
Letter to House on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Letter to Senate on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Examining the Impact of Obamacare on Doctors and Patients	Hearing	Witness and Testimonies	7/10/2012
Testimony of Kelvyn Cullimore Jr., President and CEO of Dynatronics	US House of Reprs Committee on Oversight and Government Reform's Subcommittee on Health Care and D.C.	Kelvyn Cullimore Jr., President and CEO of Dynatronics	7/10/2012
MDMA Statement on MDET Repeal Inclusion in Tax Ref. Plan	Press Statement	MDMA	2/26/2014
MDMA Statement on MDET Repeal Efforts in Senate Finance	Press Statement	MDMA	4/4/2014
MDMA Statement on House Jobs Package	Press Statement	MDMA	9/18/2014
MDMA, AdvaMed, MITA Support Bipartisan Efforts to Repeal MDET	Press Statement	MDMA	1/7/2015
Coalition Letter to House to Repeal MDET	Letter	1,000 undersigned organizations, associations, companies, patients, providers, and venture capital firms	1/13/2015
MDMA Statement on House Ways and Means Comm Markup of Legislation to Repeal MDET	Press Release	MDMA	6/2/2015
MDMA Letter to House Leadership	Letter	Mark B. Leahey, CEO of MDMA	6/17/2015
MDMA, AdvaMed, MITA Commend House Repeal of MDET	Press Release	MDMA	6/19/2015
MDMA, AdvaMed, MITA Applaud Congress for Passage of MDET Suspension	Press Release	MDMA	12/18/2015
MDMA Statement on the First Device Tax Payments Suspension	Press Release	MDMA	1/29/2016

Figure 6 – Documents with Keyword Jobs

Documents with Keyword Jobs			
Title	Type of Source	Author	Date
MDMA Survey on Impliacations of MDET	Survey Data	MDMA	2010
MDMA Survey on Impact of MDET	Survey Data	MDMA	2013
MDMA Survey - Impact of Repealing Tax	Survey Data	MDMA	2015
Coalition Letter to Congress Against MDET	Letter	Trade Assocs., Companies,	10/13/2009
MDMA Letter to IRS	Letter	MDMA	3/28/2011
Letter to House on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Letter to Senate on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Examining the Impact of Obamacare on Doctors and Patients	Hearing	Witness and Testimonies	7/10/2012
Testimony of Kelvyn Cullimore Jr., President and CEO of Dynatronics	US House of Reps Committee on Oversight and Government Reform's Subcommittee on Health Care and D.C.	Kelvyn Cullimore Jr., President and CEO of Dynatronics	7/10/2012
MDMA Statement on MDET Repeal Inclusion in Tax Ref. Plan	Press Statement	MDMA	2/26/2014
MDMA Statement on MDET Repeal Efforts in Senate Finance	Press Statement	MDMA	4/4/2014
MDMA Statement on House Jobs Package	Press Statement	MDMA	9/18/2014
Impact of the Medical Device Excise Tax	Report	AdvaMed	1/1/2015
MDMA, AdvaMed, MITA Support Bipartisan Efforts to Repeal MDET	Press Statement	MDMA	1/7/2015
Coalition Letter to House to Repeal MDET	Letter	1,000 undersigned organizations, associations, companies, patients, providers, and venture capital firms	1/13/2015
MDMA, AdvaMed, MITA Commend House Repeal of MDET	Press Release	MDMA	6/19/2015
MDMA Statement on the First Device Tax Payments Suspension	Press Release	MDMA	1/29/2016

This chapter provides answers to the secondary questions of this thesis but also gives information that is needed to understand the primary questions further. Ultimately this thesis wants to understand how and why the medical device industry succeeded and also failed. This framing of the arguments give us a better understanding of why the medical device industry took the actions that it did and resulted in a response such as success or failure. This analysis provides an understanding of how the MDET is framed by the medical device industry and how that framing

influences the arguments of innovation and job budget impacts. This analysis also offers the ability to dig into the viewpoints of fairness and efficiency of the MDET by the medical device industry unique to innovation and jobs.

Although these arguments are important to the medical device business and are able to show discomfort with the tax, they are actually being used as political tools to get the policy outcome desired by the industry. These arguments are essentially political tools that are developed through framing, which develops into an argument, lastly developing into a political action.

2.1.1 Efficiency vis-à-vis the arguments

It is imperative to have an understanding of the basic viewpoints of efficiency and equity in regards to MDET and ACA. This understanding will allow a clearer view of efficiency and equity related to each of the medical device industry arguments, providing a clearer understanding between the relationship of equity/efficiency and ACA/MDET. This section goes deeper into what efficiency and equity mean directly related to MDET and ACA.

First from the ACA side (what is being given to those who need it) and then from the medical device side (who is paying the tax, and how efficient this tax is for them?). Noted above is that an efficient allocation of resources is one from which no person can be made to feel better off without making another person feel worse off (Reinhardt, 1992: 7). ACA in the end wants to increase the affordability and quality of insurance, lowering the rate of those that are uninsured, and reducing the cost of healthcare for individuals. ACA wants to increase the affordability and quality of insurance by requiring that all insurance companies cover applicants within new minimum standards and offer the same rates regardless of pre-existing conditions or sex (U.S. Department of Health & Human Services, 2015). ACA will lower the rate of those that are

uninsured by opening the healthcare exchange, and providing subsidies to those that need it. The subsidies can be used to purchase health insurance coverage.

Through the MDET is it possible to provide this to the public with minimum wasted effort and expense to the medical device industry? Regrettably at this time the medical device company cannot say that this tax can be paid with minimal wasted effort or expense. The medical device industry believes that this will cost the industry much more than originally thought. They believe that they will have to, and have had to slash jobs, move jobs overseas, and decrease their spending on research and development to pay this tax (Bolka, 2014: 1697). They do not find that there has been an increase in their profit margins since ACA came into existence (Bolka, 2014: 1697). Elizabeth Bolka wrote the article “The Medical Device Excise Tax – An Unfair Burden” she finds that the MDET is disproportionate to any expected increase in sales from increased number of Americans receiving medical care, and the fact that the tax is on gross revenue rather than profits will force cut costs by decreasing R&D, laying off workers, and shifting domestic production overseas” (Bolka, 2014: 1697).

Bolka also believes that the MDET would be a burden to the national well-being and the economy. By taxing the medical device industry good jobs that are extremely high paying will be killed, and by having companies reduce their R&D budgets this will stifle innovation (Bolka, 2014: 1705). Overall Bolka sees the MDET as much more of an expense to the medical device industry than she sees as a benefit to the public. However, the Congressional Research Service indicates in its report that the decrease in US output and jobs for Medical Devices is no more than .2%, and that it is unlikely that innovation will suffer consequences (Gravelle and Lowry, 2015: 11). Viewpoints of efficiency vary across the actor spectrum.

On top of the changes that will have to take place within the medical device industry to afford this tax (and still reach their previous profit), they find that there will be increased administrative costs, to determine how much of the tax is due, where it is due to, and how to ensure that it is taken care of in a timely fashion. The CRS states that administrative and compliance costs associated with MDET may be disproportionate to revenue (IRS, 2015). Through this thesis the arguments from the medical device industry are dissected and an understanding is developed around sacrifices are if they are truly worth what ACA has to offer.

2.1.2 Equity vis-à-vis the arguments

This thesis spends time looking at the two previously mentioned tax fairness principles and analyzing if this tax is viewed by the medical device industry as a fair way to pay for ACA. If the benefits principle is looked at, as done mildly above in regards to the MDET it can be noted that individuals who are benefitting most from the tax are paying for it; but are they actually benefitting or is that just if the policy works exactly as designed. This thesis dives further into this idea to really determine if in fact, those that are acquiring more affordable required healthcare will actually spend more on medical devices, contributing to the revenue that medical device companies take in, ultimately paying the MDET. This would satisfy the benefits principle, being one part of taxation fairness.

This leads further into the other principle, the ability to pay. This principle is almost certainly met with the MDET if in fact the costs are being covered by medical device companies. The medical device industry did well in 2014 and was projected to do well in 2015. According to Emergo's "Outlook for the medical device industry in 2015" who says, "[d]espite economic uncertainty in some geographic markets, the industry outlook is generally positive going into 2015 (EmergoGroup, 2015: 3). They almost mention that "[b]ased on our 2015 survey results the global

medical device industry remains stable, but different aspects (pricing, regulatory, reimbursement) of the business appear to have become more challenging in 2014” (EmergoGroup, 2015: 2). If in fact this industry is doing well, then according to this principle it would be “fair” for them to continue to pay the tax to provide benefits of the ACA to those who need it.

Another piece of the fairness argument is looking at who is included in payments of the MDET, when do they have to pay, and when do they not have to, also what type of regulation is enacted to ensure that payments are made, and made on time? This will also be an analysis of fairness within the MDET and the companies that are required to contribute. Companies actually paying the proper amount, on time, and being consistent is an important part of the fairness, especially if some companies are following the rules while others are not. According to Paul Jenks from Dow Jones, “A Treasury Department’s Inspector General Report released...indicates that taxpayer reporting on the IRS excise tax form does not account for all applicable medical device sales. Also, the tax agency is struggling to reconcile data provided by taxpayers and cannot accurately identify all of the medical device makers that are required to file the form and pay the tax” (Jenks, 2014). The auditors estimated that the tax should have collected \$1.2 billion in the tax, but the IRS received only \$913 million, this seems to be an issue not only with fairness, but with efficiency as well (Jenks, 2014). Regulation of the law is another important piece to assess when looking at the fairness of this tax.

Fairness and efficiency methods

When analyzing the fairness and equity portion of Chapter 2 within the political tools and arguments section there will be analysis connecting efficiency and equity to each argument. Qualitative methods were used to analyze both the viewpoints on fairness and the efficiency of MDET. To examine their viewpoint of fairness specifically, the MDET was examined through

primary resources such as letters written by medical device companies directly to congress will give us the viewpoint of medical device companies, and these documents are reviewed in depth in Chapter 1.

Content analysis took place mostly through secondary sources. The secondary sources gave insight into the theoretical framework of tax fairness. Malcolm Oswald's article "In a democracy, what should a healthcare system do? A dilemma for public policymakers," fairness in healthcare is directly discussed, which gave us thoughts from "several disciplines and especially philosophy, economics, and systems theory" (Oswald, 2015: 1). Also analyzing information from articles that display different viewpoints on MDET's fairness; those came from articles written by the Center on Budget and Policy Priorities (Van de Water, 2013), the Internal Revenue Service (laws on the tax) (Internal Revenue Service, 2012), Washington Post editorials (Washington Post Editorial Board, 2014), and the Advanced Medical Technology Association website (Moebius, 2012). Using data and information from these different resources offered diverse perspectives on the tax and how it is affecting each actor, giving excellent background for current viewpoints of the tax.

Other content and informational analysis is provided through qualitative data used to look at efficiency of MDET. Few primary sources were utilized, but they include letters from the CEO of Glottal Enterprises (a medical device company specializing in speech therapy), written to editorial posts on his beliefs regarding MDET (Mass Device, 2012). Theory in regards to efficiency came from Reinhardt (separation of efficiency from equity) (Reinhardt, 1992), Evans & Stoddard ("Producing Health, Consuming Health Care") (Evans & Stoddard, 1990), and Gillroy (cost-benefit comparison) (Gillroy, 2015) all authors who look at the study of efficiency within healthcare. By understanding the general framework of efficiency in healthcare, I apply that

background to MDET specific articles from the Healthcare Supply Chain Association (discussing the shift of costs to consumer) (Healthcare Supply Chain Association, 2013), Bloomberg Business (business focus) (Flavelle, 2012), and Furchtgott-Roth (understanding of employment effects) (Furchtgott-Roth and Furchtgott-Roth, 2011). Now with a better understanding of the relationship between ACA, MDET, efficiency and fairness, we can begin to look at specific arguments that the medical device industry uses to show its discontent, resulting in further action.

In the following sections, we analyze the different arguments or tools used by the medical device industry to take action when they view MDET as inefficient or not fair. To better understand the efficiency and equity argument we look deeper at the relationship between efficiency/equity and ACA/MDET.

2.2 The Innovation Argument as a Political Tool

2.2.1 Innovation: the background

Innovation was the number one word or theme that appeared in more than half of the resources that were analyzed. Innovation is the backbone of medical device companies, without it, current products would not exist, and future products would not be created. Medical device industry lobbyists know that research and development funds are the first to be cut in the industry's budget when money is short, or needed elsewhere, therefore it is one of the most commonly used and known reasons that the industry mentions when requesting a repeal of the MDET. When R&D is cut there becomes a lack of innovation and according to Kelvyn Cullimore, CEO of Dynatronics, a medical device company, “[r]esearch and [d]evelopment are the easiest short-term cuts but they lead to less innovation and growth” (Cullimore, 2012: 3). When the medical device industry must budget for a tax such as the MDET money is taken from other line items within the

budget, R&D appears to be the first thing that the medical device industry cuts. This argument immediately impacts the way that the MDET is framed by the medical device industry, especially because it is the basis for their industry. The industry begins to wonder how ACA which is supposed to increase the medical device industry's revenue, results in a tax on their industry, does not provide a greater flow of revenue, and then takes from their R&D budget, obviously framing a poor view of the MDET. This is where the negative view of fairness begins to blossom, and the political tool is born.

2.2.2 Why innovation is important to the policy story and the sources that define the argument

Medical device companies find value in R&D, and ultimately innovation. It is the basis of most of their businesses, developing a product, equipment, machine or part that not only brings in profit for their company, but also does something positive for patients in the United States, and sometimes even abroad. In a letter to the Senate on the Importance of Repeal, many medical device companies stated: “the medical device industry is a unique American success story – both for patients and our economy... (the industry) invests nearly \$10 billion in research and development (annually). The industry is fueled by innovative companies” (Medical Device Manufacturers Association, 2012: 1). By taking away from R&D budgets to pay the MDET, the industry begins to fall behind across the global industry, not being able to offer the best care possible to doctors and patients.

The medical device industry is showing its political constituents how important their budget is to not only their business but how important this budget is to Congress as a whole. They are using this argument as a political tool to make a change and guide the political story of the tax.

Many different sources provide information on the R&D argument and are important to analyze because they give validity to the medical device industry's opinion, they provide this thesis with insight into what the industry is thinking and why it frames the issues in this way. The sources also give us a clear understanding of why the medical device industry succeeded through clear arguments. The medical device industry created not only advertisements to lobby against the MDET and to advocate for its repeal, but they also wrote many letters to the House of Representatives as well as the Senate. The medical device industry also produced and released press releases as well as developed surveys to obtain data regarding medical device companies and the MDET. All of these sources more than once indicated that innovation, as well as R&D, were extremely important to medical device companies, and suffered due to the MDET.

Advertisements were used primarily to show the impact that innovation and research ultimately have on the patient. Hearings and testimony were also resources that were analyzed and often offered innovation as a major part impacted by the medical device industry. Letters to Congress, the White House, and Congressional Committees were also analyzed, and repeatedly mentioned the importance of R&D to medical device companies, and how the MDET inadvertently required that companies reduce their budget on R&D. Press Statements were frequently used by the industry, and after looking through a significant percentage innovation was almost never left off of the statements, even if they were an extremely short release, innovation is not something that would go unmentioned. The MDMA also used surveys to gather information from different medical device companies across time, these survey's responses almost always mentioned innovation.

2.2.3 Actors interested in innovation

There were different authors throughout the medical device resources, however, the ones that most frequently discussed innovation were the MDMA, presidents/CEO's of medical device companies, as well as doctors. All three of these actors are extremely vital to the success and wellbeing of the medical device industry, therefore they are well respected and provided excellent accounts that are known and trusted in the health industry, which continues to build the arguments for the medical device industry against the MDET as well as their political strategy. The MDMA collaborated through many different types of sources but in particular through letters to the House of Representative and to the Senate. When MDMA would sign these letters, they would list out all of the organizations that were considered part of their collaboration. As far as presidents/CEOs they would most often be the actors that would release press releases. We begin to see the impact of actors through this argument and will continue to see their efforts and impact on the policy process as we continue to explore other arguments.

2.2.4 Goals and objectives related to innovation

The number one goal across the board for all of the medical device industry resources was and is to ultimately have the MDET repealed permanently. However, this means a lot of different things vis-à-vis innovation.

In the Medical Device Manufacturer's Association report from 2015 "Impact of Repealing the Medical Device Tax" they said that "since enacted in 2010, the medical device excise tax has...led to drastic cuts to R&D...According to Ernst and Young, the 2.3% medical device tax on average increases the effective tax rate for America's medical technology innovators by 29 percent" (MDMA, 2015: 1). What this means is that the ultimate goal for the medical device industry is not just to repeal the MDET but to return back to a time that they could invest more in R&D. In that same survey mentioned above, MDMA stated "80% of respondents noted that they

would increase R&D investments in the cures and therapies of tomorrow” and “[w]hen asked how much they would increase their R&D budget, the average increase was 14%” (MDMA, 2015:1).

The goal of many of the press releases made by MDMA was not only to educate Congress on the MDET and the desire to repeal but also to thank them for significant steps along the way. When H.R. 4, the “Jobs for America Act” was passed, Mark Leahey, President and CEO of the Medical Device Manufacturers Association issued a press release with the following statement, “MDMA thanks the House of Representatives for working to strengthen medical technology innovation by removing a major roadblock towards developing the cures of tomorrow” (MDMA, 2014). Also when H.R. 160, “The Protect Medical Innovation Act” passed by a vote of 280-140 MDMA released a press release, not only coming from their organization but from AdvaMed and MITA stating “The Medical Device Manufacturers Association (MDMA), the Advanced Medical Technology Association (AdvaMed) and the Medical Imaging & Technology Alliance (MITA), a division of National Electrical Manufacturers Association (NEMA), today commended the House of Representatives for passing legislation to repeal the medical device excise tax.” the goal showing that they want to support the progress that is taking place, and also move forward to permanently repeal the tax, “[r]epealing the device tax will positively impact the future of medical technology and patient care by removing a barrier to medical progress and increasing resources for innovation, jobs, research and development, and manufacturing” (MDMA, 2015) And most recently from a press release in January 2016, MDMA’s statement on the First Device Tax Payments Suspension is from Mark Leahey, President and CEO of MDMA, “[f]or the first time in three years, medical technology innovators are able to invest more resources in improving patients care” this shows that part of their goal has been met, but continues with, “[w]hile many thought this day would never come, MDMA remained committed to this important work, and we will not

rest until the medical device tax is fully repealed” (MDMA, 2016). At the end of the day, the goal is to suspend the MDET for good, giving back medical device companies their ability to spend more on innovation, which is the basis of their industry.

2.2.5 Fairness vis-à-vis innovation

The medical device industry does not see the MDET as a fair and efficient way of collecting funds for the Affordable Care Act. Therefore unfairness and inefficiency were two of the driving forces for the medical device industry in lobbying to have the MDET repealed. The MDET was created to fund ACA, because the officials that created MDET believe that the increase of health insurance amongst the population would increase the number of sales that the medical device industry had, giving them more revenue. The medical device industry does not find there to be an increase in their sales due to ACA, as indicated here by a letter from MDMA to the IRS, “the justification advanced by proponents of the tax that the “windfall” from the Health Care and Education Reconciliation Act of 2010, in conjunction with the Patient Protection and Affordable Care Act, will offset the costs of the tax on innovators is baseless and not supported by any evidence” (MDMA, 2011:1). Because this increase in sales does not seem to exist the medical device industry finds it unfair to continue to assess a tax that is not bringing in further revenue for their business when that was the initial reasoning behind the selection of this funding tool. It would also be considered unfair, to continue to assess this tax which requires that this industry reduces their budget on something such as innovation. By reducing the budget on R&D not only is the medical device industry being impacted, but patients across the globe. This argument is clearly framed as unfair by the medical device industry and rings true to many Americans providing reasoning behind the success of the medical device industry in having the tax temporarily repealed.

2.2.6 Efficiency vis-à-vis Innovation

The medical device industry also cannot see where the MDET is efficient in its ability to fund ACA which offers health care that is up to date and affordable. Most certainly it is not efficient in regards to innovation, innovation being the backbone of the medical device industry. The MDET is currently assisting in the funding of ACA however, due to a reduction in R&D the medical device industry communicates that it is unable to provide the most up to date equipment, resources, and education to the community. Therefore not providing the once most advanced, and innovative resources as were provided before the MDET went into place. This is and should be a huge concern for the medical device industry and offers solid reasoning for them, and continues to secure their success in steps towards having the MDET repealed permanently.

2.2.7 Summary of the innovation argument

In summary, the innovation argument is a political tool developed by the medical device industry to get what it really desires in the policy process. Of course, as a business, the medical device industry wants to ensure that their innovation is a top priority, but they are able to influence political actors by reminding them of the importance of innovation within the U.S. This argument also continues to shed light on the importance of actors in the policy process. As discussed in the conceptual piece of Chapter 1 groups are extremely relevant to the policy process, and through the resources above that were collaborative efforts, and with a strong argument, they are able to instill change in the policy process, even as a short-term repeal.

2.3 The Jobs Argument as a Political Tool

2.3.1 Jobs: the background

Jobs are the second most frequently used term in the documents that were analyzed advocating for the repeal of the MDET from 2009 until 2016. According to a letter from a medical device industry coalition of 241 organizations (trade associations, medical device companies, and venture capital firms) “the U.S. medical technology industry is responsible for nearly 2 million jobs, including some of the highest paying manufacturing jobs in the country” (Medical Device Industry Coalition, 2009: 2). The most common discussion in regards to jobs and the MDET is that the tax will cause companies to move their jobs overseas, as well as the fact that the well-paying jobs will decrease. One of the major takeaways from a MDMA survey on the MDET was that “[w]hen asked “If the 2.3% medical device tax on total U.S. sales take effect in 2013, which of the following would your company do to address the impact of the tax?”, 64 percent said that they would reduce or immediately halt job-creation” (MDMA, 2010: 1). From 2009 until 2015 there was not a change in the belief behind jobs. The medical device industry in a letter to the House on the importance of the repeal in 2012 wrote, “Despite the 2013 implementation date, the tax is already having an adverse impact on R&D investment and job creation” (MDMA, 2012: 1). This argument is a political tool for the medical device industry. Without a doubt the industry doesn’t want to reduce the number of jobs that it can offer, possibly decreasing its revenue, but it also knows that Congress as a whole doesn’t want to impact its economy negatively through loss of jobs, especially high paying jobs. The medical device industry selects another argument that not only pertains directly to the medical device industry but also impacts the United States population as a whole, through the economy and jobs.

2.3.2 Why jobs are important to the policy story and the sources that define the argument

Because the medical device industry is largely populated by small companies, many are in the early phases of development with their sales and have small profit margins (Cullimore, 2012:

1). Kelvyn Cullimore who was mentioned earlier in regards to innovation also spoke to the impact that the MDET will have on jobs. He says that “[i]n such a difficult economic environment it is doubly hard to accept the imposition of a new tax that will further hamper our ability to innovate and provide jobs for the number of people we have traditionally employed (Cullimore, 2012: 1). Similar to the discussion regarding innovation the medical device industry finds that if money must be allocated differently to be able to pay the 2.3% tax, budgets must continue to be adjusted which means the R&D and jobs budgets are the two main focuses of these adjustments. With yet another obstacle for the medical device industry and their budget, their framing of the argument continues to darken.

Many diverse documents discuss the issues behind jobs and the MDET including, survey data, letters to Congress, hearings/testimony, and press statements. Each of the documents discusses jobs and the way that they are impacted by the MDET, they also give insight into the medical device industry and how they frame the ideas behind the MDET’s impact on jobs within their industry. MDMA has created surveys annually since the MDET was put into effect in 2013, and each of the surveys requests responses from medical device companies. All three of these surveys highlighted jobs, how many are provided by the medical device industry, and how they would be and currently are impacted by the MDET. Letters to congress were written from 2009 when the MDET was first being developed, all the way through 2016 to both the House and Senate, as well as the IRS, and specific committees amongst Congress. Press Statements although often were very short, always mentioned jobs and their impact on the MDET. These sources offer details into the jobs argument and provide a good argument for the medical device industry allowing for some success in their steps toward the MDET being completely repealed. All of the documents that were linked to the keyword jobs can be seen in Figure 6. These sources like mentioned above

provide us insight into the industry, but for the purpose of this thesis they give us a look at the political argument they are bringing to the table. This is an argument that not only impacts the industry, but also is strongly highlighted in politics, and could be identified as a reason behind the success of the industry in bringing forward the temporary repeal of the MDET.

2.3.3 Actors interested in jobs

Throughout this research, MDMA is the main actor showing interest in the topics of jobs and how they are impacted by the MDET. The MDMA was the author of most of the documents that mentioned jobs, and also seemed to bring together the coalitions that wrote many of the letters. In one coalition letter from 2009 over 241 organizations were included in the signature and they were companies as well as trade associations (MDMA, 2009: 3-9), in 2012 there was a letter to the House that included over 700 companies (MDMA, 2012: 2-17), and in 2015 there was letter written to the House that included over 1,000 organizations, associations, companies, providers, and venture capital firms (MDMA, 2015: 2-12). As time progressed, more and more companies joined the MDMA coalitions, evolving and growing across time. The growth in the MDMA coalition is a huge accomplishment for MDMA and shows that the viewpoint of the MDET is negative across quite a large number of industry related actors. It also is a call out to the political constituents that if all of these actors within the industry are interested in having the MDET repealed, they bring in large sums of money, and have large numbers to contribute to the job economy. Again, the industry realizes the importance of jobs within their business, but they are able to see even more strongly the connection politically and the arguments they must express to get their desired outcome.

2.3.4 Goals and objectives related to jobs

Similar to what was discussed in the innovation section, the immediate or main goal/objective for the medical device industry was to stop the MDET, or repeal it, however; this ultimately means something different in relationship to jobs. What this means for jobs is bringing money back to the budget for medical device companies that they can put towards new and well-paid jobs. It also means stopping the movement of jobs overseas, and keeping them in the U.S.

Over time not only were the resources analyzed offering educational tools or requests to Congress, but they were also letters of gratitude thanking them for support, for passing legislation that would assist in repealing the MDET, and put more money back into medical device jobs. In a statement from MDMA on April 4th, 2014, Mark Leahey, President, and CEO of MDMA issued the following statement regarding efforts in the Senate Finance Committee to address the medical device tax in the “Expiring Provisions Improvement Reform and Efficiency (EXPIRE) Act”: “We thank Senators Hatch, Toomey, Thune, and Enzi for offering the amendment, and all Members who spoke in favor of eliminating this tax on innovation. MDMA remains committed to ending a policy that is destroying jobs” (MDMA, 2014). The medical device industry understands that to get the request that it desires they must continue to keep a strong rapport with those that are taking action and making changes for their cause. This is a political game that is being played amongst the actors involved.

In 2014 MDMA made a statement on H.R. 4, the House Jobs Package, “which included language that would repeal the medical device excise tax” stated “[r]epealing the medical device tax not only empowers patients and providers but will allow America’s innovators to create more high-tech manufacturing jobs that our communities desperately need” (MDMA, 2014). And similarly in 2016 MDMA made a statement thanking and recognizing the first set of payments that were suspended. It was noted that for the first time in three years companies could focus and invest

in creating jobs instead of paying the tax (MDMA, 2016). Although the tax has not been completely repealed, you can see throughout this goals and objectives section that there have been many successes for the medical device industry. The successes were the result of using jobs as a political tool, to reframe the arguments and make the desired change.

2.3.5 Fairness vis-à-vis jobs

Mentioned above in the “Fairness vis-à-vis innovation” section the MDET was created as a funding source for ACA. The medical device industry does not communicate its view of MDET as a fair way to tax their industry to fund this program. Even further it can be seen that it is not fair to U.S. job holders to tax these companies because it reduces the number of jobs available to them. Medical Device companies were targeted as a tax to fund ACA because there was a belief that there would be an increase in sales due to ACA. Since the medical device industry has not seen a notable increase in their revenue, it does not view the MDET as a fair way to fund ACA. It is surely not viewed as fair if there is not an increase in sales due to ACA and these companies have to reduce their workforce to afford the tax. In the end, innovation is even suffering from the loss of jobs, because of the lack of ideas, and resources that are no longer able to contribute to the medical device industry.

As reviewed in Chapter 1’s conceptual framework we remember the “Benefits Principle” which states that those who benefit from the tax should pay to support the expenditure. Although this relates to the policy design of MDET, through analysis of these documents it doesn’t seem to be the reality because the expected increase in purchases of medical devices, due to availability/affordability of health insurance didn’t result in an increase in revenue for Medical Device companies, giving them the chance to afford the tax. This failed viewpoint of fairness, and utilizing jobs as a political tool gives the medical device industry a leg up in the argument over

repealing the MDET. Moving into the next section, we can determine if the viewpoint of efficiency related to jobs was the same as fairness and jobs.

2.3.6 Efficiency vis-à-vis jobs

In 2011 MDMA wrote a letter to the IRS expressing discontent with the MDET and asking for more administrative guidance. This comes across as an efficiency issue because the medical device industry doesn't find that the current process for the IRS collecting the MDET is working as smoothly as it should. The number one request that relates directly to jobs in the medical device industry is "[g]uidance should minimize the additional administrative burden on affected manufacturers" (MDMA, 2011:2). In this letter, MDMA explains that the medical technology industry is mostly small business, "which are the engine of job creation in this country" (MDMA, 2011: 2). They found that "approximately 80% of the companies in the medical technology industry have fewer than 50 employees, and 98% of the companies have less than 500 employees" (MDMA, 2011: 2). They ask that guidance should reduce the number of requirements to change existing financial and recordkeeping systems, as well as business practices. MDMA says that if these changes aren't reduced or removed entirely that the "law will divert precious resources away from the necessary investments these companies make in research and development that eventually lead to more effective and less costly healthcare for all Americans" (MDMA, 2011: 2). Not only do these changes take away from R&D but also in the jobs that they create and sustain as small businesses. The medical device industry communicates that its viewpoint on the MDET's relationship to jobs is not positive, therefore they frame the argument in a way that it is taking away money from their job budgets, and sending them overseas, and then it is causing administrative issues by causing the precious jobs that they do keep to be pulled into other parts of the business making them less effective. Referring back to the methodology and conceptual

understanding of efficiency in Chapter 1, Reinhardt says that efficiency is “meant to reflect social welfare, because the concept is based on the way people “feel” about different allocations” and in this argument it is clear that the medical device industry is communicating that it is not good to lose budgets for jobs (Reinhardt, 1992: 7).

2.3.7 Summary of the jobs argument

The jobs argument that was developed by the medical device industry documents turns into the perfect political tool for the medical device industry. It is evident that the industry does not find the MDET to be efficient or fair and through the documents that were analyzed in the analytical grid, it is clear that the jobs argument is one that can be politicized. These documents share an in-depth look at the viewpoints that the industry has surrounding the MDET and its impact on jobs. Not only does the job budget argument impact the medical device industry, but it also will impact the economy and the population as a whole, this is the exact seed that the medical device industry wants to plant into Congress and the population as a whole to get what it wants, which is the long-term repeal of the MDET. As we move into Chapter 3, the patient story argument and the global leadership argument will be dissected further. These arguments tend to step away from the business need and more towards the general public and a tougher political argument.

CHAPTER 3: PATIENT CARE AND GLOBAL LEADERSHIP AS POLITICAL TOOLS

3.1 Introduction

If there is one argument that everyone can relate to that is patient care. No matter who you are, where you live, or what you do for a living you want to know when you go to the doctor that you are getting the best care that is available to you. The first argument that will be covered in Chapter 3 is the patient care argument, followed by the global leadership argument. These arguments were placed into a different chapter than innovation and jobs because they are more removed from the business of the medical device industry, and they have a deeper connection to the general public and the political actors involved.

In a sense Chapter 3 is very similar to Chapter 2 as it looks at the viewpoints and arguments behind the medical device industry. However, this chapter looks specifically at the impact the MDET has on patient care and global leadership positioning within the medical device industry. The documents analyzed in this Chapter were pulled from the analysis grid that was mentioned in the methods section of Chapter 1 above. This chapter looks at the keywords patient care and global leadership which were identified amongst the sources and was analyzed by each source type, actor, and keyword (the grid can be seen in the appendix). This section, like Chapter 2 also helps us mostly the secondary questions to this thesis but also gives us the information that is needed to further understand the primary questions. These arguments provide us with a better understanding of why the medical device industry took the actions that it did and helped us to understand how the MDET is being framed by the medical device industry. Through this analysis, we can also understand the ways in which this framing translates into the arguments of patient care and global leadership. Then these arguments can be understood and translated into political tools used by the

medical device industry to take action. The first half of the chapter will look closely at the patient argument, and how it transforms into a political tool, while the second half of the chapter will look specifically at the United States as a global leader in the medical device industry and how the MDET is taking that leadership away creating a strong argument and political tool as well.

3.2 The Patient Care Argument as a Political Tool

3.2.1 Patient Care: the background

At first, it seemed as though the medical device industry failed because it was not successful in having the policy makers select another form of funding for ACA, but later in the process, the medical device industry succeeded in having the MDET repealed temporarily. During these successes and failures, there was an understanding that patient care is a concern across the entire industry, Congress, and all of the U.S. population. Patient care takes everything back to the broad view; it is because of patients that there is a medical device industry, and their care is the ultimate reward for everyone involved. Congress wants their population to be happy and healthy, while the medical device industry wants to create and manufacture good products that improve the health and wellbeing of all their customers of course while also making a profit. Patient care is something that everyone can get on board with, so it was one of the best arguments that the medical device industry can utilize. Not only will it influence the perceptions of Congress it will impact the broader audience of the general population. When patient care is affected by the MDET there is without a doubt a negative viewpoint of the tax, not just for the medical device industry but also the broader public, therefore, this was an incredibly strong argument to bring to the table and assists in the current and potential future success of the medical device industry.

It is important to note that patient care, which will be discussed now, and global leadership, which will be considered in the next segment, are two arguments that are valid arguments and become an issue because of a domino effect from the first two arguments, R&D and job budget reduction. When R&D and job budgets are reduced in the medical device industry, this hurts patient care and their global leadership position. The way that it is framed by the medical device industry is that the MDET doesn't allow for enough resources to provide the best patient care and then is unable to keep up with the surrounding world in regards to its products.

One of the most powerful documents that were analyzed with an argument for patient care was an advertisement from MDMA. It shows a man sitting on a hospital bed, hooked up to an IV, and looking out the window. Large words across the image read, "Innovation isn't all that suffers from a tax on medical devices" (MDMA, 2009). The small writing at the bottom of the advertisement indicates that the Medical Device Tax will be a tax that impacts everyone. It continues to explain that the MDET will truly impact innovation and technologies that are currently being produced and also those of the future. It says, "Americans deserve the best care we can provide them, not this tax" (MDMA, 2009). This is an excellent example of where the medical device industry is taking this argument and turning it into a political tool, what politician doesn't want to get on board with something that has a negative perception like this one against the general public.

The medical device industry uses patient care as one of its main arguments because it truly is the backbone of their industry. This topic is very intricately linked to innovation and research and development. What the industry is saying with this argument is that this tax will push companies to reduce their R&D budgets, which ultimately prevents the industry from developing

the most advanced products, which means they are not receiving the top caliber product that they once could have been receiving before the tax.

3.2.2 Why patient care is important to the policy story and the sources that define the argument

Like the other key topics of discussion, this topic was covered by resources such as witness testimonies in court, press releases, survey data, as well as letters and memos. See Figure 7 where all the resources are listed that were identified as referencing patient care. Witness testimonies that were analyzed through this work were from Kelvyn Cullimore, the CEO of Dynatronics. A chief executive officer of a medical device industry is considered the best subject matter expert for this topic and is a reputable resource to have on hand to debate the patient care argument. During his testimony Cullimore states, “[m]ost importantly, what does this mean to patients and providers? Sadly, policies such as the medical device tax are placing huge hurdles to delivering on promises of improved patient care and a better quality of life” (Cullimore, 2012: 5). As was eluded to earlier, the medical device tax truly impacts innovation which in the end only hurts the patient, again from Cullimore – “I cannot emphasize enough just how delicate the innovation ecosystem is for medical device makers. Any cuts to R&D today will manifest themselves down the road in ways that hurt patients and providers the most” (Cullimore, 2012: 5).

Figure 7 – Documents with Keywords Patient Care

Documents with Keyword Patient Care			
Title	Type of Source	Author	Date
Innovation isn't all that suffers from a tax on medical devices.	Advertisement	MDMA	2009
MDMA Survey - Impact of Repealing Tax	Survey Data	MDMA	2015
Letter to Senate Finance Committee	Letter	MDMA	10/6/2009
MDMA Letter to IRS	Letter	MDMA	3/28/2011
Dentistry Comments	Memo to IRS	Coalition for Dentistry	5/7/2011
Letter to House on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Letter to Senate on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Examining the Impact of Obamacare on Doctors and Patients	Hearing	Witness and Testimonies	7/10/2012
Testimony of Kelvyn Cullimore Jr., President and CEO of Dynatronics	US House of Reps Committee on Oversight and Government Reform's Subcommittee on Health Care and D.C.	Kelvyn Cullimore Jr., President and CEO of Dynatronics	7/10/2012
MDMA Statement on MDET Repeal Efforts in Senate Finance	Press Statement	MDMA	4/4/2014
MDMA, AdvaMed, MITA Support Bipartisan Efforts to Repeal MDET	Press Statement	MDMA	1/7/2015
Coalition Letter to House to Repeal MDET	Letter	1,000 undersigned organizations, associations, companies, patients, providers, and venture capital firms	1/13/2015
MDMA Statement on House Ways and Means Comm Markup of Legislation to Repeal MDET	Press Release	MDMA	6/2/2015
MDMA Letter to House Leadership	Letter	Mark B. Leahey, CEO of MDMA	6/17/2015
MDMA, AdvaMed, MITA Commend House Repeal of MDET	Press Release	MDMA	6/19/2015
MDMA Statement on the First Device Tax Payments Suspension	Press Release	MDMA	1/29/2016

Letters and memos to Congress were of course extremely well used. Over time the letters evolved and increased gradually their number of actors involved. In 2009 some of the MDMA letters included 700 organizations in support and by 2015 they had over 1,000 organizations in support. In these letters, MDMA typically was asking for the repeal of the MDET and expressed

all of the organizations, associations, companies, patients, providers, and venture capital firm’s strong support of repealing the MDET. The main argument is best phrased through the first sentence of this letter to Congress in 2015, “[i]mplementation of this excise tax – now estimated to collect approximately \$25 billion in taxes – is adversely impacting patient care and innovation, and will compromise patient access to cutting edge medical technologies” (MDMA, 2015: 1).

Like the other topics, jobs and innovation, patient care was also mentioned in the surveys that were produced by the Medical Device Manufacturer’s Association. There were quite a few surveys that were analyzed, but the 2015 survey explicitly indicated that patient care was a major issue with the medical device excise tax. The survey says, “[s]ince enacted in 2010, the medical device excise tax has eliminated tens of thousands of good paying jobs, led to drastic cuts to R&D and harmed patient care in the United States” (MDMA, 2015: 1).

Press releases were also key documents for the medical device industry in expressing their dislike of the medical device excise tax. These press releases were good sources for the industry in educating not only on patient care, and how it is impacted by the MDET but also showing the medical device industry’s gratefulness to Congress when different legislation was passed that was supportive of the repeal of the MDET. Obviously, these sources express the discontent that the medical device industry has with the MDET and give their reasoning behind their viewpoint of tax and the way in which they decide to frame this argument.

3.2.3 Actors interested in patient care

Almost all actors showed some interest in patient care, as it is a topic that impacts everyone. Lobby groups such as MDMA, AdvaMed, and MITA all contributed to the press releases, survey data, and letters that were analyzed. Doctors, dentists, and hospitals also contributed through the

letters and witness testimonies. In the letters that were written by MDMA to Congress over 1,000 organizations were included in the signature, including associations, companies, patients, and providers. By obtaining all of these organizations the medical device industry surely was being noticed and without a doubt, this would have been one of the biggest reasons that it succeeded in the getting the two-year temporary repeal of the MDET. These actors contributed, and the patient care argument turns into a political tool. Thinking back to the methodological section in Chapter 1 we are reminded by Birkland that “the power of the individual is greatly magnified when they form groups” (Birkland, 2014: 134). With this argument, there are so many actors that contributed through these sources, and many through the MDMA were combined bringing together a strong force, and an even stronger political tool for the industry. Next, we will understand the goals and objectives of the documents that utilize the patient care argument.

3.2.4 Goals, viewpoints, and objectives related to patient care

Patient care is identified as one of the main arguments made by the medical device industry for requesting the repeal of the MDET. It is an argument that applies to every human being. As mentioned before through analysis of these documents it was determined that the ultimate goal of the medical device industry is the repeal of the MDET, but one of the reasons behind having the MDET repealed is because of patients, and the fact that patient care suffers due to the MDET. Throughout these resources, it is determined that patient care and innovation are directly related because the MDET impacts innovation which results in patient care suffering. Therefore these two arguments together provide standing ground for the medical device industry in the permanent repeal of the Medical Device Excise Tax. This becomes a strong political tool for the medical device industry because it is not only impacting the medical device industry, but it is also impacting the general population.

The MDMA understands the importance of patient care, and even uses it as part of their mission, which is shared when writing to the IRS, “MDMA’s mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies” (MDMA, 2011: 1).

One very important part of the patient care argument that is discovered while analyzing these documents is why the MDET was selected as a piece of the funding for ACA. The MDET was designed to provide funding for ACA which is intended to provide quality health care at a lower cost, giving more patients the opportunity to utilize medical devices, increasing the medical device sales. What testimony from Kelvyn Cullimore states, CEO of Dynatronics is that the MDET instead of helping, actually hurts patients. By placing this tax on medical device companies, there is a reduction in R&D budgets which then impacts patient care. He expresses this during his testimony:

“There is also talk that adding millions to the rolls of the insured will bring more patients needing care, thus more business for those paying the tax. That may be comfortable rhetoric for justifying the imposition of the tax, but at least in our case and in the case of many like us, we do not expect the additional coverage to increase sales of our products” (Cullimore, 2012: 4).

“Most importantly, what does this mean to the patients and providers? Sadly policies such as the medical device tax are placing huge hurdles to delivering on the promises of improved patient care and better quality of life...Any cuts to R&D today will manifest themselves down the road in ways that hurt patients and providers the most” (Cullimore, 2012: 5)

This testimony shows that the policy design that was expected at the time by decision makers, was not only the opposite of what actually happened but what was even projected to happen by the medical device industry at the time it was being developed. However one of the biggest challenges as reviewing these documents was that there was rarely another alternative suggested. It is almost as if the objective of the argument, getting money back into R&D and

back to patient care was the alternative, which gives no other funding option to pay for ACA.

This was definitely a missing link discovered over and over through this argument, and the other arguments as well. Next, we will look at fairness in regards to patient care.

3.2.5 Fairness vis-à-vis patient care

The medical device industry's viewpoint on fairness of the MDET is directly addressed in regards to patient care throughout the patient care resources, where it is not always directly mentioned in some of the other topics. Most commonly discussed are (1) what Americans deserve, (2) what should and should not be taxed, and (3) fairness in developing a tax that without proof can increase sales and better patient care.

In the advertisement created by MDMA with the patient sitting in the hospital and the verbiage saying: "Innovation isn't all that suffers from a tax on medical devices" the comments below the image state, "Americans deserve the best care we can provide them, not this tax" the advertisement is trying to show that this tax isn't fair, that it isn't actually providing what it was designed to do, rather it is hurting those it was created to help (MDMA, 2009: 1). Here the documents are asking if it is fair to have a tax that actually hurts the patient.

A document from a coalition group specific to dentistry wrote a letter to the IRS, not asking for the repeal of the Medical Device Excise tax, but asking for a review of what is actually taxed, most obviously pertaining to dentistry. This coalition views the tax as unfair to orthodontic patients. Therefore this source is not expressing how fair the tax is overall, but specifically for their part of the industry, and asking for a review of what is actually taxed to make it fairer for them (Dental Coalition, 2012: 1). This argument is asking if the actual process is fair, and the administrative burden that is required from the tax.

Lastly, fairness in regards to patient care is directly addressed by Kelvyn Cullimore in his testimony to the U.S. House of Representatives. He along with the medical device industry frame the issue as an unfair way to tax a business without proof that the company will receive a benefit from the tax. He says that “[e]xisting capital equipment may get used more, but it will not necessitate the purchase of additional capital equipment. It may help with those who sell consumable products, but not capital products” (Cullimore, 2012: 4). He also notes in regards to patients that “many of those newly insured being added were already accessing necessary care through existing charitable and emergency room channels” (Cullimore, 2012: 4) this means that more devices are likely not to be sold, but possibly used more, not leading to more sales. Overall the medical device industry’s framing of the MDET as not fair, and their major focus through this political tool is that the patient will suffer, not the business, as in other arguments. Fairness in regards to health policy has been a focus of some research, and as mentioned in Chapter 1 Paula Braveman provides some definitions of what fairness means in this field. She says that, “[e]quity in health means that all persons have fair opportunities to attain their full health potential, to the extent possible” this is interesting because possibly the MDET is removing the potential for the best patient care, resulting in proof of unfairness through Braveman’s definition (Braveman, 2006: 7). Patient care as a political tool brings to the forefront the equity of the MDET and as we continue forward gives us some answers in regards to efficiency as well.

3.2.6 Efficiency vis-à-vis patient care

We discover through the medical device industry documents that the MDET is not viewed as an efficient tax in regards to the patient care argument. Through the analysis, we find that if the tax had followed the policy design, it would help fund ACA, however, because what was expected to happen did not this tax causes innovation to be stifled, which in turn causes patients not to get

the best care that could have been possible for them. The tax actually is viewed as the opposite of efficient causing more administrative burden on the companies, causing a decrease in their R&D budgets, job removal, and in the long run impacting the patients that were supposed to be helped.

Along with the tax being inefficient in regards to the amount, the tax also appears to cause issues with medical device companies and the providers due to the complication of its rules. According to dental coalition they are requesting “an easy to understand and administer rule concerning application of the medical device excise tax [which] will serve to reduce greatly the hidden costs and inefficiencies that would otherwise be engendered by it” (Dental Coalition, 2012: 2). The American Dental Association is asking the IRS to “simplify compliance with the excise tax by eliminating the factors, dropping distinctions that do not have relevant substance differences, and exempting any device used outside the medical institution or office and exclusively by a single patient” (Dental Coalition, 2012: 2). Overall a simplification of the tax and more clarity seems to be what the American Dental Association is asking for, and those changes would assist in the efficiency of the tax execution and payment.

3.2.7 Summary of the Patient Care Argument

The patient care argument is one of the best political tools used by the medical device industry. It appears that the medical device industry uses patient care as one of its top arguments because it is an argument that not only affects the medical device industry but also the general public. The medical device industry finds something that is political in nature and uses actors that can impact the policy process, especially coalitions. As discussed throughout this section it is also evident that the argument shows that the MDET is unfair and inefficient due to the patient care argument which gives the medical device industry an excellent tool to get what it wants and desires from the policy process.

3.3 The Global Leadership Argument as a Political Tool

3.3.1 Global Leadership: the background

The United States strives to be the best in the world in everything that it can and does do. Through analysis of the documents when the medical device industry started to bring in an argument such as reduction in Global Leadership this sparks some attention, and most certainly becomes a political tool. This was a very valid argument that likely assisted in the success of the medical device industry having the MDET temporarily repealed. According to Kelvyn Cullimore:

“[...]we are the global leader in medical technology innovation. This is probably not the first time you have hear this, but I want to be very clear that the United States is in very real danger of losing our leadership position, and if this happens, it will be virtually impossible to get this position back as capital and human resources flow to new centers of innovation out of our country” (Cullimore, 2012: 2).

This argument is the perfect tool to grab the attention of policy makers and officials. What is more tempting than being a global leader in something like medical devices, and scarier than losing that position? The medical device industry knows that this will be an argument that will turn heads and bring special attention to the issue at hand. With the argument being framed as the United States’ leadership position will fall inside of this industry the medical device industry is creating a perfect argument.

3.3.2 Why global leadership is important to the policy story and the sources that define the argument.

Global leadership is a very important political tool that is used by the medical device industry in getting the policy story changed. Leadership is such an important value in the United States; it is something that is appreciated by our political leaders, Congress, and the society in

general. It is a cultural value that can't be ignored. Global power and leadership are things that everyone can agree are important in the current state of affairs, and therefore this argument wins a lot of votes. The medical device industry is a huge contributor to the United States' economy and when leadership positions are dropped there can be an impact on the business and possibly the economy especially with such a large contributor. Also, just framing the idea of losing a global leadership position develops a very strong political tool for the medical device industry to use.

The sources that most discussed the argument of world leadership were letters from coalitions, press statements, and testimony to hearings. Like the other key arguments the letters that were written by coalitions to Congress evolved over time by including more and more signees. In 2009 a letter from over 700 companies and organizations to congress said, “[c]urrently, the U.S. is the global leader in the development and commercialization of medical devices, and it represents one of the few industries with a net trade surplus” also they said, “[s]hould the device tax be implemented, the U.S. will lose its status as a global leader in this market” (MDMA, 2009: 2). Press Statements were used as well to share this argument but were not as used as frequently as some of the other key topics. This argument offers a viewpoint shift for not only the medical device industry but also those that are involved in the policy-making processes. There could not have been a better argument to grab attention throughout the U.S., and these sources were able to shed light on exactly how the medical device industry framed these ideas and developed influence. All the documents that were matched with the keyword global leadership can be found in Figure 8.

Figure 8 – Documents with Keywords Global Leadership

Documents with Keywords Global Leadership			
Title	Type of Source	Author	Date
Coalition Letter to Congress Against MDET	Letter	Trade Assocs., Companies,	10/13/2009
Letter to House on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
Letter to Senate on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	6/6/2012
MDMA, AdvaMed, MITA Support Bipartisan Efforts to Repeal MDET	Press Statement	MDMA	1/7/2015
MDMA Letter to House Leadership	Letter	Mark B. Leahey, CEO of MDMA	6/17/2015
Testimony of Kelvyn Cullimore Jr., President and CEO of Dynatronics	US House of Reps Committee on Oversight and Government Reform's Subcommittee on Health Care and D.C.	Kelvyn Cullimore Jr., President and CEO of Dynatronics	7/10/2012

3.3.4 Actors interested in global leadership

The medical device industry coalitions MDMA, AdvaMed, and MITA, were significant in utilizing the Global Leadership argument, other successful actors in developing this argument were Kelvyn Cullimore in his hearing testimony, and well as a large number of companies and organizations that were included in the coalition letters. Again actors and the way in which they frame their arguments are extremely important to the policy process. As we discussed in Chapter 1, unofficial actors are critical to the policy process and by having each of these unofficial actors author these documents and argue with the global leadership political tool there can't help but be an expectation that the medical device industry would frame this argument as a success. It is important to note that these actors are considered unofficial by Birkland because their

“participation in policy making is not fully specified in the constitution” (Birkland, 2014: 1). The actors that contributed to this argument had goals and objectives around what they wanted to happen while using the political tool; that will be covered in the next section.

3.3.5 Goals and objectives related to global leadership

Knowing that the overall aim of the medical device industry is to repeal the medical device tax, there is further understanding that the medical device industry also wants to save the U.S.’ global leadership position by keeping the leadership that is currently in place and providing a space that the industry can further grow its position. This is all dependent on innovation, patient care, and jobs, all three topics that were argued in the previous sections of this analysis. As the major medical device coalitions said in a press statement supporting Bipartisan efforts to repeal the tax:

“[r]epealing the medical device tax is critical for the United States to maintain its global leadership in this high-tech manufacturing sector and to allocate resources toward the development of new cutting-edge technologies... The United States is a global leader in healthcare innovation and is a net exporter of medical devices but the medical device tax threatens to undermine this position. The device tax remains a drag on medical innovation and has resulted in the loss or deferral of tens of thousands of industry jobs” (MDMA, Advamed, and MITA, 2015: 1).

Without a doubt, the medical device industry views the MDET as the culprit to a decrease of any leadership ranking in the world for the industry. The industry argues that the medical technology industry is paramount to economic growth in the U.S. because it is employing over 400,000 workers across the nation, while generating approximately \$25 billion in payroll, and “paying out salaries that are 40 percent more than the national average (\$58,000 vs. \$42,000) and investing nearly \$10 billion in research and development annually” (MDMA, Advamed, and MITA, 2015: 1). There is importance to the viewpoint of global leadership domestically, as well as internationally, and the way in which this is framed is that the loss of this global leadership isn’t fair, which takes us into the next section of the analysis.

3.3.6 Fairness vis-à-vis global leadership

Fairness in regards to global leadership turns out to be the easiest to understand, but the hardest to defend. None of the documents that address global leadership looked a fairness in relationship to leadership. However, it is clear that throughout the documents the medical device industry is trying to prove that it is unfair to lose a global leadership position in something just because of a tax, especially one that isn't working the way that it was designed. Although the topic isn't explicitly broached in the resources that were analyzed, the conclusion can be determined that the medical device industry frames the issue as an unfair way to take away the leadership role of the U.S. globally for a tax that isn't benefitting its citizens in the way that was it was originally designed. From the 2015 letter to House Leadership the MDMA shows how the tax is poorly affecting the industry, "in many cases, smaller companies who are operating at a loss have to borrow money to pay this tax since it is on revenues not profits" and then they later state that "now is the time to act before we lose our global leadership position" (MDMA, 2015:2). If the "Ability to Pay Principle" was the route that was followed to determine if the MDET was fair, it doesn't seem to be following the design, and therefore it is impacting the ranking of the United States across the globe in innovation and patient care (Head, 1992: 65).

3.3.7 Efficiency vis-à-vis global leadership

Efficiency in relationship to global leadership is like fairness; it is evident from the medical device industry resources shared above, and from previously mentioned arguments that this specific argument certainly shows the inefficiencies of the medical device tax. By taxing this industry, jobs are reduced, innovation is stifled, patients aren't cared for, and all of this brings down the ranking of the U.S. in its leadership position in this industry. The MDET is not viewed an efficient tax practice since it is tearing down and ruining parts of the business that contribute in

large ways to Congress, the economy, and its citizens. We know from earlier discussions of efficiency that efficiency is a hard term to define because it means so many different things for many different actors, however, if we do as we did in other sections above and use the definition of “Pareto Efficiency” then we can say that through the analysis of global leadership that the MDET was not viewed as efficient because it isn’t “one from which no person can be made to feel better off without making another person feel worse off”(Reinhardt, 1992: 7). This is absorbing because according to Reinhardt “the term efficiency is meant to reflect social welfare, because the concept is based on the way people “feel” about different allocations” (Reinhardt, 1992: 7). The medical device industry used tactics throughout these documents to influence the view of policy makers, which ultimately impacts the policy process.

3.3.8 Summary of the global leadership argument

The global leadership argument translates very well into a strong political tool for the medical device industry. Through these documents, we find that many coalitions and groups believe in the argument and are able to influence the perception of those that might be reading the materials such as political actors, actors within congress, and the general public. Although this argument didn’t have documents that dove deeply into the equity or efficiency of the MDET, it was clear what the viewpoint of the MDET was, and how to share that analysis. This argument is such a powerful one that the only anecdote that might be contributed to this scenario is the idea of providing another option. Throughout the documents that were analyzed the fact that global leadership will be a loss was repeatedly highlighted, but there was no alternative solution suggested. Overall the global leadership argument is an excellent tool for the medical device industry’s argument against the MDET and fight to have the MDET permanently repealed.

3.4 Chapter 2 and 3 Conclusion

Innovation, jobs, patient care, and global leadership arguments are unyielding, and consistent issues brought to the surface by the medical device industry against the MDET. The arguments play a central role in the failure and success of the medical device industry, strengthening the overall argument that the tax is viewed as unfair and is inefficient. These arguments contribute to the medical device industry's success in having the MDET repealed even if only temporarily. The arguments also provide insight into the way in which the medical device industry framed the issue and explains why the MDET is not viewed as a fair and efficient way to spread the cost of ACA across the health industry. They provide strong reasoning for their viewpoint of the unfairness and inequity of the MDET and lead to explanations of why the medical device industry succeeded in its efforts.

However, these arguments may have also contributed to the overall inability of the medical device industry to stop the policy makers from selecting the MDET as the ACA funding source. Because the medical device industry so strongly framed the MDET as unfair and inefficient based on these arguments they became limited in the ability to truly think of other policy options, and only focused on the fact that the MDET was not the correct solution. Therefore it is important to note that for further success the medical device industry should have also included in my any of its sources alternative funding methods for ACA rather than focusing all its energy on the political arguments and tools dissected above.

The two major conclusions that we can come to as a result of this chapter are the (1) importance of actors coming together with the same argument to frame the issue, and (2) the importance of all these arguments linking together to become individual political tools. All four arguments had multiple sources that utilized hundreds of companies or businesses that came

together as a coalition. Actors are important to the policy process and in particular through these unofficial actors they could not have framed the issue the way that they did without leaning on one another.

Finally the importance of these arguments individually as political tools, but then ultimately coming together as one larger argument. Each of these arguments relies on one another, innovation and jobs being the budget arguments, and patient care and global leadership relying on the budget arguments. Without one argument you couldn't have the other, and we identified that the medical device industry had these four major arguments and by tying them together they were able to come forth with an adamant argument, that would influence viewpoints across many different audiences. By tying these arguments together, they were able to seek success in having the policy process change. The arguments that have been laid out in the last two chapters lay the pavement for the policy story in Chapter 4, which takes these policy tools and outlines them within the actual actions that were taken.

CHAPTER 4: FRAMING & POLITICAL ARGUMENTS TURN INTO ACTION

4.1 Policy story: the background

This Chapter not only provides a better understanding of the MDET as a tax policy and how it has evolved over the past six years, but it also dives deeper into the keywords discussed in

Chapter 2 and 3. Those keywords have been defined as policy arguments, derived from the ways in which MDET was framed by the medical device industry, and those arguments turn into political tools for this policy story. Arguments are vital to the policy story and they are often the starting point within the policy process as Deborah Stone argues in her seminal work, *Policy Paradox*, on the importance of public policy as political arguments:

“For centuries, governing through knowledge instead of politics has been a utopian dream. [...] The enterprise of extricating policy from politics assumes that analysis and politics can be separate and distinct activities. [...] Most social scientists and practitioners [...] chafe at a strict dichotomy between reason and power [...] This book [and this thesis] challenges the dichotomy of analysis and politics from which such middle grounds are blended. [T]he categories of thought behind reasoned analysis are themselves constructed in political struggle, and nonviolent political conflict is conducted primarily through reasoned analysis. Therefore, it is not simply a matter that analysis is sometimes used in partisan fashion or for political purposes. *Reasoned analysis is necessarily political*. Reason doesn't start with a clean slate on which our brains record their pure observations. Reason proceeds from choices to notice some things but not others, to include some things and exclude others, and to view the world in a particular way when other visions are possible. Policy analysis is political argument, and vice versa”. (Stone, 2012: 379-380)

The political tools or arguments that are framed by the medical device industry then become action by the medical device industry, and this chapter takes a look at those actions and how they have impacted the policy process for the MDET. There are three major actionable items that were identified through this Chapter's analysis that the medical device industry uses to activate and try to have the MDET repealed, and they are:

- (1) Campaign contributions
- (2) Interest groups
- (3) Lobby expenditures

This chapter unlike Chapters 2 and 3 analyzes documents from the political actor side. The House of Representatives resource website, the Senate resource website, OpenSecrets.org, and

maplight.org were each searched for the “Medical Device Excise Tax”. The top twenty documents from each site were then saved and reviewed, and then were processed through the following questions:

- 1. What were the actions taken to have MDET repealed and how were those actions shaped and impacted by the framing of the MDET by the medical device industry?*
- 2. How did these actions help medical device industry succeed and how did these actions allow medical device industry to fail?*
- 3. How did these actions impact the policy process?*
- 4. What did these actions teach us in terms of the politics behind the MDET?*
- 5. What did these actions teach us in terms of the politics of health care reform*

To complete this Chapter a search was done of the MDET on the House of Representatives resource site, the Senate resource site, OpenSecrets.org, and maplight.org. Both the House and Senate resource sites returned mostly press releases. Opensecrets and Maplight provided more data-driven results. Opensecrets.org is a website that describes itself as “nonpartisan, independent and nonprofit, the Center for Responsive Politics is the nation’s premier research group tracking money in U.S. politics and its effect on elections and public policy” (Opensecrets.org, 2016). Maplight describes itself as “a nonpartisan organization that reveals money’s influence on politics” (Maplight.org, 2016). Maplight researches and compiles data around campaign contributions in the U.S. presidential, state, and local ballot and candidate elections and was founded in 2005 (Maplight.org, 2016).

Once these resources were collected and read, they were then analyzed by answering the questions indicated above. By responding to these questions, there is a better understanding of the answers to the primary research questions: how and why the medical device industry failed, and

at times succeeded, in having the MDET repealed? To fully understand how they succeeded, and at times failed, there must be an understanding around what actions were actually taken, which is provided in this chapter.

Throughout this chapter it cannot go unnoticed that partisanship plays a very important role in the policy making process, however this thesis focuses directly on the external factors that come in to play. It is important to realize that the partisanship piece cannot be ignored and has made a large influence with democrats and republicans having different viewpoints throughout the life of this tax but will not be a major focus of this chapter or this thesis. By understanding the arguments and viewpoints of medical device industry through the analysis in Chapter 2 and Chapter 3, we can better understand the actual actions that were taken and how they influenced the policy process.

4.2 Political actions being taken and how they were shaped by framing

4.2.1 Campaign Contributions shaped by framing

The action that will be described in this section is campaign contributions from the medical device industry to policymakers. These campaign contributions were offered to policymakers in support of the politician, but we know that these contributions are also an effort to have the MDET repealed. There is some evidence to show that campaign contributions were a huge reason behind the two-year moratorium that was put on the medical device excise tax from January 1, 2016, through December 31, 2017, which would be considered a success for the medical device industry. Over the years that the MDET was put into place there has been some dissatisfaction across parties. Five years after the President signed ACA into law, republicans that have been against the law finally have the chance to permanently repeal the MDET, along with democrats that are getting on board. According to Clark Mindock from opensecrets.org, Center for Responsive Politics, “the

tax (MDET) is anything but a wedge partisan issue” (Mindock, 2015). But the bipartisanship may not have much to do with ideology” (Mindock, 2015). Mindock finds that the representatives leading the efforts behind the moratorium on the MDET have ties to the medical device industry, as well as many democrats who are cosponsoring. Mindock continues by saying “the debate is framed, though, there’s no arguing that the medical device and supply industry has poured money into a relentless lobbying effort, as well as into lawmakers’ campaign coffers, and that may be paying off soon” (Mindock, 2015).

In 2012 the medical device industry gave \$10.3 million to candidates, parties, and outside spending groups, during that year Republicans were favorite and brought in 61 percent of the money the industry contributed. In 2014 during a nonpresidential cycle, donations went back down to \$6.3 million, around the same level in 2011. During that time the top recipient was Rep. Erik Paulsen (R-Minn) who has sponsored several versions of the legislation to take out the MDET, and he received \$92,549 from the medical device industry. On January 6 of that year, he introduced the Protect Medical Innovation Act of 2015 with 271 cosponsors (Mindock, 2015). The cosponsors were 32 Democrats, and 27 of them had received money in the last cycle from the medical device industry. One of those Representatives was Ron Kind (D-Wis), and he received the eighth-highest amount. Among the House candidates, Kind was second to Paulsen and a spot ahead of the Speaker John Boehner (R-Ohio) (Mindock, 2015).

In regards to the Senate, the Medical Device Access and Innovation Protection was introduced by Sen. Orrin Hatch (R-Utah) with 23 Republican cosponsors and five democrats had signed on. All of the democrats had received money from the medical device industry in 2014, both democrats from Minnesota, were on top of the list. Minnesota being the home of Medtronic, one of the largest medical device industry. Medtronic was the biggest donor in the 2014 cycle

from the medical device industry at \$604,772. The individuals that got the most cash from Medtronic in 2014 were all 3 Minnesota lawmakers (Mindock, 2015).

Below (Figures 9 and 10) you can see the top five industries that contributed to Rep. Erik Paulsen across his career, as well as in 2014, during the year in which medical device industry lobbied most heavily for the repeal of the MDET.

Figure 9 – Campaign Contributions to Rep. Erik Paulsen (Opensecrets.org)

Top 5 Industries, 2007-2016			
INDUSTRY	TOTAL	INDIVS	PACS
Retired	\$1,017,063	\$1,017,063	\$0
Insurance	\$863,978	\$272,977	\$591,001
Pharmaceuticals/Health Products	\$782,529	\$277,530	\$504,999
Health Professionals	\$682,495	\$237,485	\$445,010
Securities & Investment	\$621,400	\$435,650	\$185,750

Figure 10 – Campaign Contributions to Rep. Erik Paulsen (Opensecrets.org)

Top 5 Industries, 2013 – 2014			
INDUSTRY	TOTAL	INDIVS	PACS
Insurance	\$256,075	\$72,325	\$183,750
Pharmaceuticals/Health Products	\$239,179	\$75,430	\$163,749
Retired	\$224,285	\$224,285	\$0
Health Professionals	\$187,569	\$67,559	\$120,010
Securities & Investment	\$164,000	\$101,500	\$62,500

Because the industry is not happy with the tax, and the impact that it could have on its industry, described in Chapter 1, the medical device industry knew that it had to approach its lawmakers to try and get the tax repealed. The law was framed in a way that it would impact the industry’s R&D, patient care, jobs, and global leadership rank. These reasons contributed to a poor viewpoint of the law, causing the medical device industry to look at ways it could impact policy. By offering campaign contributions to those individuals they knew would be elected, and be able to create a bill to repeal the tax temporarily, they were taking action to see results. Across party lines, the medical device industry contributed to individuals and it shows that those

individuals were the most active and influential in passing laws to benefit the medical device industry, including H.R. 2029 which put the moratorium on the tax (OpenSecrets.org, 2016).

4.2.2 Interest Groups shaped by framing

Interest groups are groups of people that work together towards the same political goal, and the theory of “[p]luralism is based on the assumptions that interest groups are the political actors that matter most in shaping public policy” (Howlett, Ramesh, and Perl, 2009: 38). The interest group that is examined in this thesis is defined as “Medical Devices & Supplies” interest group and is identified and analyzed by Maplight.org (Maplight.org, 2016). Figure 11 shows the top Senate recipients that were funded by this interest group, as well as the top House recipients that were funded. It cannot be a coincidence that the top funded House recipient is Erik Paulsen (discussed through the campaign contribution analysis) is receiving the high dollar amount from interest groups over the past two years of data and was the sponsor of H.R. 160 – Protect Medical Innovation Act (Maplight, 2016).

Figure 11 – Interest group contributions (Opensecrets.org)

Contributions			
Top Senate Recipients Funded		Top House Recipients Funded	
Recipient	Amount	Recipient	Amount
Orrin G. Hatch	\$249,233	Erik Paulsen	\$71,030
Amy Klobuchar	\$164,825	Robert. J. Dold	\$57,350
Mark Kirk	\$160,850	Ron Kind	\$53,250
Mitch McConnell	\$132,423	Anna G. Eshoo	\$51,409
Harry Reid	\$127,650	Fred Upton	\$48,750
Ron Wyden	\$127,378	Paul Ryan	\$48,187
Robert P. Casey, Jr.	\$126,899	Kevin McCarthy	\$40,100
Rob Portman	\$110,299	Marsha Blackburn	\$39,100
Richard Burr	\$107,051	David P. Joyce	\$35,200
John Cornyn	\$95,300	Tom Reed	\$35,100
Contributions show for last six years of available data, April 1, 2009 – Mar 31, 2015, including contributions to presidential campaigns.		Contributions show for last two years of available data, April 1, 2013 – Mar 31, 2015, including contributions to presidential campaigns.	

Interest groups are not new to the medical device industry, they have been around for medical devices way before the Medical Device Excise Tax came into play. However, since the tax was implemented there has been an increase in political interest surrounding medical devices and supplies resulting in the collaboration of groups and efforts to suspend the medical device excise tax. This can be shown through the documents that were analyzed in Chapters 2 and 3. Within those documents, there were letters written to the House and Senate that were often signed by interest groups. Each year the number of organizations that signed increased from 2012 700 organizations signed, while in 2015 there were over 1,000 (MDMA, 2015: 1; MDMA, 2012: 1). These groups are most influenced by the reasons that were analyzed in the first section of this thesis, through the analysis. The interest groups are made of medical device and medical supply businesses; they view that jobs, research and development, patient care, and global leadership ranking will be impacted by the medical device tax and will come together to do whatever they can to stop it. Even if there is competition amongst these groups, they are willing to collaborate to make an impact on the policy making process. The more that these interest groups frame the tax as unfair the further they continue to band together through contributions and lobbying efforts to ensure that some sort of policy alteration is completed.

4.2.3 Lobbying shaped by framing

Lobbying groups are those who influence policy makers in their decision-making, and remember Birkland finds that without groups and lobbyists our democratic system of policy formation and implementation could not function (Birkland, 2014: 1). According to Opensecrets.org, the lobbying group for the medical device industry is classified as “Medical Devices & Supplies” (Opensecrets.org, 2016). The amount of spend on lobbying can be seen in

was over \$32 million in 2014 (Opensecrets.org, 2016). Notably, the highest spend was in 2014 and 2015 when there were strong attempts to have the MDET repealed.

According to OpenSecrets.org “The industry spent more on lobbying in 2014 than it did in any other year going back to 1998, the first year the Center for Responsive Politics has data for the category (OpenSecrets.org, 2016). In 2014 over \$32.8 million was spent on lobbying over the \$31.8 million spent in 2009 – which was at the time that the industry wanted to make sure that their devices would be covered under President Obama’s healthcare bill (OpenSecrets.org, 2016). As time went on and medical device industry thought that they might finally be able to get the tax repealed their lobbying efforts continued to increase. It seems almost as if their lobby efforts would have continued to raise, and they wouldn’t have backed down until they saw some sort of change. The industry builds a very strong negative framing of the MDET and believes the bill will impact their business in very negative ways, so they continue to push for the permanent repeal.

4.3 Political action: success and failure

4.3.1 Campaign Contributions success and failures

In this policy story, the temporary repeal of the MDET is considered a success. Although it is not a permanent repeal, it is still a step in the right direction for the medical device industry. By contributing to the policy makers’ campaigns who ultimately could write and sponsor laws that would repeal the tax permanently the medical device industry was able to make an impact the political actors resulting in success. Even if the policy maker wasn’t the author of the bill, they may be someone that would vote for the passage of a bill possibly due to the industry’s contributions which would also overall be portrayed as a success.

Because the medical device industry has not yet seen a permanent repeal of the MDET, there could also be an argument that campaign failures could be considered a failure. Therefore the medical device industry is partly failing in the permanent repeal of the MDET. Although the campaign contributions appear to mostly be a success, maybe we can take the stand that if additional campaign contributions would have been given to other sponsors, or if more money had been paid to the politicians that already sponsored the laws, the medical device industry would have been able to get the tax fully repealed. However, this could put the industry in jeopardy with its campaign contribution budgets, and overall doesn't have a good moral feeling.

4.3.2 Interest Groups success and failures

Interest groups for the medical device industry could be considered successful just for the reason that they have been able to come together as such a large group. By coming together, these interest groups have been able to put more towards lobbying than they ever have in the past, contributing to the efforts that brought the tax to a moratorium. Collaboration seems to be a huge part of the interest groups and also one of the major reasons that policymakers have begun to understand the negative framing of the MDET that the medical device industry has developed.

Throughout the research that was done for this thesis, interest groups are actually one of the most likely actions to not have a failure. Throughout this research, the interest groups have come together in success. However, there is still the fact that the MDET is not permanently repealed, which means that there is still work to be done for the medical device industry. Perhaps the failure would just mean that the interest groups have to continue pushing forward. The timeline of the MDET is still short, and interest groups could be an action that needs more time to make an impact.

4.3.3 Lobbying success and failures

Over time the lobbying efforts that went into effect against the MDET seemed to be successful. According to Modern Healthcare, “most healthcare stakeholders have slowed their spending on Washington lobbying, one sector has cranked up the pressure – the medical-device industry” (Demko, 2015). These efforts financially and through influential meetings and networking have influenced the development of laws that are against the MDET.

However, like the other actions, one could consider the lobbying efforts across the industry as a failure due to there currently not being a law signed permanently repealing the tax. However, even if this is a current failure, success is around the bend for those that were contributing to the lobbying efforts:

“Despite the odds facing repeal, the array of well-funded business and lobbying interests pushing for elimination of the tax guarantees it will not die soon. “The congressional forces who support it and the downtown forces that support it are never giving up on it,” said one lobbyist working on repeal efforts who did not want to be identified. “This is not going away.” (Demko, 2015).

The industry doesn’t appear to be giving up anytime soon, and will continue to fund lobbying dollars until it sees the permanent repeal that it seeks.

4.4 How these actions impact MDET, the policy process, and healthcare reform

4.4.1 Campaign Contributions impact on policy

The action of campaign contributions definitely had a bearing on the policy process. By offering campaign contributions, the industry was able to get decision makers to listen to their

arguments. They were able to get the attention of Rep. Erik Paulsen and impact the legislation that he wrote against the MDET. It is very likely that the campaign contributions that were given by medical device industry to lawmakers assisted in the development of legislation that gave a temporary repeal on the tax, and that could potentially lead to a permanent repeal of the tax.

This action and the response teaches us that there are lots of politics behind the MDET. Just like Mindock said the temporary repeal of the MDET “may not have much to do with ideology” it had a lot to do with the individuals that were influenced through their campaign contributions (Mindock, 2015). It teaches us that campaign contributions actually do have an impact on the policy making process and that the industry will likely continue to contribute in the manner because it has seen a benefit. Currently, there is large dissatisfaction with ACA and possibly there will be more and more campaign contributions in an effort to have it repealed or changed. Since the medical device industry saw a success by utilizing campaign contributions, this can be a continued form of action from industries and individuals that are trying to make an impact on health care and its reform. The question becomes how ethical is it, though, and what is the limit?

4.4.2 Interest Groups impact on policy

In such large numbers, medical device industry interest groups have lots of weight in influencing policy makers. The medical device industry is a large industry and has a lot of sales across the globe which impacts the nation’s economy. The medical device industry views the MDET as an unfair tax due to many reasons, but one of them being the decrease in global ranking. The framing that was developed behind global ranking was one that was likely used in not only interest group lobbying but across the board in influencing policy makers. By coming together

through lobbying, campaign contributions, as well as through educational influencing the medical device industry is able to increase the number of votes against the MDET.

Without interest groups, there would not be an in-depth awareness of the medical device industry’s viewpoint on issues of the MDET. Also, there would likely be fewer campaign contributions and overall lobbying. By coming together in larger groups and coalitions, resources can be pooled together to make a difference and make more of an impact. The action of developing interest groups teaches us that these are an extremely effective way for industries such as medical device industry to ban together in an effort to make policy changes, even when they are competitors.

Figure 12 – Interest Group Contributions for H.R. 160 (Opensecrets.org)

H.R. 160 – Protect Medical Innovation Act of 2015 Taxation, 114 th Congress (2015-2016) Sponsor: Erik Paulsen Summary: To amend the Internal Revenue Code of 1986 to repeal the excise tax on medical devices. (by CRS) Status: The bill was voted on in the House on June 18, 2015					
Average contributions given to House members from interest groups that...					
support this bill			oppose this bill		
Interest groups: Other physician specialists, Republican/Conservative, Dentists, Medical Devices & Supplies, Biotech products & research, Manufacturing, Chambers of commerce, Fiscal & tax policy, Elderly issues/Social Security (split)			Interest groups: Physicians, Democratic/Liberal, Teachers unions, Women’s issues, Manufacturing unions, State & local gov’t employee unions, Federal employee unions, Commercial service unions, Communications & hi-tech unions, Automotive manufacturing unions, Health, Education & Human Resources, Small business associations, Health & welfare policy, Health worker unions, Health professionals, Human Rights, Consumer groups, Elderly issues/Social Security (split)		
	Yes	No		Yes	No
	117% more			52% more	
Avg. given to House	\$66,849	\$30,843	Avg. given to House	\$48,019	\$73,013

members who voted:			members who voted:		
House Vote: On Passage PASSED on June 18, 2015 1/2 required to pass Voted yes: 280, Voted no: 140 14 voted present/not voting					

4.4.3 Lobbying impact on policy

Lobbying has certainly made an impact on the policy process behind the MDET. The medical device industry has been relentless with its lobbying efforts and like OpenSecrets.org says these efforts are paying off. Through lobbying the industry has been able to get policymakers to not only understand, but agree that this tax poorly impacts not just the medical device industry but the economy as well.

With increased amounts of lobbying from the medical device industry over the past 3-5 years and the evolution of the laws, there is evidence that the action of lobbying made an impact on policy makers. This tells us that the industry will likely continue to put monetary and influence efforts in place through lobbying until it reaches its desired permanent result which is that the MDET is permanently repealed and other more desirable healthcare reforms.

4.5 Policy Story Conclusion

Through three major actions: campaign contributions, interest groups, and lobbying expenditures there is now a better understanding of the MDET as a tax policy and how it has evolved over the past six years. The major actions defined in this chapter are the backbone for the impact on the MDET and have a strong connection to the evolution of the process behind the MDET. These actions were all initiated by the negative framing that was done by the medical device industry and were developed by the arguments that stemmed from the arguments (R&D,

jobs, patient care, and global leadership). These actions were able to help medical device industry in successfully getting the moratorium on the MDET, but also somewhat contributed to their failure of not getting a permanent repeal of the tax. Through these actions, the political science discipline can better understand how framing creates and develop arguments which often translate into political action. This teaches us how unofficial actors can change policy process overall and specifically within healthcare reform.

CONCLUSION

This thesis concludes with answers not only to the original research questions but also with many answers yet to be explored through the future of the MDET. The MDET was first signed into law in 2010, went into effect in 2013, and then shortly thereafter was temporarily repealed in 2015. Still, with continuing efforts to have it definitively repealed by the medical device industry, these actions brought many great questions to the table. Those questions again were:

- (1) How exactly is the MDET framed by the medical device industry?
- (2) Why is the medical device industry first unsuccessful in stopping the tax from becoming law, and then partly successful with a temporary repeal?
- (3) What exactly did the medical device industry do?
- (4) What does it tell us about the policy process?
- (5) What can we learn in terms of the politics behind the MDET and the overall healthcare reform?

By using these questions the main objective was to dissect the (1) different arguments that the medical device industry has against the MDET, (2) their framing of fairness and efficiency and (3) their actions in terms of lobbying and political support. Then explain how the medical device industry has both failed and succeeded in regards to the MDET and what that says about the policy process in the United States.

The main hypothesis that was developed and was tested through qualitative analysis was that the medical device industry failed to provide an alternative option for funding ACA. This failure ultimately linked to the fact that the medical device industry frames the tax as being by

nature unfair and inefficient, thus limiting its ability to think about other policy options. This idea did show itself throughout many of the resources. When analyzing the medical device industry documents in Chapters 2 and 3, it was very clear that the framing of the MDET was very negative. However, there was almost no mention of additional funding thoughts or ideas that came from the medical device industry. Not one of the sources that were analyzed during this research shared another idea of a source of financing. However, moving forward the industry should certainly use more clear specifications around what other options there are so that the political actors know what options are also available to them.

The next hypothesis stated that the medical device industry succeeded in having the tax repealed temporarily due to (1) the coalitions that were developed throughout the industry and (2) because of the medical device industry's consistency in their arguments since the tax came into existence. This hypothesis does have the backing to be confirmed. Coalitions through interest groups were vital to the industry in the actions that it took, and the coalitions grew over time increasing their capabilities. One of the most notable things throughout the arguments from the medical device industry was consistency. Throughout the timeline of the MDET, there are many arguments, but the four that are shared through this thesis were consistently brought up and utilized as arguments even until today. This steadiness and perseverance cannot be ignored and possibly created different viewpoints and ideas for the policy makers from start to finish.

Notably, the use of arguments based on innovation, jobs, patient care, and the loss of global leadership seemed also to play a central role in the failure and success of the medical device industry, strengthening the arguments that the tax was framed as unfair and/or inefficient by the medical device industry. Finally, I had hypothesized that both Congress and the medical device industry's viewpoint was that the MDET did not fund ACA as it was intended to when it was first

written into law, bringing force to the main arguments of the industry, and leading to this mix of success and failure. This did ring true throughout this research. After the MDET had taken hold it did not bring forward the dollars that were expected, nor was it an easy tax to manage administratively. It also did not provide the medical device industry with the increase in sales that was expected. All around this tax did not work the way in which the actors involved in designing it thought that it would. Therefore, once this failure was noticed the actors (medical device industry and politicians) were able to grab ahold of this failure and push forward with a temporary repeal.

Many of the main research questions could be answered without a doubt. The first question was how the medical device industry views the MDET. Without question, the conclusion is that the medical device industry finds the MDET to be very unfair and inefficient as detailed by its arguments in Chapter 2 and 3. This is critical to this research because we know from our theoretical work in Chapter 1 that framing plays a very central role in the policy process (Cochran et al., 2015) and according to Birkland, how an issue is framed or presented by a different actor (and influenced by perceptions, ideas or strategy for example) are considered the driving factors behind the policy process (Birkland, 2014). Our research aligns closely with Cochran et al. and Birkland's ideas because we find that due to these strong negative viewpoints the medical device industry develops arguments against the MDET which translates into their political tools and actions.

The actual actions that the medical device industry took to attempt change within the policy process were campaign contributions, lobbying, and interest groups. These three actions were identified through the research from the House and Senate websites, as well as OpenSecrets.org and Maplight.org. These actions were the result of the development of the arguments: R&D, jobs,

patient care, and loss of global leadership. Once those arguments were developed, the actions were taken. Being unofficial actors within the policy process, the medical device industry displays the importance of framing and how unofficial actors are involved. Both the “stage model” and the “rational process” are rigid and miss this important collective action taken by the medical device industry (Cochran et al., 2015: 7; Andrew, 2006: 161) and throughout this research, we can understand how important these collection actions are.

It is safe to say that today the medical device industry is communicating more success than failure due to the current repeal of the tax. There is hope at the end of the tunnel for the industry, and they believe a complete repeal is on its way. The medical device industry first failed in stopping the MDET from passing into law because they did not suggest alternatives, but then they seemed to succeed partially because they translated their viewpoints into actions. However, as Schuck says, “all policies succeed in some respects and fail in others” (Schuck, 2014: 42). The MDET is a clear representation of this theory because there were lots of times that the medical device industry may not have felt the success that it is currently communicating. Once the shininess of the current win wears off, and the tax comes back in 2018 what will the satisfaction be for the industry?

This story tells a lot about the policy process, but most important, and in answering the research questions, it teaches us that the framing done by the actors are vital to the results of their actions. The framing not only influences arguments, and then the actions that are taken, but then those viewpoints also influence other actors within the policy process to make a change. In regards to the politics behind the MDET and the overall healthcare reform, it is important to realize again the importance of framing, ideas, and influencing them amongst political actors. Also, there is

some room to learn more through this specific process dealing with the MDET. With this story being such a short policy story, there is more to learn and understand in future research.

The biggest limitations to this thesis are the timeline and a large number of actors involved. With the short timeline, there wasn't enough information related to this topic, and because there were so many actors it felt like not all of their viewpoints could be analyzed. Now that we understand the importance of framing and unofficial actors, this topic should continue to be researched and analyzed from different perspectives and timelines, especially after the two-year temporary repeal of the tax. Different research vantage points would be:

1. Different vantage points related to time:
 - a. After the moratorium on the MDET is stopped in 2018
 - b. After permanent repeal of the MDET (if this takes place)
2. Different vantage points through unofficial actors:
 - a. Insurance companies, their viewpoints, and their political actions
 - b. Hospitals (the medical device industry's customer), their viewpoints, and their political actions
 - c. Citizens that are utilizing healthcare provided through ACA, their viewpoints, and their political actions (if any?)
3. Different vantage points through official actors:
 - a. Specific political actors that were a part of the writing, development, and activation stage of this tax, and their views pre and post-tax (and during the repeal)

Along with different vantage points and timetables it would be interesting to look at this policy story through a lens that analyzes the policy planning prior to the development of the tax.

This research has shown to be a success for the medical device industry, however, maybe it truly originated as a policy planning problem. Now that this tax has been temporarily repealed there doesn't seem to be a replacement revenue for ACA, this is a violation of the PAYGO rule or "Pay-as-you-go rule." The PAYGO rule "requires that new direct spending and revenue legislation be deficit neutral" (Bradford: 2005, 2). Now that this tax has been repealed and there is not a new replacement does that mean that there did not need to be a replacement? Was this revenue stream not actually needed? These thoughts raise very good questions and provide opportunity for further research regarding the revenue stream provided by this tax. Possibly this success for the medical device industry was actually just proof that the tax was not well thought out, either way the medical device industry can see this as a win.

In conclusion, the framing of the medical device industry, lead to strong political tools and actions which resulted in both success and failure within the policy process. These successes and failures helped us to write a story of the policy process within this industry, but more importantly helped us to recognize the importance of framing and unofficial actors within the policy process.

Appendix

Title	Type of Source	Author	Type of actor	Time period (before/after + data)	Goals/objectives vis-à-vis the MDET	Policy target	Main perception/argument	Other perceptions/arguments	Alternatives offered	Quotes (highlight quotes in original doc, or note page, para, etc.)	Keywords (+ type of vocabulary involved, threatening, cooperative, etc.)	Pol Actor Resources with similar arguments (or direct connection with pol actor)	Mention of Intra-category group/actor (specify)	Relationship/arguments related to fairness	Relationship/arguments related to efficiency
Innovation isn't all that suffers from a tax on medical devices.	Advertisement	MDMA	Lobbyist	2009	• encourage others to not support MDET • indicates that innovation is stifled through MDET		• innovation is stifled by MDET and patients will suffer	• this tax makes it more difficult for companies to compete	• none	"The proposed tax on medical device companies will be felt by everyone. The majority of these companies are small businesses that work tirelessly to provide remedies, seek cures and put patients first. But this tax will make it harder for all companies to compete and likely stifle innovations and technologies of the future. Americans deserve the best care we can provide them, not this tax."	• stifle • innovation • competition • small business		NA	• "Americans deserve the best care we can provide them, not this tax" - this seems to be saying that it isn't fair to the American people	• concerned with this being an efficient tax for medical device industry
Behind every medical device breakthrough stand the people who make it possible	Advertisement	MDMA	Lobbyist	2009	• educate Americans about who MDMA is	NA	• no argument here, just educating people on who MDMA is	NA	NA	NA	• medical technology • innovation • technology	NA	NA	NA	NA
Health Costs Letter to President	Letter	Advanced Medical Technology Assoc., American Medical Assoc., America's Health Insurance Plans, Pharmaceutical Research and Manufacturers of America, American Hospital Association, Service Employees International Union	Lobbyist	2009	• agreement to support the president in efforts to reform health care • offer concrete initiatives that could reform health care		• Reducing over-use and under-use of health care by aligning quality and efficiency incentives among providers across the continuum of care so that physicians, hospitals, and other health care providers are encouraged and enabled to work together towards the highest standards of quality and efficiency • Encouraging coordinated care, both in the public and private sectors, and adherence to evidence-based best practices and therapies that reduce hospitalization, manage chronic disease more efficiently and effectively, and implement proven clinical prevention strategies • Reducing the cost of doing business by addressing cost drivers in each sector and through common sense improvements in care delivery models, health information technology, workforce deployment and employment, and regulatory reforms	• this source isn't arguing against MDET because at this point it hadn't been put into law yet, but it gives some good alternatives	• see main perception/argument	"We stand ready to work with you (the president) to accomplish this goal."	• access • affordable • healthcare reform • health • savings • quality • efficiency • commitment	NA	• Executive branch • Insurance Company • Hospitals	• "Reducing over-use and under-use of health care by aligning quality and efficiency incentives among providers across the continuum of care so that physicians, hospitals, and other health care providers are encouraged and enabled to work together towards the highest standards of quality and efficiency"	
Letter to Senate Finance Committee	Letter	MDMA	Lobbyist	10/5/2009	• letting the finance committee know that MDMA does not support MDET		• happy to see reform but not through MDET		• willingness to consider targeted cuts in the MD industry related to fraud, waste, and abuse • repeat of GPO safe harbor	"In conclusion, MDMA would like to reiterate its steadfast opposition to the proposed medical device tax. Furthermore, we would like to clarify that the creation of a new fee, no matter what the amount, is not a proposal supported by the overwhelming majority of the device industry"	• efficiency • reform • cost reductions • opposition	NA	• GPO Safe Harbor • small to mid-size companies		
Coalition Letter to Congress Against MDET	Letter	Trade Assoc., Companies	Coalition/Lobbyist	10/13/2009	• expresses opposition to MDET		• "If enacted, this fee would have a devastating impact on innovation, investment and the nation's economy"	• this bill ruins small medical device companies • offered alternatives • MDET will "stifle medical innovation, limit patient access, prohibit research and development, and force companies to reduce their workforce"	• none	highlighted	• innovation • revenue • sales • leaders • global • jobs	NA	NA	NA	NA
MDMA Survey on Implications of MDET	Survey Data	MDMA	Lobbyist	2010	• shared discontent with the MDET and wanted to stop it from happening • stop tax from happening		• MDMA conducted a survey of its members and senior execs of medical device companies all across the US. 200 responses were recorded	• 35% of companies are not yet profitable • if tax were to take effect 64% said they would reduce or halt job creation • 62% would reduce research and development • 35% would relocate outside of US	• none	highlighted	• jobs • research • development • relocate • jobs	NA	NA	NA	NA
MDMA Letter to IRS	Letter	MDMA	Lobbyist	3/28/2011	• discontent with the tax, and wanting to create administrative guidance from IRS for payment • encourage repeal prior to effective date in 2013		• opposes tax because impact on patient care, innovation, and job creation	• declares that the "windfall" from Health Care and Ed Reconciliation Act of 2010 is baseless • guidance should minimize the additional administrative burden on affected manufacturers • guidance should avoid the double-taxation of medical devices • guidance for the constructive sales prices rules should take into account the unique nature of the medical device industry and market • guidance should take into account the unique nature and use of many medical device technologies	• repeal	highlighted	• windfall • administrative burden • guidance • patient care • innovation • jobs	NA	NA	NA	NA
Letter to House on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	Coalition/Lobbyist	6/6/2012	• repeal MDET		• MDET will adversely impact patient care and innovation • will substantially increase the costs of health care	• stifles innovation and U.S. competitiveness • adverse impact on R&D investment, job creation, jeopardizing the U.S. global leadership position in medical device innovation • if not repealed it will continue to force affected companies to consider cutting manufacturing operations, research and development, and employment levels to recoup the lost earnings due to the tax • will also adversely impact patient access to new and innovative medical technologies	• none	highlighted	• innovation • research and development • jobs • patient access •	NA	NA	NA	NA
Examining the Impact of Obamacare on Doctors and Patients	Hearing	Witness and Testimonies	Hospitals and Doctors	7/10/2012	• repeal of MDET		• stifles innovation, gave the perspective from a Medical Device Company	• "windfall" might exist for those companies that produce consumable products, but for those that are capital products there will not be an increase in purchasing	• none	highlighted	• innovation • research and development • jobs • small business • profit	• patients • insurance providers	NA	NA	NA
Testimony of Kelynn Cullimore Jr., President and CEO of Dynatronics	Testimony	Kelynn Cullimore Jr., President and CEO of Dynatronics	CEO of a Medical Device Company	7/10/2012	• repeal MDET		• small companies are impacted by taxes like MDET, impacts their ability to innovate, and provide jobs	• patient care is impacted • a lot of these companies haven't created the hit of profitability • hurt patients and providers	• none	highlighted	• innovation • research and development • jobs • small business • profit	• patients • insurance providers	• it is fair to ruin these businesses without solid evidence that there will be an increase in their sales?	NA	NA
Medical Device Tax Workshop	Workshop	AdvaMed	Lobbyist	9/19/2012	• educate medical device companies on the tax		• This source doesn't share a ton of arguments but gives medical device companies education surrounding the tax: 1. Legal Update 2. Overview of Existing and Proposed Rules 3. Implementation Issues 4. What leading companies are doing right now 5. Implantables, wound care, surgical and medical supplies, diagnostics and capital equipment 6. Technical overview/systems approach/automation on considerations	NA	NA	NA	• legal • education • implementation • technical • best practices	NA	NA	NA	NA
Letter to Senate on Importance of Repeal	Letter	700 undersigned organizations, associations, companies, patients, providers, venture capital firms, representing hundreds of thousands medical technology jobs	Coalition/Lobbyist	6/6/2012	• repeal MDET • same letter written to the house in June 2012		• MDET will adversely impact patient care and innovation • will substantially increase the costs of health care	• stifles innovation and U.S. competitiveness • adverse impact on R&D investment, job creation, jeopardizing the U.S. global leadership position in medical device innovation • if not repealed it will continue to force affected companies to consider cutting manufacturing operations, research and development, and employment levels to recoup the lost earnings due to the tax • will also adversely impact patient access to new and innovative medical technologies	• none	highlighted in letter to house	• innovation • research and development • jobs • patient access •	NA	NA	NA	NA
MDMA Survey on Impact of MDET	Survey Data	MDMA	Lobbyist	2013	• shared discontent since the tax is functioning		• cost us over 10,000 jobs and threatens 43,000 American jobs • causing the reduction and halt of job creation • reducing R&D • offers media reports that are not in favor of the tax	NA	NA	highlighted	• jobs • job creation • research and development • innovation	NA	• unfair to Americans that lose their jobs • unfair to Americans losing innovation that could improve their healthcare	• cutting jobs doesn't seem to make this tax very efficient in what it is trying to do in strengthening American citizens health care	NA
MDMA Statement on MDET Repeal Inclusion in Tax Ref.	Press Statement	MDMA	Lobbyist	2/26/2014	• still trying to get the tax repealed		• President and CEO applauds tax reform from Dave Camp	NA	NA	highlighted	jobs, innovation, repeal, bipartisan, reform	Dave Camp, House Ways and Means Chairman	NA	NA	NA
MDMA Statement on MDET Repeal Efforts in Senate Finance	Press Statement	MDMA	Lobbyist	4/4/2014	• applauds Senators Hatch, Toomey, Thune, and Enzi for offering the amendment to eliminate tax		• want to end this policy that destroys jobs, slows R&D, and harming patient care	• disappointed that MDET was not addressed as part of the tax extenders legislation	NA	highlighted	EXPIRE ACT, tax extenders, bipartisan, amendment, innovation, jobs, Research and development, patient	Senators Hatch, Toomey, Thune, and Enzi	NA	NA	NA
MDMA Statement on House Jobs Package	Press Statement	MDMA	Lobbyist	9/18/2014	• applauds House for passing H.R. 4, the "Jobs for America Act"		• MDET did not allow America's innovators to create more high-tech manufacturing jobs that the community needed	• MDET was a major roadblock towards developing the cures of tomorrow	NA	NA	jobs, repeal, innovation, innovators	House of Representatives (through passage of H.R. 4)	House of Representatives	NA	NA

Appendix

MDMA Survey - Impact of Repealing Tax	Survey Data	MDMA	Lobbyist	2015	<ul style="list-style-type: none"> educate other actors on the impact of repealing MDET 	<ul style="list-style-type: none"> repeal MDET 	<ul style="list-style-type: none"> MDET has eliminated tens of thousands of jobs, led to drastic R&D cuts, 72% of companies slowed or halted job creation job loss reduced R&D deferred or cancelled capital investments deferred or cancelled plans to open new facilities reduced investment in start up companies more difficult to raise capital reduced or deferred increases in employee compensation 	<ul style="list-style-type: none"> 85% of respondents said they would hire new employees if the tax was repealed 80% of respondents said they would increase R&D investments in the cures and therapies of tomorrow R&D budgets would increase by 14% when asked 	NA	NA	<ul style="list-style-type: none"> jobs, research and development, patient care, tax rate, job creation, new employees, cures, budgets 	NA	NA	NA	NA	
Impact of the Medical Device Excise Tax	Report	AdvaMed	Lobbyist	1/1/2015	<ul style="list-style-type: none"> impact of MDET 	<ul style="list-style-type: none"> repeal MDET 	<ul style="list-style-type: none"> MDET is a major roadblock for MD industry stifles innovation, costs thousands of jobs heavy burden on US companies struggling with uncompetitive tax systems, giving overseas competitors advantage tax isn't being offset by increased demand for medical devices 	<ul style="list-style-type: none"> 80% of respondents said they would increase R&D investments in the cures and therapies of tomorrow R&D budgets would increase by 14% when asked 	NA	NA	<ul style="list-style-type: none"> jobs, R&D, capital investments, facilities, start up companies, capital, compensation 	NA	NA	<ul style="list-style-type: none"> tax seems unfair to MD industry 	NA	
MDMA Advocates, MITA Support Bipartisan Efforts to Repeal MDET	Press Statement	MDMA	Lobbyist	1/7/2015	<ul style="list-style-type: none"> applaud HR 160 "The Protect Medical Innovation Act" 	<ul style="list-style-type: none"> repeal MDET 	<ul style="list-style-type: none"> MDET is a major roadblock for MD industry stifles innovation, costs thousands of jobs heavy burden on US companies struggling with uncompetitive tax systems, giving overseas competitors advantage tax isn't being offset by increased demand for medical devices 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	highlighted	<ul style="list-style-type: none"> legislation, innovators, job, innovation, patient care, global leadership, economy, industry 	NA	House, Senate, Reps. Erik Paulsen and Ron Kind, House of Dems	NA	NA	
Coalition Letter to House to Repeal MDET	Letter	1,000 undersigned organizations, associations, companies, patients, providers, and venture capital firms	Coalition/Lobbyist	1/13/2015	<ul style="list-style-type: none"> asking for repeal of MDET 	<ul style="list-style-type: none"> repeal MDET 	<ul style="list-style-type: none"> MDET is a major roadblock for MD industry stifles innovation, costs thousands of jobs heavy burden on US companies struggling with uncompetitive tax systems, giving overseas competitors advantage tax isn't being offset by increased demand for medical devices 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	highlighted	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	NA	NA	NA	
MDMA Letter to House Leadership	Letter	Mark B. Leashey, CEO of MDMA	Lobbyist	6/17/2015	<ul style="list-style-type: none"> asking for repeal of MDET 	<ul style="list-style-type: none"> repeal MDET 	<ul style="list-style-type: none"> support of HR 160 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	NA	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	Congress	NA	NA	
MDMA Advocates, MITA Commend House Repeal of MDET	Press Release	MDMA	Lobbyist	6/19/2015	<ul style="list-style-type: none"> commended HR for passing legislation to repeal MDET through HR 160 "The Protect Medical Innovation Act" passed 	<ul style="list-style-type: none"> repeal MDET 	<ul style="list-style-type: none"> glad that the bill passed, will continue to work until it is repeal for good 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	highlighted	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	House of Representatives (through passage of H.R. 160)	House of Reps	NA	NA
MDMA Advocates, MITA Applaud Congress for Passage of MDET Suspension	Press Release	MDMA	Lobbyist	12/18/2015	<ul style="list-style-type: none"> thankful for suspension desire to complete repeal 	<ul style="list-style-type: none"> complete repeal of MDET 	<ul style="list-style-type: none"> thankful that congress came together to suspend the tax Congress and the administration have demonstrated that they recognize the negative effects of the tax 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	NA	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	NA	NA	NA	
MDMA Statements on House Ways and Means Comm Markup of Legislation to Repeal MDET	Press Release	MDMA	Lobbyist	6/2/2015	<ul style="list-style-type: none"> repeal tax 	<ul style="list-style-type: none"> repeal tax 	<ul style="list-style-type: none"> since 2009 MDMA has asked that this tax be removed 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	highlight	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	repeal, warned, innovation, patient care, bipartisan,	House Ways and Means Committee	NA	na
MDMA Statements on the First Device Tax Payments Suspension	Press Release	MDMA	Lobbyist	1/29/2016	<ul style="list-style-type: none"> thanks congress for the suspension permanently repeal the tax 	<ul style="list-style-type: none"> permanent repeal of the tax 	<ul style="list-style-type: none"> reminder that the suspension gave MD industry a chance to put that money towards innovation for the first time in three year 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	NA	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	suspend, payment, innovators, patient care, jobs, full repeal, bipartisan	Congress	NA	NA
Dentistry Comments	Memo to IRS	Coalition for Dentistry	Dentistry Coalition	5/7/2011	<ul style="list-style-type: none"> repeal of MDET 	<ul style="list-style-type: none"> repeal of MDET 	<ul style="list-style-type: none"> MDET will increase the cost of dental care by over \$160 million annually resulting in harm to patients and increase the overall cost of healthcare 	<ul style="list-style-type: none"> MDET is taking away global leadership position 	NA	highlighted	<ul style="list-style-type: none"> innovation, jobs, smaller companies, uncompetitive tax system, overseas, windfall, support, innovation, advancements, department of commerce, windfall, innovators, repeal, patients, small companies, revenues, health care system, national deficit, global leaders, 	NA	<ul style="list-style-type: none"> tax on specific services gives lot of indications of what they would like changed, but not sure these are alternatives to the tax 	<ul style="list-style-type: none"> dental, medical devices, cost, administration, burdens, coalition 	<ul style="list-style-type: none"> fairness of the tax is discussed in regards to what should and should not be taxed efficiency is discussed in the form of what is efficient for the dental practices 	

References

- Andrew, C.J. *Rationality in Policy Decision Making, Handbook of Public Policy Analysis*. 2006.
- Birkland, T. A. "An introduction to the policy process: Theories, concepts and models of public policy making. ." *Routledge* (2014).
- Bolka, Elizabeth M. "The Medical Device Excise Tax: An Unfair Burden." *HeinOnline* (2014): 1691-1722.
- Bradford, E. "PAYGO Rules and Sequestration Procedures." Harvard Law School (2005): 2-26.
- Braveman, Paula. "Health Disparities and Health Equity: Concepts and Measurements." *Annual Review Public Health* (2006): 1-30.
- Cline, Seth. *News & Analysis*. 8 November 2011. <<https://www.opensecrets.org/news/2011/11/the-bill-sponsored-by-rep/>>.
- Cochran, C. E., Mayer, L. C., Carr, T.R., Cayer, N.J, McKenzie, M. *American Public Policy: An Introduction*. Nelson Education, 2015.
- Creswell, Creswell, Hanson, Plano Clark, Petska. "Mixed Methods Research Designs in Counseling Psychology." *Journal of Counseling Psychology* (2005): 224-235.
- Cullimore, Kelvyn. "Testimony of Kelvyn Cullimore Jr., President and CEO of Dynatronics, U.S. House of Representatives, Committee on Oversight and Government Reform's Subcommittee on Health Care and D.C." Washington, 10 July 2012.
- Demko, P. *Devicemakers step up lobbying to kill ACA tax*. 7 March 2015. <<http://www.modernhealthcare.com/article/20150307/MAGAZINE/303079963>>.
- Dental Coalition. "Internal Revenue Service Notice of Proposed Rulemaking, Taxable Medical Devices." 7 May 2012.
- EmergoGroup. *Outlook for the Medical Device Industry in 2015*. Austin: Mergo Group, 2015.
- Evans, Robert G and Gregory L Stoddart. "Producing Health, Consuming Health Care." *Soc. Sci. Med* (1990): 1247-1363.
- Fischer, F., Miller, G. *Handbook of Public Policy Analysis*. 2007.
- Flavelle, Christopher. "How Much Will the Medical Device Tax Hurt?" 2012.
- Furchtgott-Roth, D and H Furchtgott-Roth. "Employment Effects of the New Excise Tax on the Medical Device Industry." 2011.
- Gillroy, John Martin. "The Ethical Poverty of Cost-Benefit Methods: Autonomy, Efficiency and Public Policy Choice." *Springer* (2015): 83-102.
- Gravelle, Jane G and Sean Lowry. "The Medical Device Excise Tax: Economic Analysis." 2015.
- Hanson, William E, et al. "Mixed Methods Research Designs in Counseling." *DigitalCommons@University of Nebraska - Lincoln* (2005): 224.

- Head, John G. "Tax Fairness Principles: A Conceptual, Historical and Practical Review." *Journal Linker* (1992): 65.
- Healthcare Supply Chain Association. *HSCA Launches "Medical Device Tax Watch" Website to Raise Awareness of Efforts by Some Device Manufacturers to Shift Cost of Excise Tax Directly to American Hospitals, Healthcare Providers, Patients and Taxpayers*. Washington DC: Healthcare Supply Chain Association, 2013.
- Hesse-Biber, Sharlene. "Qualitative Approaches to Mixed Methods Practice." *Sage* (2010): 2.
- HHS. *Department of Health and Human Services*. 28 March 2015. 28 March 2015. <<http://www.hhs.gov/healthcare/rights/law/index.html>>.
- Howlett, M., Ramesh, M., Perl, A. *Studying Public Policy: Policy Cycles and Policy Subsystems*. Toronto: Oxford University Press, 2009.
- Industry, Medical Device. "Coalition Letter to Congress Against MDET." 13 October 2009.
- Ingram, Helen, Anne Schneider and Peter Deleon. "Social Construction and Policy Design." (2006): 93-126.
- Internal Revenue Service. "Department of the Treasury." *Taxable Medical Devices*. Government, 7 February 2012.
- IRS. *IRS*. 28 March 2015. 28 March 2015. <<http://www.irs.gov/Businesses/Small-Businesses-&Self-Employed/Excise-Tax>>.
- . *Medical Device Excise Tax*. n.d. 1 August 2016. <<https://www.irs.gov/uac/newsroom/medical-device-excise-tax>>.
- . *Medical Device Excise Tax: Frequently Asked Questions*. n.d. 2016 August 1. <<https://www.irs.gov/uac/medical-device-excise-tax-frequently-asked-questions#Two-Year>>.
- Jann, W., Wegrich, K. *4 Theories of the Policy Cycle, Handbook of Public Policy*. 2006.
- Jenks, Paul. "IRS Struggles to Collect the Medical Device Excise Tax." *Dow Jones* (2014): 1.
- Johnson & Johnson. "2014 Year in Review." 2014.
- Kraft, M., Furlong, S.R. *Public Policy: Politics, Analysis, and Alternatives*. CQ Press, 2012.
- Kramer, D.B., Kesselheim, A.S. "The Medical Device Excise Tax - Over before it Begins?" *The New England Journal of Medicine* (2016): 1767-1769.
- Kuhn, Christina. *Congress Enacts 2-Year Moratorium on Medical Device Excise Tax*. 22 December 2015. <<https://www.insidemedicaldevices.com/2015/12/congress-enacts-2-year-moratorium-on-medical-device-excise-tax/>>.
- Lynch, Julia and Sarah E. Gollust. "Playing Fair: Fairness Beliefs and Health Policy Preferences in the United States." *Journal of Health Politics, Policy and Law* (2010): 850-887.
- Maplight. "Maplight.org." 08 June 2016. *Maplight*. <<http://maplight.org/us-congress/interest/H4100>>.
- Maplight.org. *H.R. 3590 - Patient Protection and Affordable Care Act*. n.d. August 1 2016. <<http://maplight.org/us-congress/bill/111-hr-3590/423082/contributions-by-vote>>.

Mass Device. *Mass Device*. 25 September 2012. 25 September 2015.
 <<http://www.massdevice.com/cutting-jobs-over-device-tax-nonsense-says-medtech-ceo/>>.

McConnell, A. "Policy Success, Policy Failure and Grey Areas In-Between." *Cambridge University Press* (2010): 345-362.

MDMA. Washington, 06 06 2012.

MDMA - Coalition. "Letter to House on Importance of Repeal." 6 June 2012.

MDMA. "Ad Protesting MDET." 2009.

MDMA Coalition. "Coalition Letter to Congress Against MDET." 13 October 2009.

—. "Coalition Letter to House to Repeal MDET." 13 January 2015.

—. "Letter to House on Importance of Repeal." 6 June 2012.

MDMA. *Innovation isn't all that suffers from a tax on medical devices*. 2009.

—. "Letter to Congress." 13 October 2009.

—. "Letter to Internal Revenue Service." 28 March 2011.

—. "Letter to Senate on Importance of Repeal." 13 11 2012.

—. "Letter to Senate Finance Committee." 6 October 2009.

—. "MDMA Impact of Repealing the Medical Device Tax." 2015. n.d.

—. "MDMA Statement on House Jobs Package." 18 September 2014.

—. "MDMA Statement on House Jobs Package." 18 September 2014.

—. "MDMA Statement on Medical Device Tax Repeal Efforts in Senate Finance Committee." 4 April 2014.

—. "MDMA Statement on the First Device Tax Payments Suspension." 29 January 2016.

—. "MDMA Survey - Impact of Repealing Tax." 2015.

—. "MDMA Survey on Implications of MDET." 2010.

—. "MDMA Survey on Implications of the Medical Device Tax." 2013.

—. "MDMA, AdvaMed & MITA Commend House Passage of Legislation to Repeal the Medical Device Tax." 19 June 2015.

MDMA, AdvaMed, and MITA. "Support Bipartisan Efforts to Repeal the Device Tax." 7 January 2015.

Medical Device Companies. "Letter to Senate Leaders." 13 November 2012.

Medical Device Industry Coalition. "Letter to Congress ." 13 October 2009.

Medical Device Manufacturers Association. Washington, 13 11 2012.

—. "Impact of Repealing the Medical Device Tax." 2015.

Medtronic. "Annual Report." 2013.

Mindock, Clark. *News & Analysis*. 29 January 2015. <<https://www.opensecrets.org/news/2015/01/repeal-of-medical-device-tax-more-likely-with-friends-across-party-lines/>>.

Moebius, Wanda. *AdvaMed Newsroom*. 14 November 2012. 26 September 2015. <<http://advamed.org/news/19/leading-executives-from-across-the-country-urge-senate-to-repeal-the-device-tax>>.

OpenSecrets.org. 29 January 2015. *OpenSecrets.org*. <<https://www.opensecrets.org/news/2015/01/repeal-of-medical-device-tax-more-likely-with-friends-across-party-lines/>>.

Opensecrets.org. *Influence & Lobbying*. n.d. 1 August 2016. <<https://www.opensecrets.org/lobby/induscode.php?id=H4100&year=>>>.

Oswald, Malcolm. "In a democracy, what should a healthcare system do? A dilemma for public policymakers." *Politics, Philosophy & Economics* (2015): 23-52.

Pennic, Jasmine. *HIT Consultant*. 21 January 2016. <<http://hitconsultant.net/2016/01/21/medical-device-excise-tax-suspension-could-rejuvenate-market/>>.

Reinhardt, Uwe. "Reflections on the Meaning of Efficiency: Can Efficiency Be Separated from Equity?" *Yale Law & Policy Review* (1992): 302-315.

Schnattschneider, E.E. *The semi-sovereign people*. Ed. Reinhart, and Winston Holt. New York, 1960.

Schuck, Peter H. *Success, Failure, and In Between*. Princeton: Princeton University Press, 2014.

Stone, D. *Policy Paradox: The Art of Political Decision Making*. London and New York, NY: WW Norton and Company, 2002.

Stryker. "2014 Annual Review." 2014.

Thibault, Marie. *Congress Gives Device Makers a Break from Excise Tax*. 18 December 2015. <<http://www.mddionline.com/article/congress-gives-device-makers-break-excise-tax-12-18-15>>.

Van de Water, Paul. *Excise Tax on Medical Devices Should Not Be Repealed*. Washington DC: Center on Budget and Policy Priorities, 2013.

Washington Post Editorial Board. *Washington Post*. 29 January 2014. 26 September 2015. <https://www.washingtonpost.com/opinions/bipartisan-efforts-to-repeal-the-medical-device-tax-are-galling/2015/01/29/b243c81a-a34d-11e4-9f89-561284a573f8_story.html>.

Williams, Richard and Katelyn Christ. "Taxing Sins: Are Excise Taxes Efficient?" *Mercatus on Policy* (2009): 1-4.

Wolgamott, Kensington. "No Longer Left To Their Own Devices: Evaluating The Non-Traditional Medical Device Excise Tax." *Notre Dame Journal of Law, Ethics & Public Policy* (2015): 497-522.