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Organizational complexity and innovation portfolio decisions: Evidence from a quasi-natural experiment☆

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ABSTRACT

We examine how a firm's organizational complexity affects innovation portfolio decisions in response to a shock to innovation incentives. Using the 2013 medical device sales tax as a quasi-natural experiment, we find that firms with a complex organization structure, as proxied by organization size and multi-division structure, generate fewer radical innovations (introduction of new products) but more incremental innovations (improvements on existing products) after the tax. Multidivision firms also shift capital investment to their corporate divisions that are not affected by the tax, thereby decreasing their innovation output. Collectively, these responses cause a significant decline in the radical innovation output of the industry in aggregate. We contribute to the literature by advancing the understanding of how organization structure influences managers' innovation portfolio decisions in response to economic shocks.

1. Introduction

Innovation is a key driver of firm performance and growth (Audretsch, 1995; Danneels, 2002). Incremental innovations, i.e. improvements on existing products, increase the profitability of firms while radical innovations, i.e. new products that create new revenue streams, fuel the growth of firms (Dewar & Dutton, 1986; Sheng & Chien, 2016). Since incremental innovations are less risky and offer returns in the short-term while radical innovations have high risk/return profiles and long-term horizons, most firms pursue multiple incremental and radical innovation projects simultaneously, referred to as the *innovation portfolio* of the firm (Klingebiel & Rammer, 2014; Nagji & Tuff, 2012). Managers routinely adjust their firms' innovation portfolios to maintain an appropriate mix of incremental and radical innovations in line with their strategic goals and environmental circumstances.

A major stream in the innovation literature examines how organization characteristics affect firms' innovation portfolio choices (Christensen, 1997; Czarnitzki & Kraft, 2004; Damanpour, 1996; Hansen, 1992; Messeni Petruzzelli, Ardito, & Savino, 2018; Teirlinck, 2017). While established firms typically create more incremental innovations (Christensen, 1997), small and young firms are better at pursuing radical innovations (Henkel, Rønde, & Wagner, 2015). However, prior literature views the relationship between firm characteristics and innovation portfolios in a static way, leaving a gap in our understanding of the drivers of change in managers' innovation portfolio choices. In addition, prior literature has not examined the flexibility with which a firm can adjust its innovation portfolio configuration in response to external changes, such as economic shocks.

This paper examines how firms with simple vs. complex organization structures (which we henceforth refer to as *simple firms* and *complex firms*, for parsimony) adjust their innovation portfolios in response to an exogenous shock to the profitability of the projects within the firm's innovation portfolio. Specifically, we use the change in each firm's innovation portfolio caused by the 2013 medical device excise tax to examine the responses of firms to changes in project profitability. We expect complex firms with large product lines to shift their investments from radical to incremental innovation projects within the medical device industry, thus creating more of cost-saving incremental innovations and fewer radical innovations that might generate new revenue streams. Second, we expect complex firms with internal capital markets, i.e. those that have multiple business divisions within their corporate structure, to shift some of the innovation investments from their medical device division that is subjected to a new tax to other divisions that are not (Lamont, 1997; Stein, 1997). Contrastingly, we expect to see little to no change in simple firms' innovation portfolio configurations because simple firms do not have the ability to reallocate resources strategically in response to a change in project profitability. Since complex firms account for the majority of the total innovation

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output, we also expect that these shifts will decrease the total and specifically the radical innovation outputs of the medical device industry.

We make several important contributions to the literature. First, we develop a conceptual model that clarifies the different incentives for radical vs. incremental innovations. Second, we explain two mechanisms via which a complex organization structure affects a firm's innovation portfolio choices. Third, we construct a unique and rich dataset of product innovations using medical device premarket approvals (PMAs) from the Food and Drug Administration (FDA), which allows us to characterize innovation reliably as radical vs. incremental at the product level. Fourth, we use a quasi-natural experiment setup and an analytical approach that mitigates the econometric difficulties of prior studies. In addition, using a difference-in-differences technique enables us to control for unobserved time and firm-specific characteristics, allowing us to mitigate reverse causality and other endogeneity concerns that are common in this literature.

2. Literature review

Firms in innovative industries such as medical devices, pharmaceuticals/biotechnology, information technology, and consumer electronics allocate significant resources to develop incremental and radical innovations. The literature is rife with studies that examined the effects of firm size, age, and organization structure on innovation (e.g. Acs & Audretsch, 1988, 1991; Chang, Chang, Chi, Chen, & Deng, 2012; Cohen & Klepper, 1996; Forés & Camisón, 2016; Hansen, 1992; Laforet, 2008; Yin & Zuscovitch, 1998). Prior literature suggests that decisions about organization structure are affected by efficiency of transactions between parties, as well as management and monitoring considerations (e.g. Drechsler & Natter, 2012; Holmstrom, 1989), and that without considering transactions costs, there is little justification for multi-division firms (Teece, 1982).

The organization structure of a firm affects its innovation portfolio choices. Incremental and radical innovation processes rely on different knowledge creation or acquisition capabilities (Forés & Camisón, 2016), which complex firms can better manage by separating organizational units that undertake radical and incremental innovations. Simple firms, however, lack the resources and administrative systems needed to manage the contradictory knowledge creation processes that are needed to pursue radical and incremental innovations simultaneously (Lubatkin, Simsek, Ling, & Veiga, 2006). In addition, firms with established product lines have a disincentive to disrupt their stable revenue streams (Christensen, 1997; Holmstrom, 1989; Uotila, Maula, Keil, & Zahra, 2009). Thus, complex firms tend to pursue more of incremental innovations with easy-to-monitor inputs and predictable outcomes that increase profits by lowering the costs of their existing products (Christensen, 1997; Utterback, 1994). Contrastingly, simple firms have an incentive to pursue risky radical innovations with potentially high payoffs (Coad, Segarra, & Teruel, 2016; Ettlie, Bridges, & O'keefe, 1984; Henkel et al., 2015). Still, firms typically pursue many projects that lie along a continuum of innovation. We use the term innovation portfolio to refer to all innovation projects that a firm undertakes through its normal operations (Klingebiel & Rammer, 2014).

The literature offers mixed findings on the relationship between organization complexity and innovation portfolio configuration as to which firms can manage their innovation portfolios more flexibly. Some studies show that complex firms tend to invest relatively less in R&D, create more of incremental innovations, and can fail to adapt to technological change that radical innovations bring (Christensen, 1997; Utterback, 1994). On the other hand, simple firms invest relatively more in R&D and create relatively more radical innovations (Coad et al., 2016; Czarnitzki & Kraft, 2004; Henkel et al., 2015). However, other studies find that complex firms may be better suited to create radical innovations due to their organizational capabilities, human capital, and slack resources (Nohria & Gulati, 1996). For example, complex firms can pursue radical innovations via dedicated organizational units (O'Connor & DeMartino, 2006), especially when they are willing to cannibalize their existing products (Chandy & Tellis, 1998).

The literature on innovation portfolio choices, however, has largely overlooked the fact that innovative industries have high environmental dynamism and they frequently experience external shocks that can alter firm incentives to pursue different types of innovation. Said changes in innovation incentives can occur due to a variety of reasons such as economic recessions (Filippetti & Archibugi, 2011), technological discontinuities (Hill & Rothaermel, 2003), or tax policy interventions (Bozeman & Link, 1984; Czarnitzki, Hanel, & Rosa, 2011; Mansfield, 1982, 1986). While it is known that such shocks can change firms' incentives for innovation drastically (Jaffe & Palmer, 1997; Mazzanti & Costantini, 2012), we do not know much about the mechanisms via which firms respond to such changes. Further, most studies examining these influences have pooled large and small firms, and merged incremental and radical innovations in their data using generic measures of innovation such as R&D expenses, thus obtaining general yet imprecise findings (Bloom, Griffith, & Van Reenen, 2002).

3. Research hypotheses

3.1. Effects of product portfolios on innovation portfolio decisions

Any shock to innovation incentives, e.g. a new sales tax, will cause firms to reconsider their resource allocation decisions. Such shocks increase uncertainty in the industry and make it harder for firms to predict the potential payoff of innovation projects. Firms typically mitigate higher uncertainty with more conservative resource allocation decisions. Incremental innovations require small amounts of investments, benefit from economies of scope via the use of existing resources such as R&D personnel, production facilities, and marketing know-how, and have more predictable and short-term payoffs than radical innovations. Radical innovations require a costly and time-consuming *distant search* with higher risk and longer payoff horizons (Dubois, De Mouzon, Scott-Morton, & Seabright, 2015; Tushman & Anderson, 1986). When facing new external pressures and uncertainty, complex firms would invest more in incremental innovations to use their existing resources and expertise to improve their returns from existing products, instead of investing in radical innovation projects to pursue costly and uncertain payoffs that might pan out in the long-term.

Another argument for this shift is the change in the relative appeal of innovation projects. Firms choose investment prospects with the highest expected payoff. When expected payoff from different types of innovation projects change relative to each other, e.g. due to new costs, firms will favor the projects that are now more appealing. An excise tax makes incremental innovation projects more appealing than radical innovation projects on the margin.[1] This is simply because an excise tax is a tax on revenues, not profits. New products that radical innovations create bring new revenue streams to the firm, thereby increasing the firm's marginal tax burden (Klepper, 1996; Utterback, 1994). Incremental innovations, on the other hand, mainly reduce production costs via minor changes in product design, production processes, materials, packaging, etc.[2] (Lorenzini, Mostaghel, & Hellström, 2018). Thus, a firm with several radical and incremental innovation projects in its

[1] A conceptual model that clarifies this rationale is available from the authors upon request.

[2] We are not suggesting that the firm subject to the excise tax will abandon all radical innovation projects. Rather, our model suggests that the radical innovation project that was chosen on the margin becomes less attractive than an incremental project that was not chosen on the margin. Thus, the implementation of the excise tax will cause the firm to shift its investment in these no-longer-attractive radical innovation projects to the now-relatively-more-attractive incremental innovation projects that will increase profits without increasing revenues and the tax burden.

innovation portfolio will invest more in incremental innovations rather than the radical innovations because the former will improve profits without increasing sales and the tax burden. However, a firm pursuing only radical innovation projects in its innovation portfolio, e.g. a startup or a specialist firm that is focused on a single breakthrough medical device technology or product segment, will have no choice but to continue investing in the now less attractive radical innovation projects after the excise tax. Thus, we hypothesize:

Hypothesis 1a. Firms with large product portfolios will create more incremental innovations and fewer radical innovations after an excise tax.

Hypothesis 1b. Firms with small product portfolios will exhibit little to no shift from radical to incremental innovation after an excise tax.

3.2. Effects of internal capital markets on innovation decisions

The strategic reallocation of resources will also be impacted by the complexity of the corporate structure of the firm. It is known that multi-division firms utilize internal capital markets when making decisions about investment opportunities, e.g. when investments are evaluated with respect to their potential to generate future cash flows (Shin & Stulz, 1998; Teece, 1982). When investment opportunities in one division of a multi-division firm become less attractive, some of the investments will shift to other divisions (Lamont, 1997). Maksimovic and Phillips (2002) develop a model that shows how multi-division firms allocate resources to most profitable divisions. They find that in multi-division firms, when a division's prospects diminish, the firm will reallocate resources to other more promising divisions. This is because corporate headquarters aims to increase firm value by allocating resources to the divisions under their corporate umbrella that offer the best prospects (Giroud & Mueller, 2015; Petsas & Giannikos, 2005; Stein, 1997).

What if there are no divisions within the corporate structure to which investments can be shifted? This is precisely the case for single-business firms (i.e. those that are active only in the medical device industry). These single-business firms cannot shift resources away from the medical device industry despite the new tax burden since they do not have other corporate divisions or businesses to which resources can be shifted when the medical device division becomes less profitable. Therefore, an industry-specific tax (e.g. a tax levied on only medical device sales, but not on pharmaceuticals or consumer electronics sales) will affect the investment decisions of a multi-business firm, but not the decisions of a single-business firm. An industry specific tax should consequently cause a shift in innovation investments away from the division of a complex firm that is subject to the new tax, into other divisions of the firm that operate in industries not subject to the tax. These arguments lead to the following hypotheses:

Hypothesis 2a. Complex firms with business divisions that operate in multiple industries, some subject to a new industry-specific tax and others not, will create fewer total innovations in the industries that are subjected to the tax.

Hypothesis 2b. Simple firms that operate in only one industry will exhibit little to no change in their innovation output after a new industry-specific tax.

3.3. Aggregate innovation output of the medical device industry

Since decisions of individual actors responding to market incentives collectively determine aggregate technology outcomes at the industry level (Romer, 1990), the effects of innovation portfolio decisions of complex and simple firms should also affect the overall innovation output of the industry significantly. Any firm can *invent* new technologies (Trajtenberg, 1990). However, large firms are typically better able to *innovate*, i.e. convert inventions into new or improved products, in comparison to small firms. This is because of the extensive resources and capabilities of large firms that allow them to create, market, and support their product lines in the marketplace. Not surprisingly, large firms account for the majority of product innovation—particularly in concentrated and capital-intensive industries (Acs & Audretsch, 1988; Dubois et al., 2015). Coupled with the fact that firms' R&D spending is responsive to changing tax incentives (e.g. Bloom et al., 2002; Hall & Van Reenen, 2000; Koga, 2003; Mansfield, 1986; McCutchen & William, 1993), we expect that the total and, in particular, the radical innovation output of the medical device industry would decrease, after the tax:

Hypothesis 3a. The total innovation output of the medical device industry will decline, after an industry-specific excise tax.

Hypothesis 3b. Radical innovation output will decline more than the incremental innovation output of the industry, after an industry-specific excise tax.

4. Research methods

4.1. Empirical setting

We use the US medical device industry as the empirical setting and the medical device excise (sales) tax implemented in 2013 as an exogenous shock to the relative attractiveness of radical vs. incremental innovations. The medical device industry offers an ideal empirical setting for our study for several reasons. First, it is a prominent industry in which innovation is a critical activity for firm survival and success (Thirumalai & Sinha, 2011; Wu, 2013). As such, it is representative of other innovative industries such as pharmaceuticals/biotechnology, industrials, and consumer electronics. Second, the industry is regulated by the FDA, which examines and approves incremental and radical medical device innovations through established processes and reliable measures of product innovation. Third, the industry exhibits considerable variance in organization size, as it contains startups and niche medical technology firms, in addition to large corporations with multiple established medical device product lines, as well as those that have businesses in other industries such as pharmaceuticals or consumer goods. And lastly, the nature of the 2013 sales tax allows us to find some firms that were completely unaffected by the tax. These zero-revenue firms that predominantly pay for their expenses from their equity while developing emergent technologies and products, serve as the control group for the treatment, i.e. a tax levied on sales. In sum, the US medical device industry and the 2013 medical device excise tax offer an ideal quasi-natural experiment setup for our tests and bolster our causal inferences.

4.2. Data

We collected data from the FDA on PMAs for new or improved medical devices obtained by US medical device firms starting in 2004, when the FDA started to assess fees for original PMAs for radically new medical devices and supplemental PMAs for various improvements on existing products. PMA data has been used in the literature to measure innovation in certain medical device categories, e.g. orthopedic or cardiovascular medical devices (Chatterji & Fabrizio, 2014; Wu, 2013). Our data includes all original and supplementary PMAs issued by the FDA for all 19 medical device specialties since 2004. We use COMPUSTAT and Mergent Intellect databases to determine if a firm filing a PMA is private or public, and check if a firm is a subsidiary of another firm. Subsidiary firms are considered as a part of the parent. We also use the Mergent Intellect database for firms' number of employees and total sales. Any firm missing this data is excluded from the dataset. This yields 20,725 PMA filings filed by 153 firms between 2004 and 2017.

Table 1
Sources of data and definitions of variables.
This table describes the construction of the major variables used in the paper. The sample is composed of the firms with at least one premarket approval (PMA) issued between 2004 and 2017, and with sales data and employee data available in Mergent Intellect. We calculate the number of PMAs for each firm by applicant name. Our sample consists of $N = 20,725$ PMAs filed by 153 firms over the years 2004–2017. The original data from the US FDA is available at: http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm

Variable name	Data source	Variable definition
Conglomerates (indicator)	Forbes (2004)	We define conglomerates as firms that are listed as such in the Forbes (2004) list of conglomerates
Firm age	Mergent intellect	The age of the firm measured in years
Firm size	Mergent intellect	The total number of employees in the firm
Incremental PMAs	US FDA web site	PMAs classified by the FDA as 180 day supplement, Real-Time supplement, and 30 day supplement
Large firms (indicator)	US FDA web site, Mergent intellect, COMPUSTAT	Firms with greater than $100 million in revenue are defined as large firms by the FDA
Mean PMA fee	US FDA web site	The average dollar value of the fees paid to the FDA for filing the PMA, based on the 2015 prices listed as follows: Original PMA: $261,388; Panel Track: $196,041; 180 Day Track: $39,209; Real Time supplement: $18,297; 30-Day supplement: $4211.
Multidivisional firms (indictor)	COMPUSTAT	Firms are considered multidivisional firms if they have multiple divisions listed in the COMPUSTAT segment level database
Post tax	NA	An indicator variable taking a value of 1 starting in the first year of the excise tax (2013), and 0 before.
Public firms (indicator)	COMPUSTAT	Firms that are listed in the COMPUSTAT database are considered public firms
Radical PMAs	US FDA web site	PMAs classified by the FDA as original or panel track PMAs
Sales ($, millions)	Mergent intellect, COMPUSTAT	The total revenue of the firm in Mergent Intellect (for private firms) or COMPUSTAT (for public firms)
Segment capital investment	COMPUSTAT	The dollar value of capital investment by firm segment.
Supplement number	US FDA web site	The number of supplements from the original PMA to the current supplement.
Time from filing to granting PMA	US FDA web site	The number of days from the filing of the PMA to the granting of the PMA.
Zero revenue firms (indicator)	Mergent intellect, COMPUSTAT	Firms with zero revenue as reported either in Mergent Intellect or COMPUSTAT

Table 1 provides the sources of data and definitions of variables used in our paper.

4.3. Variables and measures

FDA classifies PMAs into five categories: 1) original, 2) panel-track supplement, 3) 180-day supplement, 4) real-time supplement, and 5) 30-day supplement. It is clear that original PMAs constitute radical innovation since original PMAs are not modifications to existing products, but rather are new products that have not been offered to the marketplace in the past.[3] We include panel-track supplements in our definition of radical innovation, because the statutory definition of panel-track supplements entails "significant change in design or performance of the device or a new indication for use of the device, and for which clinical data are generally necessary."[4] In contrast, a 180-day supplement is defined as a "significant change in components, materials, design, specification, software, color additive, and labeling." A real-time supplement is defined by the FDA as "… a minor change to the design of the device, software, manufacturing, sterilization, or labeling…" A 30-Day notice is clearly the least radical of the PMA documents filed with the FDA since such a notice "… is limited to a request to make modifications to manufacturing procedures or methods of manufacturing…".[5]

Table 2 reports the total number and radicalness of PMAs per year. We find a consistent increase in the total number of PMAs filed per year, starting with 500 PMAs in 2004 to 1520 PMAs in 2017. Splitting PMAs by category, we find that incremental PMAs account for the vast majority (82%) of PMAs filed by the industry. Table 2 Panel A shows that in 2004, 339 of the 500 PMAs (68%) are incremental, whereas in 2015, 1532 of 1780 PMAs (86%) are incremental. We also see that radical PMAs, defined as original PMAs and panel-track PMAs, slightly increase in absolute figures from 161 PMAs in 2004 to 248 PMAs in 2015.

Table 2 Panel B shows the different degrees of radicalness of PMAs. There are 3046 radical PMAs (original PMAs and panel-track PMAs) (17% of our sample). We find that there are 1,402,180-day supplemental PMAs (8%), 2946 real-time supplemental PMAs (16%), and 10,191 30 day supplemental PMAs (58%). As expected, radical innovation is not dominant in our sample, making up only 18% of all innovation in the period examined.[6] We tabulate the total innovation in Fig. 1 and find that there is a substantial decline in total innovation starting in 2013, the year of the excise tax implementation. However, Fig. 2 makes it clear that the decline in radical innovation is the substantial driver of this decline. This is consistent with H3b.

One of the strengths of the PMA data is the availability of alternative measures of radicalness in it. In addition to our discrete measure of radicalness, the PMA data allows us to generate several continuous measures of the radicalness of innovation since radicalness actually lies along a continuum. In particular, the FDA's PMA data includes both the fees for the PMAs filed and the time from the filing date of the PMA to the date the FDA issues the PMA. The fee for original and panel-track PMAs averages $189,128 where the fee for 180 day supplements, real-time supplements, and finally for the 30 day supplements average $35,857; $18,297; and $4206, respectively. This monotonic decline in cost is consistent with our conjecture that the fee charged should be a good proxy for the radicalness of the PMA. Fees are charged to "support the process for the review of device applications."[7] Detailed applications that require more scrutiny from the FDA incur larger costs for

[3] This is well acknowledged: "Congress has mandated that the FDA give priority review to PMA applications that have innovative or breakthrough technology." (p. 86) D.R. Challoner, 2011. *Medical Devices and the Public's Health: The FDA 510 (k) Clearance Process at 35 Years*. The National Academies Press, Washington, DC.

[4] See the FDA definition for a Panel-Track PMA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089726.htm

[5] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

[6] We recognize that our definition of radical innovation as being only original and panel-track PMAs may appear somewhat arbitrary. We therefore repeat all our major results, defining only original PMAs as radical innovation. We find qualitatively similar results. The downside of using only original PMAs as radical innovation is that original PMAs make up only 1.5% of our sample of PMAs, significantly constraining the empirical power of the tests. We also repeat our analyses defining original, panel-track, and 180-day supplement PMAs (i.e. all three) as radical innovation. Using this broader definition, we find qualitatively similar results as well.

[7] http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm109105.htm

Table 2
Total number of PMAs filed per year.

The sample is composed of the firms with at least one premarket approval (PMA) issued between 2004 and 2017 which have sales data and employee data available in Mergent Intellect. For each firm, we calculate the number of PMAs by applicant name. Our sample consists of $N = 20{,}725$ premarket approvals (PMAs) filed by 153 firms between the years 2004–2017.

Table 2. Panel A. Total number of PMAs in the sample.

Year of PMA filing	Radical innovation original and panel-track PMAs[a]	Incremental innovation supplemental PMAs	Total innovation number of PMAs
2004	161	339	500
2005	216	536	752
2006	180	779	959
2007	229	750	979
2008	253	1101	1354
2009	255	1032	1287
2010	294	1460	1754
2011	308	1582	1890
2012	324	1794	2118
2013	275	1811	2086
2014	303	1823	2126
2015	248	1532	1780
2016	182	1438	1620
2017	111	1409	1520
Total	3229	17,386	20,725

Table 2. Panel B. Kinds of PMAs by radicalness.

PMA type	N	Fee per PMA[b]	Time to grant PMA (days)	Supplement number	Percent
Most radical					
Original and panel-track	3339	$189,128	234.86	63.42	16.11%
180 day supplement	1547	$35,857	182.82	68.74	7.46%
Real-Time supplement	3188	$18,297	77.11	100.93	15.38%
30 day supplement	12,651	$4206	28.07	101.06	61.04%
Least radical					

[a] Note that the categories of original PMAs and Panel-track PMAs have been combined for brevity. There are only $N = 372$ original PMAs in our sample, making data analysis with this sample of limited value due to a lack of statistical power. Our results are qualitatively similar if we examine only original PMAs as radical PMAs.

[b] The Federal Register contains detailed information about the inflation changes in medical devise user fees for previous years. The user fees have changed proportionately over time to adjust for the inflation in payroll costs and non-pay costs associated with processing PMAs. Under section 351 of the Public Health Services Act, the FDA set the costs of all other supplemental PMAs to be a percentage of the cost for an original PMA. The cost for a Panel-track supplement was 75% of an original PMA. Likewise, the costs for a 180 day supplement, a real time supplement, and a 30 day notice were 15%, 7%, and 1.6%, respectively, the cost of an original PMA. This information suggests that we do not need to adjust for inflation of costs over time since the relationship between the costs for various PMA filings will be comparable over time. For more details, see the Federal Register, Vol 80, No. 148/Monday August 3, 2015. https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18907.pdf.

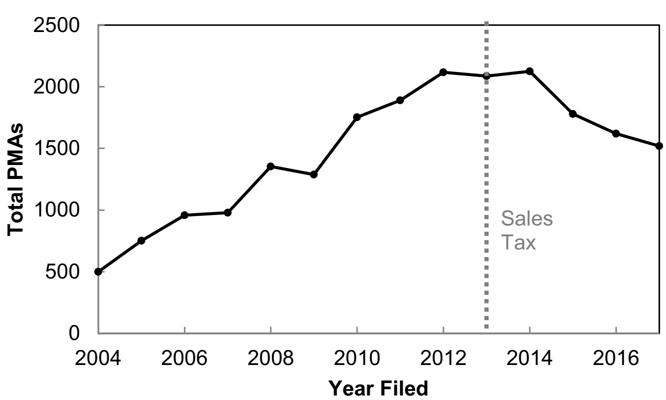

Fig. 1. Total innovation by year.
This figure shows the total number of premarket approvals filed from 2004 to 2017. The sample includes both radical innovations and incremental innovations (all PMAs). The figure shows the year in which the new sales tax was implemented in the medical device industry.

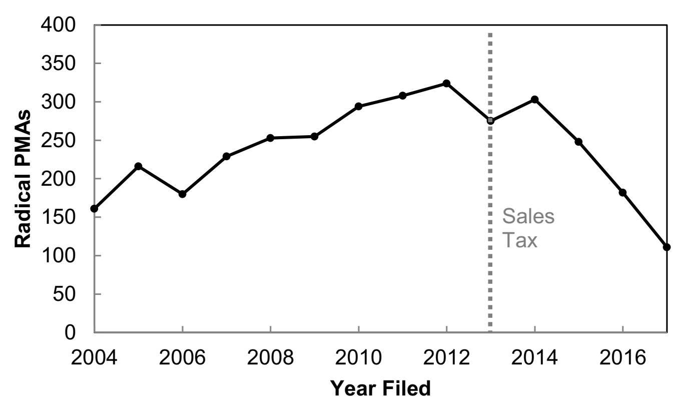

Fig. 2. Radical innovation by year.
This figure shows the total number of original and panel-track premarket approvals filed from 2004 to 2017. The figure shows the year in which the new sales tax was implemented in the medical device industry.

review, thus implying that a higher fee will be associated with a more radical PMA. Likewise, since PMAs that are more radical will require more time for review, often involving industry experts outside of the FDA, the time to approve the PMA is another good proxy for the radicalness of the PMA. We use the time the FDA takes to approve the PMAs as another proxy for radicalness, finding that the most radical PMAs (original and panel-track) take, on average, 235 days to approve. In contrast, 180-day supplements take 183 days, Real-time supplements take 77 days, and 30-day supplements take 28 days.

Table 3
Descriptive statistics.
The sample is composed of the firms with at least one Premarket approval (PMA) approved between 2004 and 2017 which have sales data and employee data available in Mergent Intellect. We calculate the number of PMAs for each firm by applicant name. Our sample consists of N = 20,725 Premarket approvals (PMAs) filed by 153 firms over the years 2004–2017.

	N	Mean	Median	Min	Max
Sales ($, millions)	153	3436.81	24.28	0.00	130,685.00
Firm age (years)	153	16.73	11.00	0.00	150.00
Employees	153	10,082.30	107.50	1.00	417,000.00
Large firms	153	0.33	0.00	0.00	1.00
Public firms (indicator)	153	0.43	0.00	0.00	1.00
Multidivisional firms	153	0.49	0.00	0.00	1.00
Conglomerates	153	0.04	0.00	0.00	1.00

Lastly, we use the actual supplement number as a measure of the radicalness of the PMA. The supplement number is the total number of supplemental PMAs filed for a specific product. Therefore, all original PMAs have a default supplement number of 1, and each additional PMA that changes the product's attributes in some way has the cumulative number of supplements for that original PMA until the additional PMA in consideration was issued. This yields a uniform increase in supplement numbers from the original and panel-track PMAs (63) to the 180-day supplements (69) to the real-time supplements (101) and finally to the 30-day supplements (101).

Following prior literature (e.g. Wu, 2013), we control for firm size, age, and access to external financing. A firm's product portfolio size should be negatively correlated with radical innovation since firms with larger existing product portfolios are less likely to engage in radical innovation (Holmstrom, 1989; Uotila et al., 2009). We measure firm size with total firm sales and a separate indicator variable taking a value of one if the FDA classifies the firm as a large firm. Firm age should also be important since younger firms create relatively more radical innovations (Holmstrom, 1989) and older firms create more incremental innovations (Nagji & Tuff, 2012). We also examine firms' access to funding, since public firms can access capital more easily, providing broader financial freedom to engage in risky innovation projects. Table 3 provides descriptive statistics for these important firm characteristics in our sample.[8] Table 4 provides the correlation table for the major variables.

4.4. Empirical tests of product portfolio effects

In order to test H1a and H1b, we first build baseline models by regressing the firm innovation radicalness onto firm characteristics. Our key variable of interest is an indicator variable that takes a value of one in years after the excise tax goes into effect (in 2013 and later years). If firm-level innovation declines after the excise tax, this variable should have a negative and statistically significant coefficient. Note that, to reduce any potentially skewing effect of any one firm on the results, we average the radicalness of innovation for each firm within a year and include only one firm observation for each year. This reduces our sample size to 1078 firm-year observations. In addition, we use year fixed effects to control for the general trend in innovation radicalness over time or changes by year due to the business cycle. We then repeat our test including an interaction between the post-tax variable and organization complexity measured by firm size, a dummy variable for multidivision firms, and a dummy variable for conglomerates. We use the number of employees to measure firm size since this is a good proxy in a high human capital industry such as the medical device industry (Crépon, Duguet, & Mairessec, 1998). The interaction terms are particularly important since they allow us to test our main hypotheses.

4.5. Empirical tests of internal capital market effects

Firms allocate resources at the corporate level based on the expected returns from various projects undertaken by different divisions (Lamont, 1997; Stein, 1997). A tax in one industry that a firm is active in should cause a decline in investments in this industry if the firm can divert investments to alternative industries in which it is active. Thus, multidivisional firms should have larger declines in radicalness compared to single division firms, since multidivisional firms can reallocate resources from divisions subject to the new tax to divisions that are not. Likewise, after the excise tax is implemented, conglomerates will use their internal capital markets to divert resources away from less desirable projects to more desirable projects. This should show up both in the radicalness of projects as well as in the capital investment of the firms.

4.6. Empirical tests of changes in aggregate industry innovation output

To determine if there is a structural break around the implementation of the new tax, we first calculate the number of PMAs filed each year and regress this count variable on a trend variable calculated by subtracting 2004 from the year of the PMA filings. If the coefficient for the trend variable is significant, this indicates either an increase (positive coefficient: more PMAs issued) or decrease (negative coefficient: fewer PMAs issued) over time. We will then need to show a statistically significant change in the number of PMAs issued in the industry after 2013 above and beyond this baseline trend to show an aggregate effect of the tax.

5. Results

5.1. Firm level effects

We first test H1a & H1b, followed by the tests of H2a & H2b. Before moving on to test the aggregate industry effects (H3a & H3b), we conduct a number of robustness checks to rule out alternative explanations of the two core sets of hypotheses that predict important foundational effects of the tax at the firm level of analysis. We then examine the aggregate industry effects before discussing our findings and their implications collectively.

We begin by testing the fee paid by the firm for its FDA approvals for its PMAs since this fee is a good proxy for PMA radicalness. The fee paid to the FDA is commensurate with the time and effort expended in the review process. More expensive PMA reviews involve more extensive review processes by the FDA. We find in Table 5A Model 1 that the coefficient for the post-tax indicator variable is −0.87, suggesting that after the implementation of the excise tax, there was a decrease in the fee for applying for PMAs by $87,000 on average. Since the fee is positively related to project radicalness, this indicates a strong decline in product radicalness for the firms in our sample. In addition, we find that multidivisional firms further exhibit a lower level of radicalness by −$19,000, compared to single division firms. Overall, our results suggest that the excise tax led to a significant decline in radical innovation at the firm level. We then examine the interaction between firm size and the post-tax variable, finding that the interaction is negative and statistically significant. This implies that larger firms are

[8] The striking differences between mean/median sales ($3.4 billion and $24 million, respectively), and mean/median number of employees (10,082 and 108, respectively) is caused by a few very large firms in the sample. Further, four firms in our sample (*Abbott Laboratories*, *Boston Scientific*, *Medtronic*, and *St. Jude Medical*) collectively account for over half of all PMAs. Because of these strong influences, we conduct our major tests on a firm-year basis (i.e. using annual PMA radicalness for each firm, instead of using a simple count of PMAs). As a robustness check, we repeat all our major tests after eliminating these firms from the sample to ensure that our results are not skewed by the largest four firms. Our results remain qualitatively same when the largest four firms in our sample are excluded.

Table 4
Correlation table for major variables.
The sample is composed of the firms with at least one Premarket approval (PMA) approved between 2004 and 2017 which have sales data and employee data available in Mergent Intellect. We calculate the number of PMAs for each firm by applicant name. Our sample consists of N = 20,725 Premarket approvals (PMAs) filed by 153 firms over the years 2004–2017.

	1	2	3	4	5	6	7	8	9	10	11	12
1. Radical PMAs	1.000											
2. Mean PMA Fee	0.713	1.000										
3. Time to grant PMA	0.343	0.514	1.000									
4. 1/Supplement number	0.202	0.266	0.131	1.000								
5. Post-tax (indicator)	−0.088	−0.152	−0.156	−0.044	1.000							
6. Multidivisional firm	−0.087	−0.100	0.004	−0.141	−0.079	1.000						
7. Conglomerate firm	0.041	0.037	0.053	−0.023	0.012	0.146	1.000					
8. Firm sales	0.006	−0.046	−0.017	−0.044	0.045	0.241	0.463	1.000				
9. Large firm (indicator)	0.028	−0.022	−0.032	−0.009	0.024	0.106	0.236	0.766	1.000			
10. Firm age	−0.018	−0.077	−0.001	−0.155	0.029	0.294	0.121	0.235	0.107	1.000		
11. Employees	−0.035	−0.097	−0.022	−0.129	−0.014	0.537	0.283	0.550	0.280	0.504	1.000	
12. Public (indicator)	−0.079	−0.102	−0.037	−0.132	−0.045	0.391	0.167	0.270	0.122	0.307	0.625	1.000

more likely to be more strongly impacted by the excise tax. This provides strong support to H1a and H1b, which state that in response to the excise tax, complex firms will exhibit a larger decline in radicalness in comparison to smaller firms.

In Table 5A Models 3–4 we test the impact of organizational complexity by looking at multidivisional firms and conglomerate firms. We interact indicators for these variables with the post-tax indicator and find that complex firms experience a larger decline in the radicalness of the projects for which the firm invests. These results support hypothesis H2a and H2b.

A major concern for our results so far is that firms might have reduced PMAs not because of the excise tax of 2013, but rather due to industry specific or macro-economic factors that naturally changed the way firms invested. If so, finding a negative and significant relationship between the radicalness of innovation and the beginning of 2013 would not necessarily be caused by the tax, but possibly by some unobservable factor. To rule out this possibility, we look for firms that are not impacted by the new tax as a control group for our tests. This would allow us to test if the reaction of the firms in our sample that are subjected to the tax, i.e. the treatment group, is significantly different from a subset of firms in the sample that are not affected by the tax, i.e. the control group. Specifically, since this tax is on sales, if a firm is filing PMAs but not making any sales now, then this firm would not be materially impacted by the new sales tax. In addition, if there is a reasonable likelihood that the tax may be repealed in the future, then firms with zero sales today may never pay this tax in the future.[9] These firms pay their expenses not with their revenues, but rather with their equity. For identification purposes, we utilize firms with zero sales, since these firms should not be affected by the implementation of a tax on sales.[10]

To implement this test, in Table 5A Model 5 we examine the impact of the excise tax on firms with zero vs. non-zero revenue by including an interaction between a non-zero revenue and the post-tax indicator. This interaction provides the key evidence for our main results. Since the excise tax has no impact on firms with zero revenue, there should be no marginal impact of the tax on zero revenue firms. We find that, for the 11 firms with zero sales, there is no significant change in the percent of original PMAs, the fees decline by $4437, the time to approval declines by 14 days, and their change in supplement number is 3.90. In contrast, for the 114 firms subject to the excise tax due to their positive revenue, we find a decline in radical innovations of 14%, and decline in fees of $34,050, a decline in time to approve the PMA of 42 days, and a change in supplement number of 9.45 (Table 6). While we find a decline in radicalness for firms with sales vs. no sales that is higher for each measure of firm radicalness, we find statistical significance for the percent of original PMAs and the change in supplement number. This implies that our results are robust to the difference-in-differences methodology, ruling out an endogenous explanation.

5.1.1. *Using alternative measures of innovation*

To rule out the possibility of our findings being an artifact of the measures of innovation that we have used so far, we repeat our major regressions using an identical framework with three additional measures of radicalness of innovation as the dependent variable: the percent of radical innovations (Table 5B); the time to obtain FDA approval (Table 5C); and 1/supplement number (Table 5D). In each case, we find almost identical results with slight variations in the significance of the variables tested, as expected of correlated but different measures.

5.1.2. *Difference-in-differences of investments in corporate divisions of complex firms*

To further ascertain this finding, and as a robustness test, we conduct a difference-in-differences test to show that the change in investment from before to after the excise tax is significantly different between the medical device divisions and the non-medical device divisions (Tables 7 and 8). We find that the non-medical device divisions have an increase in capital investment of $10 million where the medical device divisions have a decrease in capital investment of $1 million. This difference is statistically significant at the 5% level in a Wilcoxon rank-sum test, which we rely on, due to the potential skewness that might make a *t*-test inappropriate for our data. Collectively, the results suggest that the decline in innovation documented in our paper is in part the result of firms allocating resources to other divisions where the new medical device sales tax would not apply. These results provide strong support for H2a and H2b, which state that multidivisional firms, but not single division firms, shift their investments from the divisions impacted by an excise tax to divisions that are not impacted.

5.1.3. *Year fixed effects and outliers*

As another robustness check, we repeat our major analyses replacing the year fixed effects with a trend variable created by subtracting 2004 from the year of observation. We also repeat our analyses omitting

[9] In fact, the medical Device Excise Tax was later placed on a two-year moratorium based on The Consolidated Appropriations Act of 2016, signed into law on December 18, 2015. For more details, see: https://www.irs.gov/uac/newsroom/medical-device-excise-tax.

[10] That is not to say, of course, that there will be no impact in the future. A firm with zero sales in this fiscal year, e.g. a startup funded by venture capital, will still likely seek to make sales in the future. But, the excise tax will be paid in the future rather than from current profits. As long as there is a reasonable possibility that the excise tax will be repealed in future periods, the excise tax should not impact firms with zero sales today in the same way as firms with positive sales.

Table 5
Regressions of innovation radicalness on firm characteristics.

The sample is composed of the firms with at least one Premarket approval (PMA) approved between 2004 and 2017 which have sales data and employee data available in Mergent Intellect. We calculate the number of PMAs for each firm by applicant name. Our sample consists of N = 20,725 Premarket approvals (PMAs) filed by 153 firms over the years 2004–2017. All regressions have one observation per firm-year as long as the firm has at least one PMA within a year. The dependent variable is the mean percent of radical innovation within a year (Panel A), the mean cost of the PMA filing (Panel B), the log(length of time it takes to be granted the PMA) measured in days (Panel C), and the supplement number of the firm (Panel D). *t*-statistics clustered by PMA applicant are reported in parentheses next to the coefficients.

Table 5. Panel A. OLS regression of innovation radicalness based on PMA fee in $ (thousands).

	(1)	(2)	(3)	(4)	(5)
Post-tax (indicator)	−87.89*** (7.60)	−59.87*** (3.09)	−69.95*** (4.61)	−83.22*** (6.52)	−47.09**(2.01)
Organizational complexity					
Firm size	−10.63 (1.12)	−7.82 (0.36)	−10.14 (1.09)	−10.61 (1.12)	−10.60 (1.11)
Multidivision firm (indicator)	−19.07** (2.03)	−18.75** (2.03)	−12.72 (1.18)	−18.99** (2.03)	−15.57 (1.58)
Conglomerate firm (indicator)	20.29 (1.05)	20.13 (1.03)	20.14 (1.03)	33.59 (1.30)	19.74 (1.03)
Post-tax × firm size		−2.91* (1.64)			
Post-tax × multidivisional firm			−20.07* (1.72)		
Post-tax × conglomerate firm				−41.83* (1.75)	
Subject to tax					
Non-zero revenue firms (indicator)					28.86 (1.42)
Non-zero revenue firms × post-tax					−41.43** (2.10)
Control variables					
Firm sales	66.62 (0.24)	69.13 (0.25)	68.67 (0.25)	89.05 (0.33)	144.32 (0.51)
Large firm (indicator)	7.79 (0.28)	8.87 (0.33)	8.55 (0.31)	4.72 (0.18)	3.50 (0.12)
Firm age (years)	−0.12 (0.89)	−0.14 (0.99)	−0.12 (0.88)	−0.12 (0.87)	−0.12 (0.87)
Public firm (indicator)	−1.65 (0.82)	−10.40 (1.10)	−1.71 (0.85)	−1.72 (0.85)	−2.74 (1.14)
Intercept	148.40*** (11.74)	142.25*** (9.90)	144.14*** (11.04)	148.08*** (11.63)	125.79*** (6.60)
Year-fixed effects	Yes	Yes	Yes	Yes	Yes
N	1078	1078	1078	1078	1078
R^2	9.89	10.18	10.21	10.10	10.32

Table 5. Panel B. OLS regression of innovation radicalness based on percent radical PMAs.

	(1)	(2)	(3)	(4)	(5)
Post-tax (indicator)	−0.32*** (4.20)	−0.21** (2.04)	−0.23** (2.57)	−0.29*** (3.57)	−0.11 (0.85)
Organizational complexity					
Firm size	−0.01 (0.71)	0.00 (0.30)	−0.01 (0.74)	−0.01 (0.75)	−0.01 (0.96)
Multidivisional firm (indicator)	−0.09* (1.91)	−0.08* (1.91)	−0.05 (1.05)	−0.09* (1.91)	−0.07 (1.49)
Conglomerate firm (indicator)	0.11 (0.96)	0.11 (0.95)	0.11 (0.95)	0.18 (1.22)	0.10 (0.95)
Post-tax × firm size		−0.01 (1.47)			
Post-tax × multidivisional firm			0.10* (1.80)		
Post-tax × conglomerate firm				−0.22* (1.70)	
Subject to tax					
Non-zero revenue firms (indicator)					0.13 (1.28)
Non-zero revenue firms × post-tax					−0.21** (2.14)
Control variables					
Firm sales	0.32 (0.21)	0.33 (0.21)	0.33 (0.21)	0.44 (0.29)	0.63 (0.40)
Large firm (indicator)	0.06 (0.36)	0.07 (0.39)	0.06 (0.39)	0.04 (0.27)	0.04 (0.26)
Firm age (years)	0.00 (0.62)	0.00 (0.71)	0.00 (0.61)	0.00 (0.60)	0.00 (0.61)
Public firm (indicator)	−0.05 (1.12)	−0.05 (0.05)	−0.05 (1.08)	−0.05 (1.12)	−0.05 (1.11)
Intercept	0.64*** (10.76)	0.63*** (9.16)	0.62*** (9.97)	0.64*** (10.65)	0.54*** (5.76)
Year-fixed effects	Yes	Yes	Yes	Yes	Yes
N	1078	1078	1078	1078	1078
R^2	7.75	7.99	8.10	8.01	8.18

Table 5. Panel C. OLS regression of innovation radicalness based on time to grant.

	(1)	(2)	(3)	(4)	(5)
Post-tax (indicator)	−0.70** (2.63)	−0.21 (0.67)	−0.44 (1.54)	−0.65** (2.38)	−0.11 (0.37)
Organizational complexity					
Firm size	−0.02 (0.22)	−0.02(0.75)	−0.01 (0.15)	−0.02 (0.22)	−0.03 (0.31)
Multidivision firm (indicator)	−0.15 (1.54)	−0.15 (1.53)	−0.06 (0.50)	−0.15 (1.53)	−0.15 (1.51)
Conglomerate firm (indicator)	0.35*** (2.89)	0.35*** (2.82)	0.35*** (2.83)	0.49*** (3.24)	0.35** (2.88)
Post-tax × firm size		−0.03* (1.77)			
Post-tax × multidivisional firm			−0.30** (2.39)		
Post-tax × conglomerate firm				−0.43** (2.59)	
Subject to tax					
Non-zero revenue firms (indicator)					0.16 (0.73)
Non-zero revenue firms × post-tax					−0.60*** (3.67)

(*continued on next page*)

Table 5 (*continued*)

Table 5. Panel C. OLS regression of innovation radicalness based on time to grant.

	(1)	(2)	(3)	(4)	(5)
Post-tax (indicator)	−0.70** (2.63)	−0.21 (0.67)	−0.44 (1.54)	−0.65** (2.38)	−0.11 (0.37)
Control variables					
Firm sales	2.75 (1.17)	2.79 (1.17)	2.78 (1.16)	2.98 (1.31)	2.66 (1.14)
Large firm (indicator)	−0.30 (1.35)	−0.29 (1.29)	−0.29 (1.30)	−0.33 (1.57)	−0.29 (1.32)
Firm age (years)	0.00 (0.28)	0.00 (0.29)	0.00 (0.25)	0.00 (0.26)	0.00 (0.28)
Public firm (indicator)	−0.02 (1.21)	−0.02 (0.19)	−0.03 (1.25)	−0.03 (1.25)	−0.02 (1.09)
Intercept	5.18*** (37.64)	4.93*** (31.29)	5.11*** (36.56)	5.17*** (37.41)	5.02*** (22.66)
Year-fixed effects	Yes	Yes	Yes	Yes	Yes
N	1078	1078	1078	1078	1078
R^2	6.40	7.71	6.44	6.48	6.60

Table 5. Panel D. OLS regression of innovation radicalness based on 1/supplement number.

	(1)	(2)	(3)	(4)	(5)
Post-tax (indicator)	−0.16*** (4.29)	−0.10 (1.10)	−0.15*** (2.91)	−0.16*** (4.14)	−0.15** (1.99)
Organizational complexity					
Firm size	−0.04 (1.51)	0.01 (0.73)	−0.04 (1.50)	−0.04 (1.51)	−0.04 (1.45)
Multidivision firm (indicator)	−0.06** (1.98)	−0.08** (1.96)	−0.06* (1.66)	−0.06** (1.97)	−0.05 (1.55)
Conglomerate firm (indicator)	−0.01 (0.94)	−0.03 (0.74)	−0.01 (0.94)	−0.01 (0.58)	−0.02 (1.09)
Post-tax × firm size		−0.01 (0.62)			
Post-tax × multidivisional firm			−0.01 (0.21)		
Post-tax × conglomerate firm				−0.01 (0.60)	
Subject to tax					
Non-zero revenue firms (indicator)					0.05 (0.66)
Non-zero revenue firms × post-tax					−0.01 (0.21)
Control variables					
Firm sales	0.46 (0.75)	0.64 (0.76)	0.46 (0.75)	0.46 (0.76)	0.69 (1.06)
Large firm (indicator)	0.06 (0.88)	0.11 (0.98)	0.06 (0.88)	0.06 (0.86)	0.05 (0.70)
Firm age (years)	0.00 (1.41)	0.00 (1.14)	0.00 (1.41)	0.00 (1.41)	0.00 (1.39)
Public firm (indicator)	−0.01 (1.17)	−0.07* (1.65)	−0.01 (1.18)	−0.01 (1.18)	−0.01 (1.42)
Intercept	0.40*** (7.95)	0.43*** (6.38)	0.40*** (7.69)	0.40*** (7.94)	0.37*** (4.66)
Year-fixed effects	Yes	Yes	Yes	Yes	Yes
N	1078	1078	1078	1078	1078
R^2	10.13	10.20	10.14	10.14	10.19

Table 6
Difference-in-differences results.

The sample is composed of the firms with at least one Premarket approval (PMA) approved between 2004 and 2017 which have sales data and employee data available in Mergent Intellect. Two PMAs are required to calculate the change in innovation from before until after the tax change which occurred January 1, 2013. We examine the change in the radicalness of innovation from before to after the tax change for the 125 firms in our sample with sufficient data. **, and * indicate significance at the 5%, and 10% level, respectively.

	Change in radicalness of innovation from before to after tax by public firms		
	Firms with zero sales $N = 11$	Firms with sales $N = 114$	*z-test*
Change in original PMAs From before tax to after tax	0.00%	−13.96%	1.77*
Change in fees From before tax to after tax	−$4437	−$34,050	1.12
Change in time to approval From before tax to after tax	−14.17	−42.05	0.96
Change in supplement number	3.90	9.45	2.04**

year controls completely. Our results are qualitatively similar, independent of how we control for year effects. We also repeat our analyses after eliminating the four largest firms in our sample (*Abbott Laboratories*, *Boston Scientific*, *Medtronic*, and *St. Jude Medical*) since we wish to ensure that we are not observing a skewing effect driven by these largest firms. Although this reduces the number of firm-year observations to 1022, our results remain largely unchanged. Likewise, we repeat our analyses for cardiovascular PMAs only, since PMAs in this medical device specialty make up 64% of the overall sample (the most prominent of the 19 specialties categorized by the FDA). This reduces the number of PMAs from 20,725 to 13,253. We find that our results are qualitatively similar. Thus, we conclude that our results are not driven by year effects, any subset of firms in the sample, or a subset of PMAs in a particular medical device category. Rather, our results show that there was a significant decline in radical innovation, particularly for firms with large product portfolios and firms with a multidivisional organization structure, after the passage of the excise tax.

5.2. Industry level effects

In Table 9A Model 1, we find that there is a positive and statistically significant coefficient for the baseline trend variable. The coefficient of

Table 7
Investment in new capital by business division for multi-division firms.
The sample is composed of the firms with at least one premarket approval (PMA) filed between 2004 and 2017 which are publicly traded and multi-division with data available in the COMPUSTAT segment database. For each firm, we report the median investment in new capital from before to after the tax change in non-medical device divisions and medical device divisions. Our sample consists of $N = 952$ firm-year observations with 21 unique firms. ***, **, and * indicates that the coefficients are statistically significant at 1%, 5%, and 10% level, respectively.

	Capital Investment by year		
	Non-medical device segment capital investment	Medical device segment capital investment	Wilcoxon rank-sum test (*z-statistic*)
2004	99.0	68.5	0.91
2005	179.7	10.0	1.45
2006	140.5	106.0	0.53
2007	110.8	48.0	0.86
2008	54.4	18.8	0.49
2009	93.6	55.6	0.26
2010	144.0	141.9	0.48
2011	129.4	55.2	1.06
2012	48.0	17.3	0.74
2013	149.5	16.0	2.10**
2014	147.5	24.0	2.12**
2015	189.8	87.0	1.86*
2016	183.0	94.0	2.30**
2017	214.0	147.0	1.32
Total	146.0	51.5	4.71***

Table 8
Difference-in-differences test of investment in new capital by business segment.
The sample is composed of the firms with at least one premarket approval (PMA) filed between 2004 and 2017 which are publicly traded and have multiple segments with data available in the COMPUSTAT segment database. For each firm, we report the median investment in new capital from before the tax change to after the tax change in non-medical device divisions and medical device divisions. Our sample consists of N = 952 firm-year observations with 21 unique firms. *** indicates that the difference is statistically significant at the 1% level.

	Change in capital investment from before to after tax by public firms		
	Non-medical device segments, $N = 38$	Medical device segments, $N = 25$	*z-test*
Δ in Capital investment ($ millions)	10.1	−1.15	2.93***

147 implies that for each year that passes, there are an additional 147 PMAs being filed, on average. The fact that this coefficient is significant at the 1% level implies that the trend is very marked in the data. In Table 9A Model 2, we add an indicator variable taking a value of one starting in the first year of the tax (2013) and every year thereafter. We find in this model that the coefficient on the indicator for years after the tax is put in place takes a significant value of −401. This implies that in the years the tax is in place, the number of PMAs is lower by 401, on average. It should be noted that this coefficient is marginally statistically significant, at the 10% level. The relative magnitudes of the coefficient for the trend variable (147) and the post-tax indicator variable (401) suggests that the implementation of the tax eliminated 2.73 years of growth in innovation output (−401/147).

An alternative interpretation is to look at the size of the decline in total innovation as a percentage of the median year total innovation. This measure suggests that total innovation declines by 25.8% (−401/1554) in response to the implementation of the tax. This result strongly supports H2a since it is clear that the implementation of the industry-wide excise tax has a far-reaching impact on industry total innovation. The result is both statistically and economically significant in support of our model suggesting that total innovation will decline after the implementation of an excise tax, providing support for H3a.

Table 9
Industry-wide trends in total innovation and radical innovation over time.
The sample is composed of the firms with at least one premarket approval (PMA) filed between 2004 and 2015 which have sales data and employee data available in Mergent Intellect. We calculate the number of PMAs for each firm by applicant name. Our sample consists of $N = 17{,}585$ Premarket approvals (PMAs) filed by 164 firms over the years 2004–2015. *** and * indicates that the coefficients are statistically significant at the 1% and 10% level, respectively.

	(1)	(2)
Panel A. Total PMAs regressed on trend and post-sales tax indicator		
Time trend (year-2004)	147.22*** (7.96)	185.13*** (7.60)
Post-tax indicator		−401.55* (2.07)
Intercept	508.48*** (3.74)	362.47*** (2.63)
N	12	12
R^2	86.38	90.76
Panel B. Incremental PMAs regressed on trend and post-sales tax indicator		
	(1)	(2)
Time trend (year-2004)	136.44*** (8.43)	166.50*** (7.49)
Post-tax indicator		−318.44 (1.80)
Intercept	324.74*** (2.73)	208.94 (1.67)
N	12	12
R^2	87.67	90.93
Panel C. Radical PMAs regressed on trend and post-sales tax indicator		
	(1)	(2)
Time trend (year-2004)	10.78*** (3.74)	18.63*** (6.15)
Post-tax indicator		−83.11*** (3.44)
Intercept	183.74*** (8.67)	153.52*** (8.97)
N	12	12
Adj R^2	58.36	82.01

Next we separate the PMAs into those that are incremental (180-day supplement, real-time supplement, and 30-day supplement) versus those that are radical (original and panel-track PMAs). In Table 9B we find that the trend variable for incremental PMAs is similar in magnitude and continues to be statistically significant. In Model 2, we find that the indicator variable for post-tax period is no longer statistically significant. This implies that there is no significant decline in incremental PMAs after the tax is implemented. This result suggests that it is not total innovation that is negatively impacted by the implementation of the excise tax, since incremental innovation does not appear to have a significantly negative decline subsequent to the implementation of the tax, consistent with H2b.

In Table 9C Models 1 and 2, we repeat our analyses examining only radical PMAs as defined by original and panel-track PMAs. In this case, we find that the trend variable is strongly positive with a statistically significant coefficient of 11. This result implies that there are 11 more radical PMAs filed every year, on average. The difference between this coefficient and the coefficient in Table 9A is not surprising since there are far fewer radical PMAs being filed compared to total PMAs. Most interesting, in Table 9C Model 2, the implementation of the tax implies that there is a decline of 83 radical PMAs, on average, associated with the implementation of the tax. The relative magnitude of the trend variable coefficient and the post-tax indicator variable suggests that the tax reduced radical innovation by 7.55 years of growth (−83/11). To show the significance of the radical innovation decline in percentage terms, the radical innovation decline for the median year is 32.8% (−83/253).

These results are important since they provide the first concrete evidence that total innovation was negatively impacted by the medical device sales tax (H3a). The results in Table 9 provide strong evidence for the effect of the tax causing a large decline in total innovation output of the industry. In addition, the results also show that it is radical innovation, rather than incremental innovation, which has declined the most substantially in the years after the tax was implemented. These results provide strong support for H3b.

6. Discussion

We know from prior literature that organization structure matters in making overall innovation decisions. However, our understanding of the factors that influence managers' decisions to change the numbers of incremental and radical innovation projects to be pursued in response to an economic shock has been limited. In this study, we address this gap by examining the effect of firm organizational structure on innovation portfolio choices, i.e. how complex and simple firms differ in changing their allocation of resources to radical and incremental innovations in response to an economic shock. We find that a shock to the costs of a firm will cause firms with large product portfolios to shift from radical innovation to incremental innovation, i.e. they create fewer new products while they make more incremental improvements on existing products. We also demonstrate that firms with multiple divisions reallocate resources away from their medical device divisions to other divisions that are not subjected to the new tax—a mechanism not available to single-business medical device firms that have simple organizational structures. Finally, we find that the medical device excise tax implemented in 2013 resulted in a relatively minor decrease in incremental innovations, but it led to a dramatic decline in radical innovation, both at the firm and industry levels of analysis.

We make several contributions to the literature. First, we provide explanations for two distinct mechanisms by which taxes affect incremental and radical innovations. To our best knowledge, this is the first study to examine the important effects of organizational complexity, as measured by product portfolio size and organization structure, on simple and complex firms' innovation portfolio responses to an economic shock. Second, in contrast to prior literature that has focused predominantly on the creation and dissemination of knowledge in the context of innovation, as typically measured by patent and citation counts (e.g. Archibugi & Planta, 1996; Cappelen, Raknerud, & Rybalka, 2012; Hall & Ziedonis, 2001; Quintana-Garcia & Benavides-Velasco, 2008; Trajtenberg, 1990), our study focuses on innovation at the product level, i.e. new or improved products in the marketplace, using several longitudinal, consistent, and reliable measures from the FDA data. Our approach is thus more proximal to the implementations of innovations at the product level in the market, both conceptually and empirically. Using a quasi-natural experiment, we are able to measure the effects of the tax on incremental and radical innovation separately for individual firms, as well as the medical device industry in aggregate.

6.1. Implications for research

Our results show that external stimuli can influence firms' innovation portfolio decisions. In the context of our study, we find that taxes effect not just total innovation, but particularly radical innovation in a dramatic way. The research stream on radical innovation has generally focused on internal factors such as managers' characteristics (Smith & Tushman, 2005), organization structure (Tushman, Smith, Wood, Westerman, & O'Reilly, 2010), organizational knowledge (Zhou & Li, 2012), or firm strategy (McDermott & O'Connor, 2002) as important factors affecting firms' pursuit of radical innovation. Meanwhile, the impact of external factors such as competition (Cornaggia, Mao, Tian, & Wolfe, 2015) or economic crises (Archibugi, Filippetti, & Frenz, 2013) on innovation has been typically studied from a macro-level perspective, i.e. pooling radical and incremental innovation, or using aggregate R&D investment or patent data. Our study provides evidence that policy interventions such as an industry-specific sales tax can have unintended consequences on radical innovation and incremental innovation, often in dramatically different ways. It is known from prior literature that external factors can impact a wide range of innovation outcomes such as new product development (NPD) and international new product rollout (INPR) timeliness (Lee & Wong, 2012). Given the importance of radical innovation for performance of individual firms as well as the global competitiveness of economies, whether such tax distortions can result in overall firm and industry underperformance due to the intermediary effect of decreased radical innovation stands as a salient research question that future research might address.

6.2. Implications for practice

An important implication for managers is that a nuanced view of innovation that goes beyond 'R&D expenditures' is conducive to a more effective management of the innovation portfolio. Even though it is not always easy to measure or even define the differences between incremental and radical innovation (Dewar & Dutton, 1986), managers of innovative firms stand to benefit from developing a nuanced view of innovation whereby they prioritize and manage incremental and radical innovation initiatives separately, even if concurrently. This is becoming increasingly more important in accordance with the increasing complexity of organizational routines as well as the inputs to and outputs of innovation processes with regard to managing innovation processes sustainably (Mousavi, Bossink, & van Vliet, 2018). Managers should thereby aim to translate a hard-to-measure activity such as innovation into relatively easy-to-measure indicators, such as qualitatively different categories of innovation, as well as quantitative measures that capture the effort, time, and costs associated with different innovation initiatives. A clear demarcation of innovation, conceptually and empirically, can enable managers to appropriate more value from their innovation portfolios while better mitigating costs and risks.

6.3. Implications for policy

Our research shows that a tax on sales, rather than profits, caused firms to change their behavior in two important ways. First, firms engaged in less radical innovation, skewing their innovation portfolios toward more incremental innovation. Second, multidivisional firms shifted their innovation investments to businesses that were not subjected to the new tax. These effects caused a reduction in the number of new medical devices created, whilst causing firms to focus on incremental innovation that predominantly aims to decrease manufacturing costs. The decline in total innovation, as well as the decline in radical innovation seems to be an unanticipated consequence of the tax from a policy maker's perspective. Indeed, the Congressional Research Service made the following statements in their report (Gravelle & Lowry, 2015) on the medical device excise tax:

> The analysis suggests that most of the tax will fall on consumer prices, and not on profits of medical device companies. The effect on the price of health care, however, will most likely be negligible because of the small size of the tax and small share of health care spending attributable to medical devices.

The Congressional Research Service, like many other organizations and interest groups, examined the potential impacts of the tax on corporate profits, production output, and jobs, failing to predict the drastic impact on medical device innovation. Our findings suggest that the tax had unintended consequences likely due to its nature and scope (a tax on sales vs. profits). Policy makers might benefit from weighing the potential consequences of such tax interventions for innovation, when considering different types of such interventions in the future.

Another important area ripe for future inquiry is the impact of such taxes on labor markets, specifically creation or destruction of jobs. Decreasing investments into radical innovation, but maintaining or increasing investments into incremental innovation may not have the negative effects on employment that medical device executives have touted. Radical innovation entails creation of new knowledge, undertaken by scientists, physicians, and highly specialized technical staff. Meanwhile, incremental innovation entails improvements of various aspects of existing products such as design, components, materials, or packaging, which require more generic skill sets that can apply to a broad range of product families. Thus, it might be the case that radical innovation employs relatively more scientists and researchers, while incremental innovation employs more technicians, product designers, manufacturing & logistics staff, and marketing & sales specialists. Therefore, it is at least plausible that the number of jobs to be lost due to decreasing investments in radical innovation could be offset by the number of jobs to be created due to increasing investments in incremental innovation. Whether the net effect of such a tax on jobs would be positive or negative is thus debatable. Since job creation/destruction is a major issue relevant to policy makers, distinct from the economic implications of the tax for corporate profits, there is a need for further inquiry into this effect.

6.4. Limitations

While our findings are important, robust, and striking, they are also subject to several limitations. First, it is not clear that a corporate tax, in contrast to a sales tax, would have the same differential effect on radical innovation compared to incremental innovation. As has been stated before, the sales tax is particularly important in that it drives a wedge between the incentives for radical innovation, which generally increases sales, and incremental innovation, which does not necessarily increase sales but generally decreases costs. Thus, our key insight into using this exogenous shock to incentives to tease out the relative benefit of radical versus incremental innovation may not apply to a general corporate tax.

Second, although the medical device industry is an important industry and generally considered representative of innovative industries (Chatterji, 2009; Wu, 2013), we acknowledge that our study is only about one industry. Despite its limitations in generalizability, however, the novel and rich dataset that we built using FDA data on medical device premarket approvals enables us to measure radical and incremental innovation with great precision. In addition, the medical device industry is also representative of regulated industries such as pharmaceuticals, healthcare, financial services, and telecommunications. In such industries, while the mandate for policy makers and administrators to protect consumers creates constraints on firms, it also offers opportunities for researchers to adopt robust empirical approaches, and devise novel datasets and measures to study outcomes of importance for society. Therefore, we believe that focusing on the medical device industry enables us to examine the changes in firms' innovation incentives and responses to an industry-specific sales tax with a more refined methodological approach.

7. Conclusion

Overall, this study shows that firms with complex and simple organizational structures make different innovation portfolio adjustments in response to an external shock. The study also shows that the radicalness of innovation in the US medical device industry has declined significantly after the passage of the 2013 sales tax. Empirically, the quasi-natural experiment setup; the unique dataset that we created using longitudinal, consistent, and reliable FDA data at the product level; the use of several consistent measures of incremental and radical innovation; and numerous robustness checks conducted to rule out alternative explanations bolster our causal inferences. A key theoretical insight is that a tax on sales will incentivize complex firms with large product portfolios, which account for the majority of innovation, to decrease their radical innovation output in particular since new products will increase their tax burden. Consistent with our predictions, we find strong evidence for complex firms' shifting their innovation portfolios toward more incremental, cost-reducing innovations, while decreasing their radical innovation outputs. Simple firms, on the other hand, were not able to respond as flexibly as complex firms were to such an external shock. The study clarifies how the different drivers of radical and incremental innovation and organizational complexity play important roles in firms' responses to changing innovation incentives. We hope that future research would build upon and extend our findings in this literature.

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