



# Corporate lobbying and product recalls: an investigation in the U.S. medical device industry

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## Abstract

While corporate political activity is increasing, its effects on firms' marketing-relevant outcomes have been largely overlooked in the literature. We propose that corporate lobbying will decrease a firm's emphasis on product safety and, in turn, increase its product recalls. We further propose that the positive indirect effect of corporate lobbying on a firm's product recalls via lower emphasis on product safety will be moderated by the firm's (a) CEO's functional background and (b) focus on radical (vs. incremental) innovation. We provide empirical support for the proposed model using data on 86 U.S. medical device firms from 2005–2018. The findings extend the literature on the effects of non-market forces on firms' marketing-relevant outcomes. They also extend the literature on the antecedents of product recalls, which has, hitherto, overlooked the role of non-market forces. The findings on the moderating roles of the firm's marketing CEO and focus on radical (vs. incremental) innovation generate actionable managerial implications.

**Keywords** Corporate lobbying · Product safety · Product recalls · CEO · New products · Medical devices

## Introduction

The influence of politicians and regulators over firms is substantive and has been growing dramatically. As a result, firms invest considerable time and money to shape their political and regulatory environments (Werner, 2015). One key mechanism by which firms try to influence politicians and regulators is corporate lobbying (Hillman et al., 2004). In this research, we examine the effect of corporate lobbying on product recalls, a marketing-relevant outcome for firms.

From a theoretical perspective, this research is at the intersection of two influential marketing literature streams: (1) the literature on the effects of corporate political activity (Bhagwat et al.,

2020), in general, and corporate lobbying (Martin et al., 2018), in particular, on firms' outcomes; (2) the literature on the antecedents of product recalls. First, the findings from the corporate political activity literature indicate that firms' corporate lobbying affects shareholder value and risk (Martin et al., 2018). Overlooked is whether firms' corporate political activity, in general, and corporate lobbying, in particular, affect marketing-relevant outcomes. Vadakkepatt et al. (2022) is a notable exception focusing on customer satisfaction. Second, there is a rich literature on the antecedents of product recalls, which has primarily focused on organization-level antecedents, including organizational learning from prior product recalls (Haunschild & Rhee, 2004; Kalaigannan et al., 2013), R&D intensity and product scope (Thirumalai & Sinha, 2011), CEO stock option pay, tenure, and founder status (Wowak et al., 2015), and presence of a Chief Marketing Officer (CMO) (Kashmiri and Brower 2016). See Cleeren et al. (2017) for a comprehensive literature review. The effects of firms' non-market strategies, in general, and corporate lobbying, in particular, on product recalls are only now receiving some attention (Rayfield & Unsal, 2019). However, these authors investigate the main effect of corporate lobbying on product recalls and overlook the role of firm heterogeneity in this relationship, a gap we address. We develop and test hypotheses in the U.S. medical device industry, where corporate lobbying is important, because of safety regulations.

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This research is also important from a practical perspective. Product recalls in the U.S. medical device industry are, unfortunately, common and increasing (Statista 2018). In 2019, U.S. medical device firms spent U.S. \$29 million on corporate lobbying (Center for Responsive Politics 2020), resulting in high political influence in Washington, D.C. (Fang 2018)<sup>1</sup>. Further, the U.S. Food and Drug Administration (FDA), the federal agency responsible for monitoring the safety of medical devices, has been blamed for not being independent enough, resulting in calls for reform (e.g., Adashi et al., 2019; Patel, 2020).

We theorize that corporate lobbying will have a positive effect on a firm's product recalls and that this effect will be mediated by the firm's lower emphasis on product safety. Corporate lobbying can lead to privileged relationships between firms and regulatory agencies entrusted with oversight of product safety (Barber & Diestre, 2019). Building on this idea, we propose that corporate lobbying may decrease a firm's emphasis on product safety in new product development and, in turn, increase the number of its product recalls. Further, we propose a moderated mediation model where the positive indirect effect of corporate lobbying on the number of product recalls via lower emphasis on product safety is moderated by the firm's (a) CEO's functional background and (b) focus on radical (vs. incremental) innovation.

Applying the upper echelons theory (Hambrick & Mason, 1984) that CEOs' functional backgrounds shape their firms' cognitions and strategies (Barker & Mueller, 2002; Bertrand & Schoar, 2003), we propose that a marketing CEO in the firm will result in a focus on the firm's brands and customers (Paşa & Shugan, 1996), crucial strategic market-based assets to be safeguarded from product recalls, strengthening the negative effect of the firm's emphasis on product safety on the number of its product recalls. Conversely, we propose that a R&D CEO in the firm will result in a focus on developing sophisticated new products, crucial strategic technology-based assets (Maltz & Kohli, 2000) prone to technical challenges, including safety problems, weakening the negative effect of the firm's emphasis on product safety on the number of its product recalls. Finally, building on business press evidence from the medical device industry (see e.g., Lenzer, 2017), we propose that an increase in the firm's focus on radical (vs. incremental) innovation will weaken the negative effect of its emphasis on product safety on the number of its product recalls.

To test the proposed second-stage moderated mediation model (where moderators moderate the path between the mediator, i.e., emphasis on product safety, and the dependent variable, i.e., number of product recalls) (see e.g., Arunachalam et al., 2018; Harmancioglu et al., 2021), we collect data from the U.S. FDA Medical Device Product Recalls database (for

product recalls), opensecrets.org (for corporate lobbying), BoardEx (for CEOs' functional backgrounds), ExecuComp (for CEOs' characteristics), and firms' 10-Ks (for quality certifications). The final sample consists of an unbalanced panel of 86 U.S. medical device firms (696 firm-years) between 2005 and 2018.

The findings, which are robust, indicate that a firm's corporate lobbying increases the number of its product recalls and that this effect is mediated by the firm's lower emphasis on product safety. The presence of a marketing CEO and the firm's focus on radical (vs. incremental) innovation moderate the positive indirect effect of corporate lobbying on the number of product recalls. The findings substantially extend our understanding of the relationship between corporate lobbying and product recalls by (1) clarifying the theoretical mechanism through which corporate lobbying increases the number of product recalls and (2) identifying moderators that strengthen/weaken this relationship.

The findings extend the marketing literature centering on non-market forces, which has hitherto focused on the effects of corporate lobbying on shareholder value and risk (Martin et al., 2018), by investigating a novel mechanism, i.e., product recalls, by which corporate lobbying affects firms' outcomes. The findings also extend the marketing literature on the antecedents of product recalls by highlighting a novel non-market antecedent, i.e., corporate lobbying. In doing so, this research contributes to the debate on relating corporate lobbying to firm performance (e.g., Chen et al., 2015; Hadani & Schuler, 2013) by identifying a mechanism by which corporate lobbying *negatively* affects firms' outcomes. Last, the research's finding on the valuable role of the marketing CEO in amplifying the negative (and beneficial) effect of the firm's emphasis on product safety on the number of its product recalls extends the literature on the relevance of the firm's leadership in the new product development context (see e.g., Kashmiri & Mahajan, 2017).

The research's insights that corporate lobbying increases product recalls are managerially relevant. Medical devices' product recalls are associated with worsened health outcomes and needless medical expenditures for patients and loss of income and reputation for hospitals, doctors, and insurers (Lenzer, 2017; Schulte & Jewett, 2017). For managerial practice, the study's findings indicate that firms that lobby should counteract the decrease in emphasis on product safety associated with lobbying if they want to reduce product recalls. The findings also generate actionable insights for senior executives on how their corporate governance decisions, with respect to the functional background of the CEO, can affect product recalls. Finally, the findings strike a cautionary note for medical device firms which focus on incremental innovation, as the harmful effect of the decrease in emphasis on product safety associated with corporate lobbying may be especially detrimental to them.

<sup>1</sup> Fang, L., Journalist, The Intercept. From "The Bleeding Edge" (Dick, 2018), Retrieved September 20th 2020 from [Netflix.com](https://www.netflix.com).

## Corporate lobbying: A brief overview

Lobbying has a long history in the U.S. and is protected by the Constitution as a basic right pertaining to “freedom of speech”. At the federal level, lobbying is defined as “any communication made on behalf of a client to members of Congress, congressional staffers, the President, White House staff, and high-level employees of nearly 200 agencies, regarding the formulation, modification, or adoption of legislation” (Center for Public Integrity 2006).<sup>2</sup> Lobbying is regulated by the Lobbying Disclosure Act<sup>3</sup> of 1995.

Corporate lobbying refers to political activities that firms engage in, including spending money to influence government legislators to promote regulatory changes or to protect a beneficial status quo in their industry (Drutman, 2015). In the U.S., there is no limit on firms’ lobbying expenditures, whereas donations to politicians are limited to U.S. \$5000 per candidate per election cycle. As a result, corporate lobbying is more pervasive than donations to politicians as a form of corporate political activity (Chen et al., 2015). As corporate lobbying is a primary political tool to sway politicians and/or regulatory agencies, the topic has generated widespread interest from journalists, scholars, and practitioners (Baumgartner et al., 2009).

There is mixed evidence in the literature on the effects of corporate lobbying on firms’ outcomes. Some studies report positive effects of corporate lobbying on firm performance (Chen et al., 2015; Hill et al., 2013), while others report negative effects (Hadani & Schuler, 2013; Igan et al., 2011) or no effects (Hersch et al., 2008; Lenway et al., 1990). In the marketing literature, Martin et al. (2018) find that firms’ corporate lobbying improves shareholder value and decreases (increases) systematic (idiosyncratic) risk, while Vadakkepatt et al. (2022) find that it decreases customer satisfaction. These findings, which suggest a key role of corporate lobbying on firms’ outcomes, call for research on the effects of corporate lobbying on marketing-relevant outcomes. Addressing this research gap, we examine the relationship between firms’ corporate lobbying and product recalls.

## Hypotheses

We first define new product introductions and product recalls in the U.S. medical device industry, following which we develop the hypotheses.

<sup>2</sup> <https://publicintegrity.org/politics/lobby-watch/lobbying-faq/>. Retrieved May 5th 2020.

<sup>3</sup> <https://lobbyingdisclosure.house.gov/lda.html>. Retrieved May 5th 2020.

## New product introductions in the U.S. medical device industry

Medical device new product development occurs through both incremental innovation and radical innovation. Every year, the FDA receives about 22,000 submissions for approval of new medical devices. The FDA has two different tracks for granting permissions to firms for marketing new products. In the first track, under Section 510(k) of the Food, Drug and Cosmetic Act, it requires manufacturers to notify their intent to market a medical device at least 90 days in advance, as premarket notification (PMN) under which new devices are cleared for market if they are “substantially equivalent” (SE) to existing products. Many medical devices routinely receive FDA clearance based on clearances of older devices, not subject to rigorous pre-market testing. In the second track, a premarket approval application (PMA) is required. To determine that a device is safe and effective, PMA requires scientific evidence that the health benefits from the intended use of a device outweigh possible risks and that it will significantly improve health outcomes. Hence, the 510(k) process is used primarily for incremental product introductions (Ball et al., 2019). For radical product introductions, the approval process primarily takes the form of pre-market approval (i.e., PMA). Due to their complexity and novelty, these medical devices require evidence of product safety and effectiveness from clinical trials before the FDA grants approval.

## Product recalls in the U.S. medical device industry

The FDA (2021) defines a product recall as “...a firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action”. A product recall in the U.S. medical device industry is aimed at removing from the market products in violation of FDA laws. Product recalls, which are triggered by quality failures such as manufacturing defects, functional defects, packaging errors, and software glitches, represent serious threats to the health and well-being of consumers (some defective medical devices can cause fatalities). All medical device recalls are recorded by the FDA. Recent recalls of medical devices include, for example, 465,000 pacemakers by Abbott Inc. in 2017 over concerns about software vulnerabilities (Linsalata, 2017) and 160,775 vial spikes by ICU Medical in 2019 over concerns about plastic burr particulates, which can cause embolism and death (Tiash, 2019).

## Corporate lobbying and product recalls: Indirect positive effect

We propose that a firm’s corporate lobbying will decrease its emphasis on product safety and, in turn, increase the number

of its product recalls. Corporate lobbying, by building political ties, may create a privileged relationship between lobbying firms and regulatory agencies (Borisov et al., 2016; Kim, 2019; Schuler et al., 2002). As a result, regulatory agencies may help lobbying firms in their new product approval and introduction processes, eliminating bottlenecks and intermediate steps before new product introduction and lowering quality and safety standards (Barber & Diestre, 2019).

While, at first glance, corporate lobbying may appear to be advantageous for a firm, we argue that it may be a double-edged sword, reducing the firm's emphasis on the safety of new products and, thereby, increasing the number of its product recalls. Insights from the U.S. medical device industry appear to support this viewpoint. As Dr. Michael Carome,<sup>4</sup> Director of Public Citizen Health Research Group, states: “[Medical Device firms] have lobbied hard to see the standards for approval of devices watered down over the years” (2018). Thus, we argue that, as firms' corporate lobbying increases, they may become more complacent and lower safety standards. A firm's decreased emphasis on product safety may, in turn, result in the marketing of risky, unsafe products, eventually increasing the number of its product recalls. Integrating the above ideas, we propose H1a and H1b:

**H1a** The higher a firm's corporate lobbying, the higher the number of its product recalls.

**H1b** The positive effect of a firm's corporate lobbying on the number of its product recalls will be mediated by the firm's lower emphasis on product safety.

In sum, we expect a positive indirect effect of corporate lobbying on the number of product recalls. We note here that, due to the complexity of the context of investigation and to the number of actors involved, we expect lower emphasis on product safety to only partially mediate the effect of corporate lobbying on the number of product recalls.

We next formulate moderated mediation hypotheses, arguing that the positive indirect effect of corporate lobbying on the number of product recalls will be moderated by the firm's (a) CEO's functional background (i.e., marketing vs. not, R&D vs. not) and (b) focus on radical (vs. incremental) innovation.

### Moderation effect of CEO's functional background

The firm's CEO has the power, and arguably even the obligation, to set the firm's direction. CEOs influence the strategic priorities of the firm and resource allocation to the activities necessary to implement the strategy (Daft et al., 1988;

Lefebvre et al., 1997). Thus, some have argued that the “levers of power [in a firm] are uniquely concentrated in the hands of the CEO” (Nadler & Heilpern, 1998, p. 9). Experience in a function shapes CEOs' perspective, goal orientations, and time frames, and aligns them with those advanced by the functional discipline (Lawrence & Lorsch, 1967).

According to Dougherty (1992), marketing and R&D each constitute a different “thought world,” that is “a community of persons engaged in a certain domain of activity who have a shared understanding about that activity” (p. 182). With respect to new product development, “marketing's focus is on meeting customer needs. R&D's focus is on exploiting new technologies and building “neat” new products” (Maltz & Kohli, 2000, p. 483). As a consequence, we argue that CEOs with backgrounds in marketing or R&D will hold different perspectives on the new product development process and will differentially moderate the effect of a firm's emphasis on product safety on the number of its product recalls.

**Marketing CEO** A marketing CEO reflects the importance of brands and customers to the firm's performance. As marketing expertise is valued in firms with marketing CEOs (Homburg et al., 1999; Paşa & Shugan, 1996), a marketing CEO will make senior managers aware of the key importance of the firm's brands and customers, crucial strategic market-based assets which must be safeguarded from product recalls. Marketing people are, in fact, focused on customers' needs and concerned with the impact of new products on the firm's relationship with customers (Maltz & Kohli, 2000). Accordingly, we expect that the presence of a marketing CEO (vs. not) in a firm will set a stronger tone within the firm that brands and customers are crucial assets to be treated with abundant caution and not to be messed around with by offering products of poor and/or unknown quality. Will the marketing CEO's perspective be redundant in a firm that already has strong emphasis on product safety? We suggest not, based on developments in the group decision-making literature. The “common knowledge effect” in group decision-making (Gigone & Hastie, 1993) suggests that the influence of an item of information is positively related to the number of group members who have common knowledge of it. Such shared information has an undue influence on group decision-making as it is a common reference point for group members and is weighted more in the group's judgment. We propose that the importance of protecting brands and customers is common knowledge in a firm with high emphasis on product safety. When such knowledge is shared by the CEO, this should synergistically result in weighting these criteria over others (e.g., time to market, sophistication) in new product decisions. This implies that firms with a CEO with a marketing background will prioritize product safety over technological sophistication to a larger extent than firms with a CEO without a marketing background. Hence, we hypothesize that the negative (and beneficial) effect of a firm's emphasis on

<sup>4</sup> Carome, M., Director of Public Citizen Health Research Group. From “The Bleeding Edge” (Dick, 2018), Retrieved September 20th 2020 from [Netflix.com](https://www.netflix.com).

product safety on the number of its product recalls will be stronger for firms with a marketing CEO compared to firms without a marketing CEO. Thus, we propose H2a:

**H2a** The presence of a marketing CEO in the firm will strengthen the negative effect of the firm's emphasis on product safety on the number of its product recalls.

Since emphasis on product safety is more effective in reducing the number of product recalls in firms with a marketing CEO (vs. not), because of the marketing CEO's tendency to prioritize safety over technological sophistication (see H2a), an increase in corporate lobbying, which reduces emphasis on product safety (see H1b), will be more harmful for firms with a marketing CEO. Compared to firms without a marketing CEO, in fact, firms with a marketing CEO benefit more (in terms of a reduction in the number of product recalls) from higher emphasis on product safety. Hence, we expect here positive moderated mediation, i.e., that the positive indirect effect of corporate lobbying on the number of product recalls via lower emphasis on product safety will be stronger when there is a marketing CEO (vs. not) in the firm. Thus, we propose H2b:

**H2b** The presence of a marketing CEO in the firm will strengthen the positive indirect effect of corporate lobbying on the firm's number of product recalls via lower emphasis on product safety.

Importantly, we highlight that the positive moderated mediation effect arises from the multiplication of the negative effect of the firm's corporate lobbying on its emphasis on product safety, and the negative interaction effect of a marketing CEO in the firm and its emphasis on product safety on the number of product recalls. We also caution that the hypothesized strengthening of the positive (and harmful) indirect effect of corporate lobbying on the number of product recalls in firms with a marketing CEO (vs. not) does not imply that having a marketing CEO is harmful. Indeed, on the contrary, having a marketing CEO amplifies the negative (and beneficial) effect of emphasis on product safety on the number of product recalls, thereby making the decrease in emphasis on product safety associated with corporate lobbying a "waste" of the benefits potentially associated with having a marketing CEO.

**R&D CEO** R&D executives and, consequently, R&D CEOs, trained in professional basic scientific fields (e.g., engineering, medicine), have a long-term orientation (Ruekert & Walker, 1987) and are committed to the development of their personal technical skills (Diaz & Gomez-Mejia, 1997). Moreover, R&D executives are also interested in developing their technical reputations with professional R&D communities (Badawy, 1971; Gerpott et al., 1988). Executives with a

background in R&D are likely to emphasize product specifications, exploit new technologies, and build ambitious, sophisticated new products (Maltz & Kohli, 2000) that are risky, but a potential source of high sales and profits.

Hence, we anticipate that a R&D CEO (vs. not) will advocate more strongly for the development of ambitious, risky new products, which will increase their personal technical reputation. In the context of new product development, in general, and product recalls, in particular, this implies that firms with a CEO with a R&D background will prioritize product technological sophistication over safety to a larger extent than firms with a CEO without a R&D background. Hence, we hypothesize that the negative (and beneficial) effect of a firm's emphasis on product safety on the number of its product recalls will be weaker for firms with a R&D CEO compared to firms without a R&D CEO. Thus, we propose H3a:

**H3a** The presence of a R&D CEO in the firm will weaken the negative effect of the firm's emphasis on product safety on the number of its product recalls.

Since emphasis on product safety is less effective in reducing the number of product recalls in firms with a R&D CEO (vs. not), because of the R&D CEO's tendency to prioritize technological sophistication over safety (see H3a), an increase in corporate lobbying, which reduces emphasis on product safety (see H1b), will be less harmful for firms with a R&D CEO. Compared to firms without a R&D CEO, in fact, firms with a R&D CEO benefit less (in terms of a reduction in the number of product recalls) from higher emphasis on product safety. Hence, we expect here negative moderated mediation, i.e., that the positive indirect effect of corporate lobbying on the number of product recalls via lower emphasis on product safety will be weaker when there is a R&D CEO (vs. not) in the firm. Thus, we propose H3b:

**H3b** The presence of a R&D CEO in the firm will weaken the positive indirect effect of corporate lobbying on the firm's number of product recalls via lower emphasis on product safety.

Importantly, we highlight that the negative moderated mediation effect arises from the multiplication of the negative effect of the firm's corporate lobbying on its emphasis on product safety, and the positive interaction effect of a R&D CEO in the firm and its emphasis on product safety on the number of product recalls.

### **Moderation effect of focus on radical (vs. incremental) innovation**

An interesting feature of the medical device industry is its ability to clearly differentiate between different types of

innovation (i.e., incremental vs. radical) via different approval processes (i.e., 510(k) vs. PMA). Radical new product introductions, in the medical device industry, the result of the PMA process, are novel and complex products using new technology. They typically require substantial costs, resources, and time to commercialize, and may result in uncertainty and high risk to patients (Macher, 2006). Coherently with the novelty and complexity of radical new product introductions, to determine that a device is safe and effective, the PMA process requires rigorous pre-market testing, i.e., scientific evidence that the health benefits from the intended use of a device outweigh possible risks and that it will significantly improve health outcomes. Conversely, incremental new product introductions, the result of the 510(k) process, are less complex and demonstrably similar (“substantially equivalent”) to medical devices that have already received FDA approval (Ball et al., 2019), being therefore based on the redeployment of pre-existing knowledge to new products. Critics contend that the 510(k) process, not requiring any rigorous pre-market testing, results in the marketing of unsafe products, potentially harming consumers’ health. Using FDA’s high-risk List of Device Recalls from 2005 through 2009, Zuckerman et al. (2011) conclude that “Most medical devices recalled for life-threatening or very serious hazards were originally cleared for market using the less stringent 510(k) process or were considered so low risk that they were exempt from review (78%)” (p. 1006). A problem, we add, which is exacerbated by many medical devices routinely receiving FDA clearance based on clearances of older devices, themselves not subject to rigorous pre-market testing.

We argue that the negative (and beneficial) effect of a firm’s emphasis on product safety on the number of its product recalls will be weakened by the higher firm’s focus on radical (vs. incremental) innovation. We in fact conjecture that, contrary to general wisdom, an increase in the firm’s emphasis on product safety will be particularly beneficial for firms that focus their new product development efforts on introducing primarily incremental new products. Due to the absence of rigorous pre-market testing, in fact, potential safety problems are less likely to be picked up during the pre-marketing phase of incremental new products, thereby making firm’s emphasis on product safety paramount in preventing product recalls for firms with a focus on incremental (vs. radical) innovation. Thus, we propose H4a:

**H4a** An increase in the firm’s focus on radical (vs. incremental) innovation will weaken the negative effect of the firm’s emphasis on product safety on the number of its product recalls.

Since emphasis on product safety is less effective in reducing the number of product recalls in firms with higher focus on radical (vs. incremental) innovation, because of the more

rigorous pre-market approval process for radical innovations (see H4a), an increase in corporate lobbying, which reduces emphasis on product safety (see H1b), will be less harmful for firms with a higher focus on radical innovation. Compared to firms with a lower focus on radical innovation, firms with a higher focus on radical innovation benefit less (in terms of a reduction in the number of product recalls) from higher emphasis on product safety. Hence, we expect here negative moderated mediation, i.e., that the positive indirect effect of corporate lobbying on the number of product recalls via lower emphasis on product safety will be weaker when focus on radical (vs. incremental) innovation increases. Thus, we propose H4b:

**H4b** An increase in the firm’s focus on radical (vs. incremental) innovation will weaken the positive indirect effect of corporate lobbying on the firm’s number of product recalls via lower emphasis on product safety.

We note that the negative moderated mediation effect arises from the multiplication of the negative effect of the firm’s corporate lobbying on its emphasis on product safety, and the positive interaction effect of the firm’s focus on radical (vs. incremental) innovation and its emphasis on product safety on the number of product recalls.

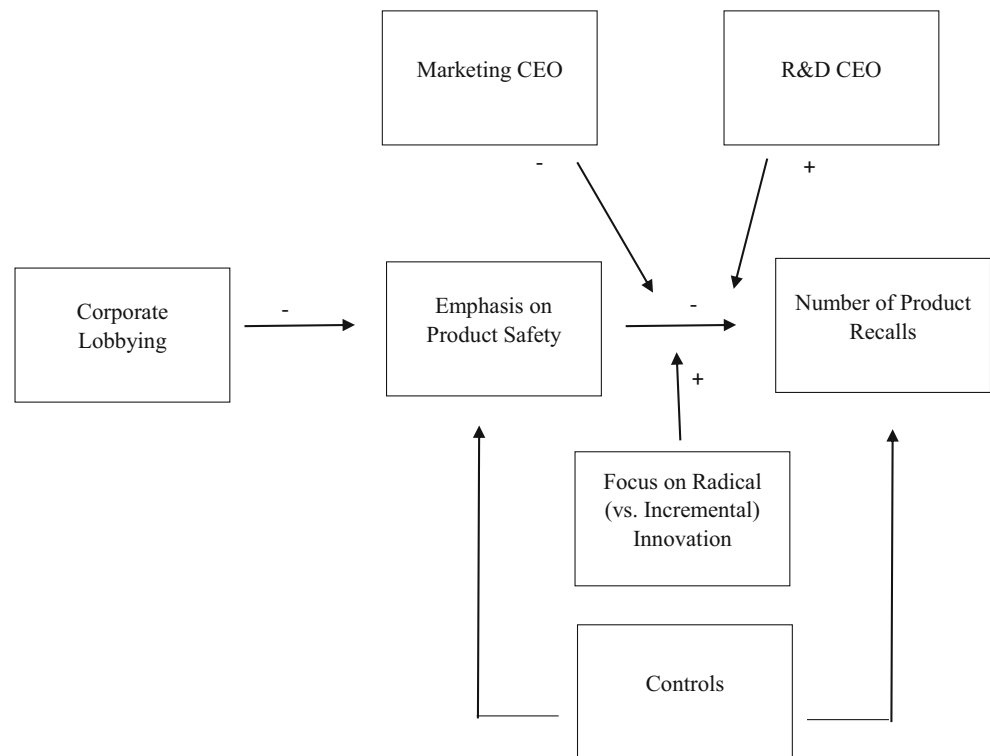
We report our conceptual framework in Fig. 1.

## Data and method

### Data

To test the hypotheses, we first collected data from Compustat on firms in the Standard Industry Classification (SIC) codes of 3841 (Surgical and Medical Instruments and Apparatus), 3842 (Orthopedic, Prosthetic and Surgical Appliances and Supplies), 3843 (Dental Equipment and Supplies), 3844 (X-ray Apparatus and Tubes and related Irradiation Apparatus), 3845 (Electromedical and Electrotherapeutic Apparatus), and 3851 (Ophthalmic Goods) between 2004 and 2017. We then collected data on firms’ product recalls between 2005 and 2018 from the FDA Medical Device Recalls database. Building on past research (Thirumalai & Sinha, 2011), to avoid overcounting product recalls, we only retain one recall when a firm experiences more than one recall with the same “root cause” on the same day. Then, we collected data on firms’ corporate lobbying expenditures from *opensecrets.org*. We collected data on CEOs’ functional background using *BoardEx*. When information was not available in *BoardEx* (e.g., a gap in a CEO’s record), we obtained data on CEOs’ professional backgrounds from other sources including *ExecuComp*, *LinkedIn*, *Bloomberg*, *Equilar*, and firms’ corporate websites, proxy statements, and 10-Ks. We also

Fig. 1 Conceptual framework



collected data on firms' quality certifications from their 10-Ks. Last, we collected data on other CEOs' characteristics from ExecuComp. After merging the data from various sources, we had an unbalanced panel of 696 firm-years for 86 publicly-listed medical device firms. This sample size is consistent with past research on the role of corporate governance in product recalls (see e.g., Kashmiri and Brower 2016).

## Measures

**Dependent variable** The dependent variable is the number of product recalls for a firm each year. The firms in our sample had a total of 3,145 product recalls. The firms with the highest number of product recalls were Stryker (488), followed by Medtronic (410) and Zimmer Biomet (371). Some firms had no product recalls between 2005 and 2018 (e.g., MSA Safety). Therefore, the number of product recalls is an over-dispersed count variable (mean = 4.52, standard deviation = 9.18) ranging between 0 and 76 (where zeros account for 41.24% of observations).

**Independent variable** Following empirical precedents in political science (Borisov et al., 2016), we measured a firm's corporate lobbying by its corporate expenditures in FDA lobbying in U.S. dollars each year. As corporate lobbying has carryover effects (Martin et al., 2018), we use a finite distributed lag model to compute corporate lobbying stock, with earlier years of lobbying receiving a lower weight. We use a decay parameter ( $\delta$ ) of 0.50. In order to preserve

sample size, we use corporate lobbying for three consecutive years. Specifically, corporate lobbying for year  $t$  is defined as  $\sum_{k=t-2}^{k=t} \delta^{t-k} \times \text{Corporate Lobbying}_k$  (Dutta et al., 1999) relative to the book value of firm  $i$ 's assets in year  $t$  (Martin et al., 2018). We subsequently establish the sensitivity of results to alternative decay parameters. The variable has a high incidence of zeros (83.62%)<sup>5</sup> which is consistent with past research that most publicly listed U.S. firms (90%) do not lobby (Drutman, 2015).

**Mediator** Following empirical precedents (see e.g., Kashmiri and Brower, 2016), for each firm-year we used the presence or absence of the firm's ISO 13485 quality certification to measure the firm's emphasis on product safety (57% of firm-years). This data was obtained from the companies' 10-Ks. ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes) is an ISO standard, specific to the medical device industry, representing the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

<sup>5</sup> Please note that, consistent with Martin et al. (2018), our measure of corporate lobbying only includes firms' individual expenditures. Firm's contributions to collective efforts (via the main lobbying group in the industry, Advamed), are not included as we focus on only one industry.

**Table 1** Variables, measures, and sources

Variable	Measure	Data Source
Number of Product Recalls	Firm's annual number of product recalls	FDA Recalls database
Corporate Lobbying	Firm's corporate lobbying targeted at the FDA in US \$, used in a finite distributed lag model with a decay parameter of 0.50 and three lags, scaled by assets	opensecrets.org
Emphasis on Product Safety	1 (0 otherwise) if the firm holds ISO 13485 certification	10-Ks
Marketing CEO	1 (0 otherwise) if the CEO has prior functional experience in either the marketing or sales functions	BoardEx and ExecuComp
R&D CEO	1 (0 otherwise) if the CEO has prior functional experience in the R&D function	BoardEx and ExecuComp
Focus on Radical (vs. Incremental) Innovation	Firm's annual number of devices introduced through the PMA process scaled by the total number of devices (PMAs and 510(k)s) introduced by the firm. Both terms are obtained using a finite distributed lag model with a decay parameter of 0.50 and three lags. The variable takes on a value of 0.50 for firms that did not innovate in the three-years period.	FDA PMA database & 510(k) database
Corporate Lobbying - Other	Firm's corporate lobbying targeted at agencies other than the FDA in US \$, used in a finite distributed lag model with a decay parameter of 0.50 and three lags, scaled by assets	opensecrets.org
Size	Total assets	Compustat
Extent of Labor Use	Number of employees scaled by assets	Compustat
ROA	Net income scaled by assets	Compustat
Tobin's Q	Tobin's Q computed as per Chung and Pruitt (1994)	Compustat
Number of Incremental Innovations	Firm's number of 510(k)s, used in a finite distributed lag model with a decay parameter of 0.50 and three lags, scaled by assets	FDA 510(k) database
Number of Radical Innovations	Firm's number of PMAs, used in a finite distributed lag model with a decay parameter of 0.50 and three lags, scaled by assets	FDA PMA database
R&D Intensity	R&D expenditure scaled by sales	Compustat
Advertising Intensity	Advertising expenditure scaled by sales	Compustat
Slack Resources	Total assets scaled by liabilities, logged	Compustat
Financial Distress	Altman's Z (Altman, 1968)	Compustat
Financial Leverage	Long term debt scaled by book value of common equity	Compustat
Democratic Power	A count variable ranging between 0 and 3. The variable takes on a value of 3 if the President is a Democrat and both the House of Representatives and the Senate are controlled by Democrats	U.S. Gov
CEO Tenure	Difference between current year and year of appointment as CEO, logged	Boardex and ExecuComp
CEO Stock Options Pay	Value of in-the-money unexercised exercisable options over total CEO's compensation in US \$	ExecuComp
CEO Age	CEO's age, logged	ExecuComp

We set R&D and advertising expenditures to 0 if these values are not reported in Compustat (see e.g., Kashmiri & Mahajan, 2017)

**Moderators** We classified a CEO as a *Marketing CEO* using a dummy variable equal to 1 (0 otherwise) if the CEO has prior functional experience in either the marketing or sales functions, which we obtained from their past job titles (35% of CEO-years). Following a method of classification of functional experience in prior research (e.g., Finkelstein & Hambrick, 1996; Nath & Mahajan, 2008), we used marketing- or sales-related words (e.g., *marketing*, *sales*, and *customer*) in CEOs' previous job titles as evidence of their marketing experience. We proceeded analogously for the R&D CEO (14% of CEO-years) using R&D-related words (e.g., *R&D*, *research*, and *technology*). We measured firm's focus on

radical (vs. incremental) innovation by the firm's annual number of devices introduced through the PMA process scaled by the total number of devices (PMAs and 510(k)s) introduced by the firm. Both terms are obtained using the same finite distributed lag model detailed above for corporate lobbying stock. We set the value to 0.50 for those firms that did not innovate in the period of interest.

**Control variables** We include a number of control variables in the model used to test the hypotheses. We provide descriptions and sources for all variables in Table 1 and the descriptive statistics and correlation matrix in Table 2. We provide the logic for the inclusion of the control variables in Table W1



in Web Appendix 1. All variance inflation factors are well below 10 indicating no threat from multicollinearity.

We split the sample into non-lobbying firms and lobbying firms (where lobbying firms are those that lobbied the FDA at least once in the period of investigation). A t-test revealed that the number of yearly product recalls is higher for firms that lobby (vs. not) ( $m_1 = 10.94$  vs.  $m_2 = 1.63$ ,  $t = -9.96$ ,  $p < 0.01$ ). Further, a t-test revealed that the probability of holding ISO 13485 certification in a given year is lower for firms that lobby (vs. not) ( $m_1 = 0.32$  vs.  $m_2 = 0.68$ ,  $t = 9.52$ ,  $p < 0.01$ ),

providing our hypothesized mechanism with some initial support.

### Model estimation

We first investigated the relationship between corporate lobbying and emphasis on product safety. We used ISO 13485 certification as a binary dependent variable and employed a random effects probit regression. The link between corporate lobbying and emphasis on product safety takes the following form:

$$\begin{aligned} \text{Emphasis on Product Safety}_{it-1} = & \beta_0 + \beta_1 \text{Corporate Lobbying}_{it-2} + \beta_2 \text{Marketing CEO}_{it-1} \\ & + \beta_3 \text{R\&D CEO}_{it-1} + \beta_4 \text{Focus on Radical (vs. Incremental) Innovation}_{it-1} + \beta_5 \text{Corporate Lobbying\_Other}_{it-2} \\ & + \beta_6 \text{Size}_{it-1} + \beta_7 \text{Entity of Labor Use}_{it-1} + \beta_8 \text{ROA}_{it-1} + \beta_9 \text{Tobin's } Q_{it-1} + \beta_{10} \text{Number of Incremental Innovations}_{it-1} \\ & + \beta_{11} \text{Number of Radical Innovations}_{it-1} + \beta_{12} \text{R\&D Intensity}_{it-1} + \beta_{13} \text{Advertising Intensity}_{it-1} + \beta_{14} \text{Slack Resources}_{it-1} \\ & + \beta_{15} \text{Financial Distress}_{it-1} + \beta_{16} \text{Financial Leverage}_{it-1} + \beta_{17} \text{Democratic Power}_{it-1} + \beta_{18} \text{CEO Tenure}_{it-1} \\ & + \beta_{19} \text{CEO Stock Options Pay}_{it-1} + \beta_{20} \text{CEO AGE}_{it-1} + \beta_{21-33} \text{Year}_{t-1} + \alpha_i + \varepsilon_{it} \end{aligned} \quad (1)$$

where  $\beta$ s are the parameters to be estimated, subscripts  $i$  represent firms, subscripts  $t$  represent years, and  $\alpha_i$  and  $\varepsilon_{it}$  are unobserved randomly distributed error terms. Because some firms never hold ISO 13485 certification, we cannot estimate a fixed effects model.

Next, we analyzed the link between corporate lobbying and number of product recalls, first without the proposed mediator, emphasis on product safety, and then with its inclusion.

As the dependent variable, i.e., the number of product recalls, is a count variable, we use a negative binomial model to account for over-dispersion (Cameron & Trivedi, 2013). Further, as our model is a second-stage moderated mediation model, we subsequently include both emphasis on product safety and its interactions with marketing CEO, R&D CEO, and focus on radical (vs. incremental) innovation:

$$\begin{aligned} \text{Number of Product Recalls}_{it} = & \pi_0 + \pi_1 \text{Corporate Lobbying}_{it-2} + \pi_2 \text{Emphasis on Product Safety}_{it-1} + \\ & \pi_3 \text{Marketing CEO}_{it-1} + \pi_4 \text{R\&D CEO}_{it-1} + \pi_5 \text{Focus on Radical (vs. Incremental) Innovation}_{it-1} + \\ & \pi_6 \text{Emphasis on Product Safety}_{it-1} \times \text{Marketing CEO}_{it-1} + \pi_7 \text{Emphasis on Product Safety}_{it-1} \times \text{R\&D} \\ & \text{CEO}_{it-1} + \pi_8 \text{Emphasis on Product Safety}_{it-1} \times \text{Focus on Radical (vs. Incremental) Innovation}_{it-1} + \\ & \pi_9 \text{Corporate Lobbying\_Other}_{it-2} + \pi_{10} \text{Size}_{it-1} + \pi_{11} \text{Entity of Labor Use}_{it-1} + \pi_{12} \text{ROA}_{it-1} + \pi_{13} \text{Tobin's} \\ & \text{Q}_{it-1} + \pi_{14} \text{Number of Incremental Innovations}_{it-1} + \pi_{15} \text{Number of Radical Innovations}_{it-1} + \pi_{16} \text{R\&D} \\ & \text{Intensity}_{it-1} + \pi_{17} \text{Advertising Intensity}_{it-1} + \pi_{18} \text{Slack Resources}_{it-1} + \pi_{19} \text{Financial Distress}_{it-1} + \\ & \pi_{20} \text{Financial Leverage}_{it-1} + \pi_{21} \text{Democratic Power}_{it-1} + \pi_{22} \text{CEO Tenure}_{it-1} + \pi_{23} \text{CEO Stock Options} \\ & \text{Pay}_{it-1} + \pi_{24} \text{CEO AGE}_{it-1} + \pi_{25-37} \text{Year}_t + \Omega_i + \mu_{it} \end{aligned} \quad (2)$$

where  $\pi$ s are the parameters to be estimated, subscripts  $i$  represent firms, subscripts  $t$  represent years, and  $\Omega_i$  and  $\mu_{it}$  are unobserved randomly distributed error terms. As some firms never experience any product recalls in the period of investigation, we are unable to estimate a fixed effects model. To ensure the correct model specification, we include the main effect of marketing and R&D CEO and the main effect of

focus on radical (vs. incremental) innovation in Eq. 2 above. We use lagged independent variables to address endogeneity concerns created by reverse causality. As we test for mediation via lower emphasis on product safety, we lag corporate lobbying by two years and emphasis on product safety by one year. In addition, one potential concern is focal construct endogeneity. We therefore offer a robustness check (with

**Table 2** Descriptives and correlation matrix of variables

	Mean	Std. Dev.	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.	17.	18.	19.	20.	21.	22.	
1. Number of Product Recalls	4.52	9.18	1																						
2. Corporate Lobbying	36.09	170.34	-.002	1																					
3. Emphasis on Product Safety	.57	.50	-.27*	.01	1																				
4. Marketing CEO	.35	.48	-.03	-.04	.04	1																			
5. R&D CEO	.14	.35	-.06	-.07	-.04	-.06	1																		
6. Focus on Radical (vs. Incremental) Innovation	.10	.22	-.16*	.02	-.10*	.06	.03	1																	
7. Corporate Lobbying - Other	165.31	544.45	-.07*	.02	-.03	.17*	-.03	.03	1																
8. Size	3383.00	9291.93	.63*	-.01	-.24*	.04	-.03	-.08*	-.06	1															
9. Extent of Labor Use	.003	.002	-.23*	.03	.18*	.05	.08*	.11*	-.01	-.25*	1														
10. ROA	.04	.15	.10*	.04	.02	-.02	-.11*	-.12*	-.17*	.04	-.17*	1													
11. Tobin's Q	2.79	2.25	-.11*	-.02	-.001	.07	.05	.29*	-.03	-.11*	.07	.02	1												
12. Number of Incremental Innovations	.01	.04	-.10*	-.06	.16*	-.06	.003	-.16*	-.04	-.10*	.21*	-.12*	.01	1											
13. Number of Radical Innovations	.0002	.001	-.04	.01	-.01	.001	.03	.34*	.03	-.03	-.004	-.16*	.17*	-.03	1										
14. R&D Intensity	.10	.17	-.06	-.02	-.07	-.07	.12*	.25*	.15*	-.02	-.07	-.42*	.15*	.01	.37*	1									
15. Advertising Intensity	.01	.02	-.15*	-.01	.10*	.17*	-.08*	.03	.17*	-.10*	-.02	-.05	.10*	-.01	-.04	-.02	1								
16. Slack Resources	1.48	.47	-.25*	-.09*	.21*	.05	.18*	-.09*	.11*	-.24*	-.11*	.21*	.18*	.05	-.05	-.04	.10*	1							
17. Financial Distress	8.02	8.57	-.16*	-.03	.05	.06	.09*	.13*	-.04	-.16*	-.06	.27*	.74*	-.04	.04	-.004	.07	.67*	1						
18. Financial Leverage	.31	1.28	.05	.01	-.13*	-.03	-.02	.06	-.02	.07	-.06	-.04	-.11*	-.06	-.03	.14*	-.03	-.23*	-.15*	1					
19. Democratic Power	1.50	1.04	.02	.10*	.12*	-.03	-.003	-.05	-.05	-.01	-.04	-.06	-.16*	.09*	-.02	.01	-.004	.003	-.15*	-.07	1				
20. CEO Tenure	1.77	.95	-.09*	-.01	.21*	-.10*	.08*	-.11*	.05	-.12*	.21*	.16*	.03	.06	-.09*	-.10*	.004	.27*	.21*	-.06	-.01	1			
21. CEO Stock Options Pay	50.05	1250.77	-.01	-.01	.03	-.03	-.02	-.02	-.01	-.01	.07	-.11*	.02	.10*	-.01	-.01	.04	-.05	-.04	-.01	.02	-.03	1		
22. CEO Age	4.00	.13	-.02	.11*	-.03	-.11*	.19*	.02	-.01	.081*	.07	.001	-.03	-.11*	-.05	-.04	-.07	-.01	-.02	-.05	-.07	.29*	.03	1	

Note: \*p < .05

generally similar results) adopting a control function approach (Petrin & Train, 2010).

## Results

Below, we first estimate the model of emphasis on product safety (see Eq. 1 above), following which we estimate the model of the number of product recalls (see Eq. 2 above) to test H1a–H4a. Combining the results from the two models allows us to test the mediation and moderated moderation hypotheses, i.e., H1b–H4b.

We first estimate the Model at Eq. 1 (Log pseudo-likelihood =  $-135.13$ ). The results, reported in Column 1 in Table 3, indicate a significant negative effect of corporate lobbying on emphasis on product safety ( $b = -0.001, p < 0.05$ ).

We then estimate the Model at Eq. 2 without including emphasis on product safety nor its interactions, in Column 2 in Table 3 (Log pseudo-likelihood =  $-1264.64$ , AIC =  $2599.29$ ).<sup>6</sup> The results indicate that corporate lobbying increases the number of product recalls ( $b = 0.001, p < 0.01$ ). We then include emphasis on product safety in the model reported in Column 3 in Table 3 (Log pseudo-likelihood =  $-1261.29$ , AIC =  $2594.58$ ). The results again indicate that corporate lobbying increases the number of product recalls ( $b = 0.001, p < 0.01$ ). Further, emphasis on product safety decreases the number of product recalls ( $b = -0.39, p < 0.01$ ). Last, we include the interactions of emphasis on product safety with marketing CEO, R&D CEO, and focus on radical (vs. incremental) innovation in Column 4 in Table 3 (Log pseudo-likelihood =  $-1255.04$ , AIC =  $2588.07$ ). The results show that corporate lobbying increases the number of product recalls ( $b = 0.001, p < 0.01$ ), in support of H1a. Further, emphasis on product safety reduces the number of product recalls ( $b = -0.34, p < 0.05$ ). A marketing CEO in the firm strengthens the negative effect of emphasis on product safety on the number of product recalls ( $b = -0.60, p < 0.05$ ), in support of H2a. Interestingly, the main effect of marketing CEO is not significant ( $b = -0.02, p > 0.10$ ). We conjecture that, as the head of the company, compared, for instance, with the CMO, the marketing CEO has to balance priorities from different functions (R&D included). Hence, a higher emphasis on product safety in a firm may provide the marketing CEO with the opportunity to fully persecute their objective to prioritize product safety in new product development.<sup>7</sup> With respect to H3a, there is no significant interaction effect between a R&D CEO in the firm and its emphasis on product safety ( $b = -0.36, p > 0.10$ ). Last, focus on radical

(vs. incremental) innovation weakens the negative effect of emphasis on product safety on the number of product recalls ( $b = 2.23, p < 0.05$ ), in support of H4a. Interestingly, the main effect of focus on radical (vs. incremental) innovation is negative ( $b = -2.44, p < 0.01$ ), supporting our reasoning that, in the medical device industry, focusing on incremental (vs. radical) innovation may expose firms to superior risks.

Having tested H1a–H4a, we now test the mediation and moderated mediation hypotheses H1b–H4b. According to Zhao et al. (2010), testing for mediation requires that: (1) the independent variable, i.e., corporate lobbying, is correlated with the mediator, i.e., emphasis on product safety; (2) emphasis on product safety is correlated with the dependent variable, i.e., number of product recalls, when corporate lobbying is controlled for. Testing for moderated mediation further requires that (3) the interactions of emphasis on product safety with the proposed moderators are correlated with the number of product recalls when corporate lobbying is controlled for.

The first requirement is satisfied by the significant negative effect of corporate lobbying on emphasis on product safety reported in Column 1, Table 3. The second requirement is satisfied by the significant negative effect of emphasis on product safety on the number of product recalls reported in Column 4, Table 3, supporting H1b. The third requirement is satisfied by the significant interactions of marketing CEO and focus on radical (vs. incremental) innovation with emphasis on product safety reported in Column 4, Table 3, supporting H2b and H4b, respectively. H3b is not supported as the interaction of R&D CEO with emphasis on product safety is not significant in Column 4, Table 3. As corporate lobbying is correlated with the number of product recalls when controlling for emphasis on product safety (and its interactions), we infer partial mediation, suggesting that other mediators may be at work.

We further check the significance of the indirect effect (Preacher & Hayes, 2004) of a firm's corporate lobbying on the number of its product recalls via lower emphasis on product safety by re-estimating the equations simultaneously via generalized structural equation modeling.<sup>8</sup> We compute the indirect effect by multiplying (a) the effect of corporate lobbying on emphasis on product safety with (b) the effect of emphasis on product safety on the number of product recalls. As indirect effects are products of regression coefficients, we bootstrap confidence intervals (500 replications). The indirect effect of corporate lobbying on the number of product recalls via lower emphasis on product safety is positive and significant ( $p < 0.05$ , bootstrapped confidence interval excludes 0). As our model is a second-stage moderated mediation model, we further explore the mechanisms behind the two significant moderating effects using the index of partial moderated mediation (Hayes &

<sup>6</sup> We also estimated a model of number of product recalls with only corporate lobbying (and year fixed effects) as a predictor. Corporate lobbying increases the number of product recalls ( $p = 0.05$ ).

<sup>7</sup> We are thankful to an anonymous reviewer for this suggestion.

**Table 3** Corporate lobbying and number of product recalls

Dependent Variable: Variable	Emphasis on Product Safety		Number of Product Recalls	
	Column 1	Column 2	Column 3	Column 4
Corporate Lobbying	-.001 (.0005)**	.001 (.0003)***	.001 (.0003)***	.001 (.0003)***
Emphasis on Product Safety			-.39 (.15)***	-.34 (.16)**
Emphasis on Product Safety x Marketing CEO				-.60 (.26)**
Emphasis on Product Safety x R&D CEO				-.36 (.38)
Emphasis on Product Safety x Focus on Radical (vs. Incremental) Innovation				2.23 (.89)**
Marketing CEO	-.66 (.75)	-.21 (.12)*	-.22 (.12)*	-.02 (.15)
R&D CEO	-4.22 (1.77)**	-.08 (.17)	-.08 (.17)	-.04 (.19)
Focus on Radical (vs. Incremental) Innovation	-2.13 (1.07)**	-1.02 (.51)**	-1.26 (.52)**	-2.44 (.78)***
Corporate Lobbying – Other	-.001 (.0004)**	.0002 (.0002)	.0002 (.0002)	.0001 (.0002)
Size	-.0003 (.0002)	.00001 (.000003)***	.00001 (.000003)***	.00001 (.000003)***
Entity of Labor Use	333.55 (238.34)	-75.84 (44.42)*	-73.22 (44.00)*	-56.42 (44.28)
ROA	-2.88 (2.29)	.15 (.62)	.07 (.62)	-.24 (.62)
Tobin's Q	.46 (.42)	.001 (.08)	.01 (.08)	.02 (.08)
Slack Resources	1.38 (.95)	-.40 (.27)	-.35 (.27)	-.18 (.28)
Number of Incremental Innovations	34.59 (23.78)	-1.98 (2.03)	-1.68 (1.97)	-1.66 (1.95)
Number of Radical Innovations	-10.67 (143.31)	22.85 (74.16)	41.00 (73.44)	16.90 (73.77)
R&D Intensity	2.69 (1.38)*	.12 (.52)	.13 (.52)	.24 (.55)
Advertising Intensity	20.06 (17.40)	-19.61 (12.50)	-20.82 (12.40)*	-18.98 (12.39)
Financial Distress	-.07 (.07)	.001 (.02)	-.001 (.02)	-.01 (.02)
Financial Leverage	.07 (.10)	.01 (.07)	.01 (.07)	.01 (.07)
Democratic Power	3.57 (1.12)***	.05 (.23)	.14 (.23)	.24 (.23)
CEO Tenure	.11 (.22)	.06 (.05)	.07 (.05)	.06 (.05)
CEO Stock Options Pay	.12 (.06)**	.0001 (.00004)*	.0001 (.00004)*	.0001 (.00004)
CEO Age	3.15 (2.34)	-.44 (.43)	-.45 (.43)	-.17 (.43)
Year-Fixed Effects	YES	YES	YES	YES
Observations	696	696	696	696
Log pseudo-likelihood	-135.13	-1264.64	-1261.29	-1255.04
AIC		2599.29	2594.58	2588.07

Notes: \* $p < .10$ . \*\* $p < .05$ . \*\*\* $p < .01$ . Unstandardized parameter estimates and standard errors in parentheses. The models are random effects models and include a constant

Rockwood, 2020). In simple terms, as an example, the index of partial moderated mediation for marketing CEO quantifies the relationship between marketing CEO and the indirect effect of corporate lobbying on the number of product recalls when focus on radical (vs. incremental) innovation is held constant. Since emphasis on product safety is supposed to be more effective in reducing the number of product recalls for firms with a marketing CEO (vs. not), we expect a positive index of partial moderated mediation for the marketing CEO (multiplication of a negative effect of corporate lobbying on emphasis on product safety, and a negative

interaction effect of marketing CEO with emphasis on product safety on the number of product recalls). Conversely, since emphasis on product safety is supposed to be less effective in reducing the number of product recalls for firms with higher focus on radical (vs. incremental) innovation, we expect a negative index of partial moderated mediation for focus on radical (vs. incremental) innovation (multiplication of a negative effect of corporate lobbying on emphasis on product safety, and a positive interaction effect of focus on radical (vs. incremental) innovation with emphasis on product safety on the number of product recalls). Consistent with our theorizing, the index of partial moderated mediation for marketing CEO is positive, meaning that the positive indirect effect of corporate lobbying on the

<sup>0</sup> We do not include the R&D CEO's interaction with emphasis on product safety in our generalized structural equation model as the effect is not statistically significant in Column 4, Table 3.

number of product recalls is strengthened for firms with a marketing CEO which, compared to firms without a marketing CEO, benefit more (in terms of a reduction in the number of product recalls) from increased emphasis on product safety. The index of partial moderated mediation for focus on radical (vs. incremental) innovation is negative, meaning that the positive indirect effect of corporate lobbying on the number of product recalls is weakened for firms with higher focus on radical innovation which, compared to firms with lower focus on radical innovation, benefit less (in terms of a reduction in the number of product recalls) from higher emphasis on product safety. In both cases, there is evidence of significant moderated mediation ( $p < 0.05$ , bootstrapped confidence intervals exclude zero) providing support for the theorized mechanisms. We note that the direct effect of corporate lobbying on the number of product recalls is also significant ( $p < 0.05$ , bootstrapped confidence interval excludes 0), confirming partial mediation.

### Additional analyses: Marketing department power (CMO) and R&D department power (CSO)

In additional analyses, we investigated whether marketing (R&D) power, as reflected in (1) the presence of a CMO (Chief Scientific Officer - CSO) on the Top Management Team (TMT) or in (2) the power of marketing (R&D) executives on the TMT, strengthens (weakens) the negative effect of emphasis on product safety on the number of product recalls. We collected data on job titles and compensation for firms' TMT members from ExecuComp. We classified an executive as a marketing (R&D) executive if their job title contained marketing- or sales-related (R&D-related) words (Nath & Mahajan, 2008). A firm was considered to have a CMO (CSO) if it has at least one marketing (R&D) executive on its TMT. We then measured the power of marketing (R&D) executives on the TMT using the measure introduced by Feng et al. (2015). After classifying each senior executive, we computed five indicators of marketing (R&D) department power for each firm each year. First, we computed (1) the proportion of marketing (R&D) executives on the TMT scaled by its size and (2) the proportion of marketing (R&D) executives' pay over the TMT's total pay. Then, we assigned a hierarchical ranking score to each marketing(R&D)-related job title as follows: president = 6, executive vice president = 5, senior vice president = 4, vice president = 3, other = 2, and no marketing (R&D) executives = 1. We computed two additional variables using this ranking score, i.e., (3) the score of the highest-ranked marketing (R&D) executive on the TMT and (4) the cumulative score of all marketing (R&D) executives on the TMT. Finally, we measured (5) the number of responsibilities of marketing (R&D) executives on the TMT listed on their job titles. Using principal

component factor analysis, we combined the five indicators into a single factor (Feng et al., 2015). In Web Appendix 2, we report details of the factor analyses. The obtained factors explain 86.30% (85.60%) of variability in marketing (R&D) power. Both CMO presence ( $\rho = 0.15$ ,  $p < 0.01$ ) and the power of marketing executives on the TMT ( $\rho = 0.13$ ,  $p < 0.01$ ) are significantly correlated, although at moderate levels, with the marketing CEO. CSO presence is significantly correlated, although at a moderate level, with the R&D CEO ( $\rho = 0.08$ ,  $p < 0.05$ ), while the power of R&D executives on the TMT is not significantly correlated with the R&D CEO ( $\rho = 0.05$ ,  $p > 0.10$ ). CMO presence and the power of marketing executives in the TMT are highly correlated ( $\rho = 0.93$ ,  $p < 0.01$ ). Similarly, CSO presence and the power of R&D executives are highly correlated ( $\rho = 0.93$ ,  $p < 0.01$ ). Hence, they cannot be included in the same model.

In Column 1 of Table 4 we report the results obtained by replacing marketing CEO and R&D CEO with CMO and CSO, respectively. Neither the main effects nor the interactions of CMO and CSO with emphasis on product safety are significant.

In Column 2 of Table 4 we report the results obtained by replacing marketing CEO and R&D CEO with the power of marketing and R&D executives on the TMT, respectively. The main effect of the power of marketing executives on the number of product recalls is negative and marginally significant ( $b = -0.16$ ,  $p = 0.06$ ) while the main effect of the power of R&D executives on the number of product recalls is positive and significant ( $b = 0.15$ ,  $p < 0.05$ ). The interaction effects are not significant.

In sum, neither the CMO (CSO) nor the power of marketing (R&D) executives on the TMT act as moderators of the effect of emphasis on product safety on the number of product recalls. Such results underscore the unique role of the marketing CEO in the context of corporate lobbying and product recalls. We next report an overview of robustness checks and additional analyses. Detailed reporting is provided in the Appendix.

### Robustness checks and additional analyses

**Endogeneity concerns** We correct for the potential endogeneity of corporate lobbying using a control function approach. The results are generally robust.

**Measure of corporate lobbying** We examine the robustness of the results to alternative decay parameters. The results are also robust without a decay parameter.

**Effect of non-FDA corporate lobbying** We find that corporate lobbying aimed at agencies other than the FDA has a positive (indirect) effect on the number of product recalls. Further, differently from what happens for FDA corporate lobbying, the effect is indirect-only.

**Table 4** CMO (CSO) and power of marketing (R&D) executives on the TMT

Dependent Variable: Number of Product Recalls		
Variable	Column 1	Column 2
Corporate Lobbying	.001 (.0003)***	.001 (.0003)***
Emphasis on Product Safety	-.34 (.17)**	-.46 (.16)***
Emphasis on Product Safety x CMO	-.07 (.22)	
Emphasis on Product Safety x CSO	-.32 (.22)	
Emphasis on Product Safety x Power of Marketing Executives		.03 (.11)
Emphasis on Product Safety x Power of R&D Executives		-.13 (.09)
Emphasis on Product Safety x Focus on Radical (vs. Incremental) Innovation	2.19 (.90)**	2.18 (.89)**
CMO	-.25 (.17)	
CSO	.21 (.16)	
Power of Marketing Executives		-.16 (.08)*
Power of R&D Executives		.15 (.06)**
Focus on Radical (vs. Incremental) Innovation	-2.52 (.78)***	-2.45 (.77)***
Corporate Lobbying – Other	.0001 (.0002)	.0001 (.0002)
Size	.00001 (.000003)***	.00001 (.000003)***
Entity of Labor Use	-63.24 (43.78)	-62.89 (44.03)
ROA	-.0003 (.62)	.09 (.61)
Tobin's Q	.005 (.08)	-.002 (.08)
Slack Resources	-.25 (.27)	-.31 (.27)
Number of Incremental Innovations	-1.42 (1.92)	-1.51 (1.91)
Number of Radical Innovations	38.90 (72.24)	25.43 (73.12)
R&D Intensity	.32 (.56)	.33 (.56)
Advertising Intensity	-20.53 (12.68)	-22.41 (12.97)*
Financial Distress	-.001 (.02)	.01 (.02)
Financial Leverage	.01 (.07)	-.002 (.07)
Democratic Power	.14 (.23)	.16 (.23)
CEO Tenure	.08 (.05)	.09 (.05)*
CEO Stock Options Pay	.0001 (.00004)	.0001 (.00004)
CEO Age	-.36 (.42)	-.43 (.41)
Year-Fixed Effects	YES	YES
Observations	696	696
Log pseudo-likelihood	-1256.30	-1255.03

Notes: \* $p < .10$ . \*\* $p < .05$ . \*\*\* $p < .01$ . Unstandardized parameter estimates and standard errors in parentheses. The models are random effects models and include a constant

**Recall class** The results are robust to the exclusion of class III recalls (i.e., recalls with minimal adverse health consequences).

**Recall root cause** The results are robust to the exclusion of recalls due to equipment maintenance and employees'/users' errors (less likely to be the result of lower emphasis on product safety).<sup>9</sup>

**Ruling out reverse causality** To rule out reverse causality of product recalls on corporate lobbying, we run a Granger Causality Test. The null hypothesis that product recalls do not Granger-cause corporate lobbying cannot be rejected at the 90% confidence level ( $p > 0.10$ ). We further rule out reverse causality of product recalls on emphasis on product safety ( $p$

$> 0.10$ ) and focus on radical vs. incremental innovation ( $p > 0.10$ ).

## General discussion

There is growing evidence of the effects of non-market forces, including corporate political activity, on firms' outcomes. Yet, the effects of corporate political activity on firms' marketing-relevant outcomes have been overlooked in the literature. Moreover, product recalls, a consequence of product safety problems with substantive health, financial, and public policy implications, are increasingly common across many industries

(e.g., medical devices, pharma, automotive, consumer packaged goods, etc.). While there is a large body of work on the organization-level antecedents of product recalls, their non-market antecedents, political antecedents, in particular, have been overlooked in the literature.

Addressing this research gap, we examine whether and how a firm's corporate lobbying affects the number of its product recalls. We hypothesize and find that corporate lobbying increases a firm's number of product recalls and that this effect is partially mediated by the firm's lower emphasis on product safety. We also show that a firm's marketing CEO (vs. not) and focus on radical (vs. incremental) innovation moderate the positive indirect effect of corporate lobbying on the number of product recalls. The findings, which shed light on the non-market antecedents of product recalls, generate relevant implications for practitioners and policy-makers. We conclude with a discussion of the paper's theoretical contributions, managerial implications, and limitations and opportunities for further research.

### Theoretical contributions

First, the findings add to the emergent marketing literature investigating the effects of corporate political activity on firms' outcomes. In particular, the effects of corporate lobbying on specific marketing-relevant outcomes (e.g., product recalls, new product introductions, etc.) have been overlooked. We address this research gap by examining the relationship between firms' corporate lobbying and the number of their product recalls, a marketing-relevant outcome with significant costs for firms, customers, investors, and regulators.

Second, the research's contributions also extend the extant literature on the antecedents of product recalls. We proposed that firms' corporate lobbying decreases emphasis on product safety, eventually resulting in an increase in the number of product recalls. The findings support this argument. We also show that a firm's marketing CEO advocates for its customers and brands, which, in turn, stimulates greater attention to product quality and safety, manifested in the strengthening of the negative (and beneficial) effect of emphasis on product safety on the number of product recalls (positive moderation of the positive indirect effect of corporate lobbying on the number of product recalls). Interestingly, we also show that, in the medical device industry, focus on radical (vs. incremental) innovation weakens the negative (and beneficial) effect of emphasis on product safety on the number of product recalls (negative moderation of the positive indirect effect of corporate lobbying on the number of product recalls) as firms focusing on incremental innovation, which is not subject to rigorous pre-market testing, benefit more from an increase in emphasis on product safety.

Third, this research's findings also extend the research on the nature of the effects of corporate lobbying on firm performance. They do so by indicating a mechanism, i.e., more product recalls, by which corporate lobbying negatively affects firms' outcomes. While a growing body of empirical research supports a positive effect of corporate lobbying on firms' outcomes (Kaiser, 2010), this research's findings indicate another path through which corporate lobbying negatively affects firms' outcomes. Further, the findings show that reconciling the discrepancies across positive, negative, and null effects of corporate lobbying on firms' outcomes may be achieved by incorporating heterogeneity in empirical testing, as we do in this research.

Finally, the findings on the moderating role of the marketing CEO contribute to the literature on the key role of the marketing function in shaping firms' actions and consequent performance outcomes. The findings highlight the critical role of a marketing CEO in the firm in strengthening the negative (and beneficial) effect of emphasis on product safety on the number of product recalls, offering a novel, hitherto unexamined top-down driver of product recalls, a key product outcome with substantial negative downsides for firms.

### Managerial implications

This research's findings generate useful implications for practitioners and policy-makers. First, the practical headline from this study's findings is that, in industries with regulations of product safety and new product introductions, firms' corporate lobbying efforts can backfire by increasing product recalls. This effect is mediated by firms' lower emphasis on product safety. Members of top management teams and boards of directors should therefore be cautious when considering corporate lobbying. A possible solution to counteract the positive – and detrimental – effect of corporate lobbying on the number of product recalls would be to put in place procedures aimed at preventing a reduction in emphasis on product safety in new product development and/or limiting its consequences (e.g., quality training, increased supervision, rigorous voluntary pre-market testing, etc.).

Further, the presence of a marketing CEO in the firm strengthens the negative (and beneficial) effect of emphasis on product safety on the number of product recalls. Practitioners, especially boards of directors of medical device firms, may take into account this insight as an additional input when considering the functional backgrounds of CEOs, as appointing a marketing CEO may be tantamount to bringing customers into the boardroom (McGovern et al., 2004). Although we recognize that CEOs' appointments are driven by many corporate governance considerations and not necessarily based only on reducing product recalls, practitioners must be cognizant of such effect, considering the growing incidence of product recalls and their harmful consequences.

Interestingly, a marketing CEO does not reduce product recalls when emphasis on product safety within the firm is low. We conjecture that, as the head of the company, compared with marketing executives such as the CMO, the marketing CEO has to balance conflicting priorities from different functions. A higher emphasis on product safety within the firm would provide the marketing CEO with the opportunity to fully persecute their objective to prioritize product safety in new product development. This viewpoint is consistent with the significant negative main effect of the power of marketing executives on the TMT on the number of product recalls (while the interaction with emphasis on product safety is not significant) reported in Table 4. Marketing executives do not need to balance priorities from different functions (Maltz & Kohli, 2000) and may prioritize product safety independently on whether their firm facilitates it or not.

Further, the findings indicate that, in the medical device industry, a firm's focus on radical (vs. incremental) innovation weakens the negative (and beneficial) effect of its emphasis on product safety on the number of product recalls. As radical innovations are subject to rigorous pre-market testing under the supervision of the FDA, the negative impact of an increase in emphasis on product safety on product recalls will grow as focus on radical innovation (incremental innovation) decreases (increases) as, for incremental innovations, which are not subject to rigorous pre-market testing, firm's emphasis on product safety is paramount in preventing product recalls. Hence, firms which focus on incremental (vs. radical) innovation should be aware that the detrimental effect resulting from corporate lobbying will be particularly severe for them.

This research's findings are relevant to policy-makers. Officials at the Inspector General's office for Health and Human Services (2017) reported that Medicare had lost U.S. \$1.5 billion because of problems with seven recent defective heart devices between 2005 and 2014 (Schulte & Jewett, 2017). The findings show that lobbying firms may place lower emphasis on product safety and experience more product recalls. Policy-makers should consider whether increased monitoring and safety checks are necessary to counterbalance this effect. Our insights also indicate that a reduction in emphasis on product safety may be particularly detrimental for firms focusing on incremental (vs. radical) innovation, which is the result of the 510(k) process. This result adds to anecdotal evidence against the 510(k) process (Lenzer, 2017; Zuckerman et al., 2011) and indicates the need for a more rigorous pre-market testing of incremental innovations, especially for firms which engage in lobbying. Further, as product recalls are the subject of lawsuits, which threaten firm performance, this research's findings are useful to hospitals, investors, doctors, and insurers in forecasting the number of

product recalls of medical device firms, based on their lobbying, CEO's functional background, and innovation profile.

## Limitations and opportunities for further research

First, we conducted our empirical investigation in the U.S. medical device industry, which allows a clean test of the hypotheses without noise from cross-industry variations. However, this context precludes consideration of industry characteristics (e.g., uncertainty, customer involvement) that may affect new product development and product recalls. Future work relating corporate lobbying to product recalls in other industries can establish this study's generalizability. Second, following precedent in the marketing literature on product recalls, we used secondary data to test the hypotheses. A potential research opportunity is to study product recalls using primary data methods, including surveys and in-depth interviews of managers. Third, while we focus on corporate lobbying, corporate political activity can take other forms (e.g., PAC contributions). Future research on the effects of other forms of corporate political activity would be an interesting research extension. Last, the proposed mediator, i.e., lower emphasis on product safety, only partially explains the direct effect of corporate lobbying on the number of product recalls. We conjecture that, in addition to decreasing emphasis on product safety, corporate lobbying may lead to easier FDA approvals of new products (see Rayfield & Unsal, 2019), resulting in more product recalls. Hence, there is room for future work accounting for such direct effect. In an additional analysis, we find that lobbying aimed at agencies other than the FDA has a positive indirect, although only marginally significant, effect on the number of product recalls. This effect is indirect-only via lower emphasis on product safety. This confirms our intuition that the unexplained mechanism between the direct effect of FDA lobbying on the number of product recalls is best explained focusing on the FDA side of the process. Notwithstanding this, future research could also try to investigate, among others, whether lobbying results in lower attention to customers/customer-focus (Umashankar et al., 2022; Vadakkepatt et al., 2022), eventually leading to an increase in product recalls.

In sum, this research takes a step toward exploring the effect of firms' non-market strategies and finds that corporate lobbying can lead to undesirable marketing-relevant outcomes, i.e., product recalls. We hope this research stimulates future work relating corporate political activity to other marketing-relevant outcomes.



## Appendix

*Endogeneity concerns* We used lagged independent variables to account for reverse causality. Further, we included time fixed effects in all our equations to alleviate potential concerns due to omitted variables. However, corporate lobbying may be endogenous as firm-level omitted variables (e.g., organizational culture) may affect both corporate lobbying and product recalls. To address this potential bias, we re-ran our analysis using a control function approach (Petrin & Train, 2010). To instrument the suspect endogenous variable, we ran a random effects panel regression of firms' corporate lobbying on the average donations to political campaigns of other firms (Barber & Diestre, 2019) in our sample (computed using the same stock measure employed before for corporate lobbying) and, for completeness, the focal firm's donations to political campaigns (year fixed effects are also included). We expect other firms' donations to be correlated with the focal firm corporate lobbying as (a) political donations are correlated with corporate lobbying because firms that are politically active in one dimension are also active in other dimensions (Barber & Diestre, 2019; Hillman et al., 2004; Ridge et al., 2017) and (b) decisions on donations are taken in similar environments, with firms facing similar challenges and opportunities (see Germann et al., 2015 for a similar logic). Other firms' donations also meet the exclusion restriction as peer firms' decisions of supporting a candidate are unlikely to affect a firm's emphasis on product safety and number of product recalls (Barber & Diestre, 2019).

The results, available upon request from the authors, indicate that peer firms' donations significantly predict a firm's corporate lobbying ( $p < 0.05$ ). For hypotheses testing, we estimate the models of emphasis on product safety and number of product recalls including the error from the instrumental variable equation (Petrin & Train, 2010). Results are robust to the endogeneity correction (Columns 1 and 2, Panel A1, Table 5), although the main effect of corporate lobbying on emphasis on product safety is only marginally significant.

*Measure of corporate lobbying* We first checked the robustness of the results to alternative decay parameters (0.4, 0.6). The results, available upon request from the authors, do not change. The results are also robust when no decay parameter is used (see Columns 3 and 4, Panel A1, Table 5).

*Recall class* When a manufacturer faces a product safety problem and recalls a medical device, the FDA

evaluates the health risk presented by the recalled device and classifies the recall as a class I, class II, or class III recall, all of which are included in the dependent variable. To examine the robustness of the results to the definition of product recalls, we excluded class III recalls (i.e., recalls with minimal adverse health consequences) from the dependent variable. The results, reported in Columns 1 and 2, Panel A2, Table 5, do not change.

*Recall root cause* To examine the robustness of the results to the definition of product recalls and provide indirect support for our mechanism, we re-ran the main model excluding recalls due to equipment maintenance and employees' and users' errors. The results, reported in Columns 3 and 4, Panel A2, Table 5, do not change.<sup>9</sup>

*Ruling out reverse causality* To further rule out reverse causality of product recalls on corporate lobbying, we ran a Granger Causality Test with three lags using the user-generated Stata command *pvar* (Abrego & Love, 2015). The null hypothesis that product recalls do not Granger-cause corporate lobbying cannot be rejected at the 90% confidence level ( $p > 0.10$ ). We further ruled out reverse causality of product recalls on emphasis on product safety ( $p > 0.10$ ) and focus on radical vs. incremental innovation ( $p > 0.10$ ).

*Effect of non-FDA corporate lobbying* Results reported in Column 1, Table 3, show that corporate lobbying aimed at agencies other than the FDA also reduces a firm's emphasis on product safety. As emphasis on product safety reduces the number of product recalls (Columns 3 and 4, Table 3) and given that the effect of corporate lobbying aimed at agencies other than the FDA is not significant when controlling for emphasis on product safety, we are in the presence of indirect-only mediation, meaning that the positive indirect effect of non-FDA corporate lobbying on the number of product recalls is fully mediated by reduced emphasis on product safety. We checked the significance of the indirect effect using a bootstrapping procedure (500 replications). The indirect effect of corporate lobbying aimed at agencies other than the FDA on the number of product recalls via lower emphasis on product safety is positive and marginally significant ( $p < 0.10$ ) while the direct effect is not significant ( $p > 0.10$ ).

<sup>9</sup> Results do not change if we also exclude packaging- and label-related recalls.

**Table 5** Robustness checks

Panel A1		Endogeneity Correction		No Decay	
Dependent Variable:	Emphasis on Product Safety	Number of Product Recalls	Emphasis on Product Safety	Number of Product Recalls	
Corporate Lobbying	−.004 (.003)*	.002 (.001)**	−.001 (.0004)**	.001 (.0003)***	
Emphasis on Product Safety		−.34 (.16)**		−.33 (.16)**	
Emphasis on Product Safety × Marketing CEO		−.61 (.26)**		−.59 (.26)**	
Emphasis on Product Safety × R&D CEO		−.37 (.38)		−.39 (.38)	
Emphasis on Product Safety × Focus on Radical (vs. Incremental) Innovation		2.21 (.90)**		2.42 (.90)**	
<i>Log pseudo-likelihood</i>	−134.43	−1,253.56	−134.20	−1,253.23	
Panel A2		Excluding Class III Recalls		Recall Root Cause	
Dependent Variable:	Emphasis on Product Safety	Number of Product Recalls	Emphasis on Product Safety	Number of Product Recalls	
Corporate Lobbying	−.001 (.0005)**	.001 (.0003)***	−.001 (.0005)**	.001 (.0003)***	
Emphasis on Product Safety		−.40 (.17)**		−.37 (.16)**	
Emphasis on Product Safety × Marketing CEO		−.60 (.27)**		−.61 (.27)**	
Emphasis on Product Safety × R&D CEO		−.32 (.38)		−.25 (.38)	
Emphasis on Product Safety × Focus on Radical (vs. Incremental) Innovation		2.54 (.92)***		2.33 (.90)***	
<i>Log pseudo-likelihood</i>	−135.13	−1,212.21	−135.13	−1,230.61	

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s11747-022-00860-z>.

## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

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