**Do Product Safety Issues Drive Innovation? The Effect of Medical Device Recalls on Market Dynamics**


## Abstract

Medical devices are critical to the delivery of health care, but malfunctioning products can pose a threat to patients, necessitating product recalls. In addition to the direct effects of medical device recalls, which include both public health protection and negative reputational and financial consequences for the recalling firm, there may be spillover effects on product development; the vacuum left by the recalled product and its reputational damage may incentivize competing firms to introduce new medical devices to the market. This study examines the impact of serious medical device recalls on subsequent new product development by competitors, as measured by new medical device submissions to the FDA. We compile data from three regulatory databases representing 11,724 new product submissions and 2,647 recalls for 7,208 unique medical device firms over a 17-year period. Using a fixed effect model and institutional features of the FDA's clearance process, we find that safety-related recalls lead to an increase in other firm's new product submissions in the affected product market. We estimate that a single recall increases subsequent submissions in a product market by approximately eight percent. Moreover, we find that this relationship is attenuated in markets with more competitors. Our results indicate that firms may currently undervalue actions to avoid product recalls and that the medical device market may be improved by regulatory efforts to enhance transparency in the recall process.



**Keywords**: medical devices, recalls, FDA, 510(k) pathway

## 1. Introduction

Medical devices are instrumental in both improving the health and well-being of patients and representing a potential public health threat: viz., when they have serious quality defects, they can pose life-threatening risks (Krumholz et al., 2007; Zipp, 2022). To help mitigate the negative health effects of defective medical devices, manufacturers are required to initiate product recalls and remove poorly performing and/or risky products from the market (U.S. Food and Drug Administration, 2024). While innovation in the medical device industry continues apace (Stern, 2017), so too do the number of serious product recalls (Danford, 2024; Hobbins, 2023). Product recalls are also often associated with financial and reputational damages to medical device firms (Thirumalai and Sinha, 2011). These negative consequences can include lower overall firm financial performance (Chen et al., 2024) or lower stock prices following a recall announcement (Darby et al., 2023).

Beyond the immediate implications for public health and firm performance, medical device recalls may also have industry spillover effects—yet this possibility has not yet been explored empirically. We consider the potential that a competitor firm recall may incentivize unaffected firms to accelerate their new product submission activities. We directly examine whether more new product submissions follow a recall, as firms seek to fill the supply chain gap created by the negative shock (U.S. Food and Drug Administration, 2023). Recalled products also have negative firm reputational ramifications: when a competitor firm announces a serious recall, it may create a window of opportunity for unaffected firms to potentially sway patients or health care providers towards seemingly more reliable products (Ball et al., 2022; Device Events, 2023). Although other studies have demonstrated that medical product manufacturers respond meaningfully to news regarding their direct competitors' products, such as in the pharmaceutical R&D setting (Krieger, 2017), the relationship between recalls of already-marketed products and the subsequent introduction of new products by competing firms has to the best of our knowledge not been examined—in either the medical device industry or any other regulated industry.

In this study, we examine the extent to which medical device recalls of competitor firms impact the number of subsequent new products introduced by unaffected firms in the affected product market. We focus on products regulated by the U.S. Food and Drug Administration (FDA) via the 510(k) pathway. These products are by far the largest category of regulated

medical devices, representing over 99 percent of FDA medical device submissions. In addition, the 510(k) pathway is substantially faster and more agile compared to alternative regulatory pathways, allowing new product submissions to respond to competitor recalls over shorter windows of time.

Our empirical setting and approach allow for an examination of the impact of the most unexpected, and thus exogenous, set of serious safety recalls on firms' new product submissions: in particular, we examine whether and how serious medical device recalls that are unprecedented by publicly-reported complaints influence the number of subsequent unaffected firms' new product submissions. We focus on this set of recalls for two reasons: first, they represent a plausibly exogenous shock to unaffected firms' market understanding; and second, it would be difficult, if not impossible, to anticipate the issuance of such recalls. In addition, we focus on those recalls that have potential major negative health consequences and are therefore the most difficult to selectively avoid initiating.

Our empirical setting leverages three FDA databases: (1) product recalls; (2) product complaints; and (3) product submissions. We follow the FDA's classification of devices into mutually exclusive and collectively exhaustive product codes to measure new product submissions within the same product market as the recalled product. Our sample includes 11,724 new product submissions and 2,647 serious recalls for 7,208 unique medical device firms over 2004-2020, inclusive. We use panelized, negative binomial fixed effects models to determine how serious, unexpected recalls shape unaffected firms' subsequent new product submission activities in a given product market. We further consider the moderating effect of competition: in crowded markets, the greater number of available substitutes may limit the potential benefits—and therefore incentives—associated with a new product submission in the impacted product category.

We find that competitor firm recalls significantly increase subsequent new product submissions in impacted product markets. The empirical results suggest that a single recall increases unaffected firms' average new product submissions by approximately eight percent in the subsequent six months. Moreover, we find that competitor firm recalls increase new product submissions most significantly in product markets with fewer competitors. These findings suggest that perceived market opportunities motivate unaffected firms to augment new product

submission activities following other firms' mistakes, but that such opportunistic approaches are less attractive in more crowded product markets.

This study makes two main contributions to the literature. First, to the best of our knowledge, it provides the first evidence of spillover effects of competitor firm recalls on unaffected firms' innovation activities in any industry. Some research suggests that firms learn from their own recalls and make quality improvements, which could hypothetically influence new product development efforts at the recalling firm (Haunschild and Rhee, 2004). Other research in the pharmaceutical industry shows that, under certain circumstances, firms observe and learn from the pre-market product development activities and R&D failures of their competitors which may, in turn, influence subsequent new product development projects (Krieger, 2021). However, these settings differ from post-market competitor product recalls with respect to the identity of the responding actor and the stage of new product development, respectively.

Second, it contributes to the literature on innovation incentives in health care product markets (Acemoglu and Linn, 2004; Budish et al., 2015; Carpenter et al., 2010; Dubois et al., 2015; Stern, 2017). While predictors of innovation incentives for medical devices (Stern, 2017) and in pharmaceutical markets (Budish et al., 2015) have been well-documented, no studies of which we are aware have associated prior product failures in general, or recalls in particular, with an increase in new product submission activity.

This study has important implications for both regulators and firms. Our results suggest that efforts to enhance transparency and communication regarding product recalls may help improve efficiency in the medical device market by increasing the information available to all stakeholders and potentially spurring new product development. Furthermore, our findings highlight a "double penalty" for firms with a recalled product: i.e., in addition to negative effects of the recall itself—including foregone revenues, legal costs, negative publicity, and potential declines in valuation—a recall incentivizes new product submissions from unaffected firms. As a result, firms may currently undervalue recall/product failure prevention and remediation activities. Finally, our results suggest an important area for future research lies in determining the extent to which new product submissions generated by competitor firm recalls translate into improvements in patient health. On the one hand, newly submitted medical devices may represent genuine innovations that provide benefits to patients and providers while increasing

firm market share or enhancing its reputation. On the other hand, new medical devices that are introduced to quickly capitalize on a market opportunity may have limited benefits or lower quality. For example, a newly-introduced medical device may have an increased risk of future recall itself if its technology is based on a recalled product, as recently demonstrated by a pair of studies (Everhart et al., 2023; Kadakia et al., 2023).

## 2. Background

To determine if new medical devices are safe and effective, the FDA reviews product submissions through two separate pathways: the "510(k) clearance process" and the Pre-Market Approval (PMA) track. As opposed to PMA track devices that are highly novel, 510(k) devices are defined by their moderate risk and similarity to previously cleared and marketed product(s).[1] Furthermore, 510(k) submissions are nimbler than PMA submissions—i.e., they are both shorter in duration and less demanding in their associated resource requirements (Sall, 2008)—suggesting that they can be more responsive to product market dynamics, such as competitor firm recalls. More than 99 percent of FDA medical device submissions are regulated via the 510(k) clearance process. Part of this clearance process categorizes devices into distinct product types, formally referred to as FDA "product codes" that precisely define individual product markets based upon use and function. Products in the same product code are thus effective substitutes because they serve the same function, are used in identical ways, and are reviewed by the same group of regulators.

After a medical device is cleared for introduction into the U.S. market, the FDA also acts as a post-market regulator. Devices that present a risk of injury, deception, or are otherwise defective are required by Federal law to be recalled and removed from the market by the infringing firm. The FDA may call upon manufacturers to recall a product, or manufacturers may voluntarily initiate a recall. Recall classifications range from Class I (most severe) to Class II (moderately severe) and Class III (least severe). Class I recalls are for medical device failures that have a reasonable probability of serious adverse health consequences or death, such as a faulty valve on

[1] Medical devices of the highest risk typically need to use the PMA track. The products using the PMA regulatory pathway are typically implantable and/or life sustaining – e.g., ventilators, hemodialysis systems and accessories, and implantable spinal cord stimulators. Such products are often novel and innovative, but they comprise a very small fraction of total regulated medical devices. Notably, only devices that come to market through the PMA process are "approved" by the FDA. 510(k)-track devices are instead "cleared" for marketing approval, and we use this language throughout in keeping with regulatory practices.

a ventilator that prevents proper air flow. Class II recalls occur when the use of a device may cause serious but medically reversible adverse health consequences, such as a defective hip implant. Class III recalls occur when a quality problem would be unlikely to cause adverse health consequences but should nevertheless be corrected, such as a labeling mistake on a percutaneous catheter.[2] Firms have significant discretion regarding whether or not to initiate a Class III recall, because of their low severity (Wowak et al., 2021). However, this discretion is significantly dampened for Class I and II recalls, which is why studies use these as proxies for firm-level product quality (Darby et al., Wowak et al., Ball 2018 (in pharma)). Appendix A provides additional information on medical device regulation and recalls.

In addition to the formal recall process, the FDA also maintains a publicly available database of medical device adverse events called the Manufacturer and User Facility Device Experience (MAUDE). The MAUDE database presents medical device performance feedback from patients, physicians and medical facilities, and firms (Mukherjee and Sinha, 2018). Manufacturers of faulty devices are required by law to report any deaths, injuries, and malfunctions within 30 days of becoming aware of such events or within five days when unreasonable risk of substantial harm to the public exists (U.S. Food and Drug Administration, 2020). Firms thus have limited discretion in reporting their serious medical device product failures soon after they occur. Moreover, if a serious product failure does occur, it will quickly be available on the MAUDE database. If and when this happens, safety or quality issues associated with faulty devices are directly observable by all firms. Nonetheless, there are many recalls with no prior MAUDE complaints. This is not surprising, as recalls are often initiated solely based upon knowledge internal to the recalling firm (Ball et al., 2018): e.g., the firm becomes aware of product, process, or materials discrepancies or other product safety issues that are not public knowledge.

## 3. Data

We collect data from three FDA databases over 2004-2020: medical device recalls, complaints, and 510(k) device submissions. We describe each database in turn.

First, we use the FDA medical device recall database to construct our independent variable, which measures the number of recalled medical devices by competitor firms. This digitized database includes unique 510(k) identification numbers of recalled products, event dates, firm

[2] See U.S. Food and Drug Administration (2025a, 2025b, 2025c) for all three recall examples, respectively.

identities, and recall severity classifications. Public knowledge of recalls occurs when they are reported on the FDA website; we use this information as the publicly-posted recall initiation date.[3] We focus on Class I and II recalls in our main empirical analyses as these are the least discretionary, constitute the most significant patient health risks, and represent the largest firm disruptions that are likely to attract the attention of other firms. Our main analysis dataset includes 2,647 recalls: 170 Class I and 2,477 Class II.[4] We consider Class III recalls in robustness tests.

Second, we associate MAUDE complaints with recalls to capture the subset of recalled medical devices with known prior complaints. Competitor recalls with no prior MAUDE complaints are more likely to be exogeneous shocks, as there is no documented public knowledge of any quality problem prior to recall initiation. We download all 12.8 million complaint records from the MAUDE database for our time frame of interest (FDA, 2025). We then use the FDA 510(k) submission number, which is included in MAUDE reports for each complaint, to directly link complaints to recalls. Of the 2,647 total recalls in our sample, 739 recalls (28 Class I and 711 Class II), or 28 percent, experience no prior reported adverse event of any kind.

Third, we use the 510(k) submission database to generate our outcome variable, which represents the number of firm-level new medical device submissions. The 510(k) submission database includes a unique 510(k) identification number for each device, submission and clearance dates, applicant firm identities, and device class and product market details. The submission data only include those products that completed the clearance process.[5] Our data include 11,724 submissions that were cleared for marketing by the FDA over 2004-2020 (inclusive). This database also includes detailed information on product and firm characteristics that we use as controls, including product age, FDA product risk classification, publicly traded

[3] All recalls in this study are firm-initiated, not FDA-initiated.

[4] There are no instances in which the recalls in our data result in full market withdrawals for the entire product line experiencing the recall. This means that new products which are added to the market following competitor recalls result in additional new product alternatives in the affected product market, instead of replacement options for products that are no longer available.

[5] While the FDA does not publish data on 510(k) submissions that do not gain market clearance, they have stated publicly that the clearance success rate is approximately 85 percent and occurs on average 95 days after the submission date (Enriquez, 2015). Because of this, our dependent variable not only measures the count of new products that were submitted for clearance, but also the count of new products cleared to enter each product market in the near future.

firm status, firm experience, number of firm product markets, and number of internal recalls from a firm (***Appendix B*** provides additional information on these variables).

We assign each recall and new product submission to a cleaned and standardized firm name based on the information included using *Cortex*, a software package for fuzzy matching of text strings, resulting in 7,208 unique firms.

We panelize our data at the firm, FDA product code, and six-month time window level for two reasons. First, we structure the analysis around firms and product codes to examine the relationship between competitor recalls and new product submissions within the same precisely identified product market. Second, we consider a six-month time window to reflect the relative agility of a 510(k) submission to respond to market dynamics. We examine this time window choice in robustness analyses.

Our main analysis sample represents the number of new medical device products submitted through the 510(k) pathway for a given FDA product code and firm linked to the corresponding number of competitor firm Class I and II recalls in the previous six months (all recalls and the subset without prior MAUDE complaints, separately). ***Table 1*** provides descriptive statistics for the analysis sample.

## 4. Empirical strategy

To estimate the effect of medical device recalls on the submission of new medical device products introduced by competitors in the affected product market, we implement a fixed effects negative binomial regression model per the following equation[6]:

$$New\ Product\ Submissions_{ijt} = \exp\left(\beta_0 + \beta_1(Competitor\ Recalls)_{ijt-1} + \beta_2(Competitor\ Number)_{ijt-1} + \beta_3(Competitor\ Recalls\ x\ Competitor\ Number)_{ijt-1} + \beta_4 C_{ijt-1} + \beta_5 F_i + \beta_6 RMS_j + \beta_7 Y_t + \varepsilon_{ijt}\right)$$

where the indices $i$, $j$ and $t$ represent firm, product code, and six-month time window, respectively. The dependent variable, *New Product Submissions*, measures the number of new medical device submissions made by the firm in a given product market and time window. The

[6] This model was selected to accommodate our dependent variable, which is an over-dispersed non-negative count measure.

independent variable, *Competitor Recalls*, represents a six-month lagged count of recalled medical devices by competitor firms in a given product market. In other words, we use the prior six-month window count of competitor recalls in a product market to predict new product submissions by the unaffected firm in that same product market in the current six-month window. We further employ a moderating variable, *Competitor Number*, which represents the number of competitor firms in the same product market in the prior six-month window. The interaction of this variable with *Competitor Recalls* captures the potential moderating effect of competition within a given product market. We also include a vector of controls $C$ for product and firm characteristics. Finally, we include firm fixed effects ($F$),[7] regulatory medical specialty fixed effects ($RMS$)[8] and year fixed effects ($Y$), as new product development and recall propensities may be partially explained by heterogeneity in products and firms or changes in industry and policy over time (Ball et al., 2017; Shah et al., 2017; Thirumalai and Sinha, 2011; Wowak et al., 2015).[9] Standard errors are robust and clustered at the firm level.

Our coefficients of interest are $\beta_1$, the effect of competitor recalls on new product submissions, and $\beta_3$, the moderating effect of competition in the market.[10] We interpret our estimates as causal under the identifying assumption that competitor recalls represent exogenous, external shocks: specifically, conditional on fixed firm and medical specialty characteristics and common time-specific factors, we are identifying effects using plausibly exogenous variation from recalls. One possible violation of this identifying assumption is that firms are aware that competitors are experiencing product quality issues, and therefore introduce new product submissions regardless of recall status. We investigate the influence of this potential endogeneity bias by separately analyzing the impact of all recalls as well as the subset without a prior MAUDE complaint. The latter represents the most exogeneous subset of recalls and is thus our preferred specification.

[7] Each firm with more than two products in the sample is assigned its own indicator; firms with either two products or one product (the reference category) are assigned an aggregate indicator.
[8] These indicator variables are based upon the FDA-assigned regulatory medical specialty (RMS) of each product code. The twenty RMS categories are aggregated product codes and grouped based upon medical specialty overlap (e.g., cardiovascular, radiology, orthopedics, etc.).
[9] We use year indicators as opposed to six-month indicators for parsimonious reasons, but our results are consistent if we use an indicator variable for each unique six-month window of time.
[10] The interpretation of estimated coefficients in a negative binomial model is as follows: a one unit change in an independent variable is associated with a (exp$\beta$-1) percentage change in the dependent variable: in our empirical setting, the number of new product submissions in a six-month time window (Wooldridge, 2010).

This analysis has several limitations, which suggest avenues for future research. First, we focus on a single industry and market, which may limit the generalizability of our findings. Second, our recall measures do not capture other relevant features, such as media coverage or financial costs, due to data limitations. Future work can analyze other R&D-intensive industries that are subject to product failures and recalls, as well as other factors that may influence our estimates. Finally, we do not examine the characteristics of the new product submissions in terms of how they relate to prior recall causes. Future studies could more directly compare the underlying technical details of each new product submission against the underlying product defect details for each product recall.

## 5. Results

### *5.1. Main results*

***Table 2*** presents the main estimation results. Columns (1) and (2) show the results for the effects of all recalls (the main effect and the full model that examines the moderating effect of competition, respectively), while Columns (3) and (4) similarly focus on the subset with no prior MAUDE complaints.

The results in Column (1) indicate that competitor recalls increase new product submissions ($\beta_1$ = 0.073; p<0.001). Each competitor recall in the prior six-month window is associated with a 7.5 percent increase in new product submissions in the current six-month window. This equates to one additional new product submitted in each product market, on average, in the 24-month period following a competitor recall.[11] Furthermore, Column (2) shows that this positive effect is attenuated in more competitive markets ($\beta_3$ = -0.040; p<0.001).

When focusing on the subset of recalls with no prior MAUDE complaints, we find comparable results, but with larger magnitudes, indicating that the impact of the most exogeneous recalls is even stronger. For example, the main effect in Column (3) indicates that a competitor recall with no prior complaints leads to a greater increase in new product submissions

[11] $\text{Exp}^{(0.073)}$ - 1 = 7.5 percent. This 7.5 percent increase applies to the mean number of new product submissions per firm per six-month window (0.084 from Table 1), multiplied by the mean number of firms in a product market (41 firms on average in a product market from Table 1). This equates to 0.26 new products per product market in the six months following a competitor recall: 0.26 = 0.075 x 0.084 x 41, or one additional new product in the 24-months following a competitor recall on average in a product market: 1.03= 0.26 x 4.

($\beta_1$ = 0.213; p<0.001). Column (4) shows that this impact is also attenuated by competition ($\beta_3$ = -0.103; p<0.001).

In all Columns, coefficients on the controls indicate that older product markets and firms with more products have fewer new product submissions. Moreover, public firms, those with more product market experience, and those that incur more internal recalls have more new product submissions. In addition, the coefficient on the number of competitors in the full models in Columns (2) and (4) show that product markets with more competitors experience more submissions.

### *5.2. Alternative time windows*

We next consider alternative recall time window lags beyond the main estimation measure of six months. By doing so, we can better understand how and when in the new product development process competitor recalls influence new product submissions. For example, if we observe that the relationship dissipates quickly—e.g., in the second six-month lag window—then we can deduce that competitor recalls are most influential in the time period immediately prior to submission. In this case, competitor recalls might simply incent firms to speed up the completion of new products that are nearly ready for submission to FDA. However, if the competitor recall effect continues for multiple lagged time periods, the phenomenon could be understood as mattering throughout the entire new product development cycle–typically, two to three years (Nazarian, 2009; Wizemann, 2010). Finally, this analysis allows us to qualitatively examine coefficient effect sizes in each lagged period, which can indicate where the relationship is the strongest—i.e., close-in or far-out from when the firm submits to the FDA.

We plot the coefficients and confidence intervals of each six-month window lag in ***Figure 1*** and include the regression results in ***Appendix Table A1***. First, we find that the competitor recall effect weakens as the lag increases, becoming statistically insignificant in the eighth time window lag (confidence interval overlaps zero). In addition, given that the average product development project for 510(k) medical devices is two to three years, recalls throughout the entire product development project appear to influence submissions—albeit the strongest effects on submissions are in the six-month period immediately after a competitor recall and dissipate steadily thereafter. In other words, new product development projects appear to be most sensitive to competitor recalls in the short-term (products that are near the completion of the product

development process) but remain influenced by these recalls for as long as seven six-month time window lags (approximately three and a half years).

### *5.3. Heterogeneity across public and private firms*

As a next step, we analyze a model that segregates competitor firm recall counts into those announced by publicly traded firms and those announced by privately held firms. We do so because it is possible that public firm recalls receive greater awareness and media attention when a recall occurs, and their recalls may therefore stimulate new product submissions more than private firms' recalls. ***Appendix Table A2*** shows very similar results when comparing both the main and the interaction effects using public and private firm recalls, suggesting that the firm ownership is not a significant source of heterogeneity in outcomes.

### *5.4. Robustness tests*

We undertake multiple robustness tests to examine the consistency of our results across alternative measures and methods. First, we estimate our model using quarter (shorter) time window and year (longer) time window interval and lag structures. In both analyses, presented in ***Appendix Table A3***, the estimates remain consistent with our main results. Second, ***Appendix Table A4*** implements logistic regression analysis, expressing new product submissions as a dichotomous measure. All of the main empirical results continue to hold.[12] Next, ***Appendix Table A5*** replaces Class I and II recalls with all recall classes (i.e., I, II, and III). Results remain consistent. Taken together, these robustness tests suggest that our results are not artifacts of model assumptions or decisions about the level of analysis.

## 6. Conclusion

We find that competitor recalls in the medical device industry increase the subsequent number of new product submissions to the FDA. Each additional recall in the prior six months is associated with a 7.5 percent increase in new product submissions, or approximately one additional new product in each product market, on average, in the subsequent 24-months. This effect is strongest in the immediate past, but continues with a diminishing magnitude for

[12] Note that positive (negative) coefficients in a negative binomial model are equivalent to odds ratios greater (less) than one in a logistic regression model.

approximately three and a half years. Furthermore, we find that this relationship is stronger in product markets with fewer competitors. To the best of our knowledge, this study provides the first evidence of spillover effects of a competitor recall on new product development in any industry and improves our understanding of innovation incentives in health care product markets.

Our findings suggest that FDA policies to enhance transparency surrounding medical device recalls may increase efficiency in the market and incentivize new product submissions. These results also suggest that firms are currently undervaluing efforts to avert product recalls given the "double penalty" created by the development activities of competing firms. Importantly, the implications of recall-initiated new product development for patient health warrants future examination.

## References


Acemoglu, D., Linn, J., 2004. Market size in innovation: theory and evidence from the pharmaceutical industry. The Quarterly journal of economics 119, 1049–1090.

Ball, G., Siemsen, E., Shah, R., 2017. Do Plant Inspections Predict Future Quality? The Role of Investigator Experience. M&SOM 19, 534–550. https://doi.org/10.1287/msom.2017.0661

Ball, G.P., Shah, R., Donohue, K., 2018. The decision to recall: A behavioral investigation in the medical device industry. J of Ops Management 62, 1–15. https://doi.org/10.1016/j.jom.2018.07.003

Ball, G.P., Wowak, K.D., Mukherjee, U.K., 2022. Product recall research: dimensions, methods, and regulator implications, in: Tutorials in Operations Research: Emerging and Impactful Topics in Operations. INFORMS, pp. 116–132.

Budish, E., Roin, B.N., Williams, H., 2015. Do firms underinvest in long-term research? Evidence from cancer clinical trials. American Economic Review 105, 2044–2085.

Carpenter, D., Moffitt, S.I., Moore, C.D., Rynbrandt, R.T., Ting, M.M., Yohai, I., Zucker, E.J., 2010. Early entrant protection in approval regulation: Theory and evidence from FDA drug review. The Journal of Law, Economics, & Organization 26, 515–545.

Chen, Y., Ma, L., Pittman, J., Yang, X., 2024. Penny Wise and Pound Foolish: Does Striving to Meet Earnings Expectations by Manipulating Real Activities Trigger Product Recalls? Management Science.

Danford, M., 2024. FDA medical device Class 1 recalls trend upward [WWW Document]. URL https://www.ormanager.com/briefs/fda-expert-expresses-concern-about-prevalence-of-medical-device-class-1-recalls/ (accessed 11.14.24).

Darby, J.L., Ketchen Jr, D.J., Ball, G.P., Mukherjee, U., 2023. CEO stock ownership, recall timing, and stock market penalties. Manufacturing & Service Operations Management 25, 1909–1930.

Device Events, 2023. Understanding the Hidden Costs of Medical Device Recalls [WWW Document]. URL https://deviceevents.com/hidden-costs-of-medical-recalls/ (accessed 11.14.24).

Dubois, P., De Mouzon, O., Scott-Morton, F., Seabright, P., 2015. Market size and pharmaceutical innovation. The RAND Journal of Economics 46, 844–871.

Enriquez, J., 2015. FDA's PMA Approval Rate Soars To 15-Year High [WWW Document]. Med Device Online. URL https://www.meddeviceonline.com/doc/fda-s-pma-approval-rate-soars-to-year-high-0001#:~:text=For%20510(k)%20applications%20covering,to%20126%20days%20in%202014. (accessed 1.9.25).

Everhart, A.O., Sen, S., Stern, A.D., Zhu, Y., Karaca-Mandic, P., 2023. Association Between Regulatory Submission Characteristics and Recalls of Medical Devices Receiving 510(k) Clearance. JAMA 329, 144. https://doi.org/10.1001/jama.2022.22974

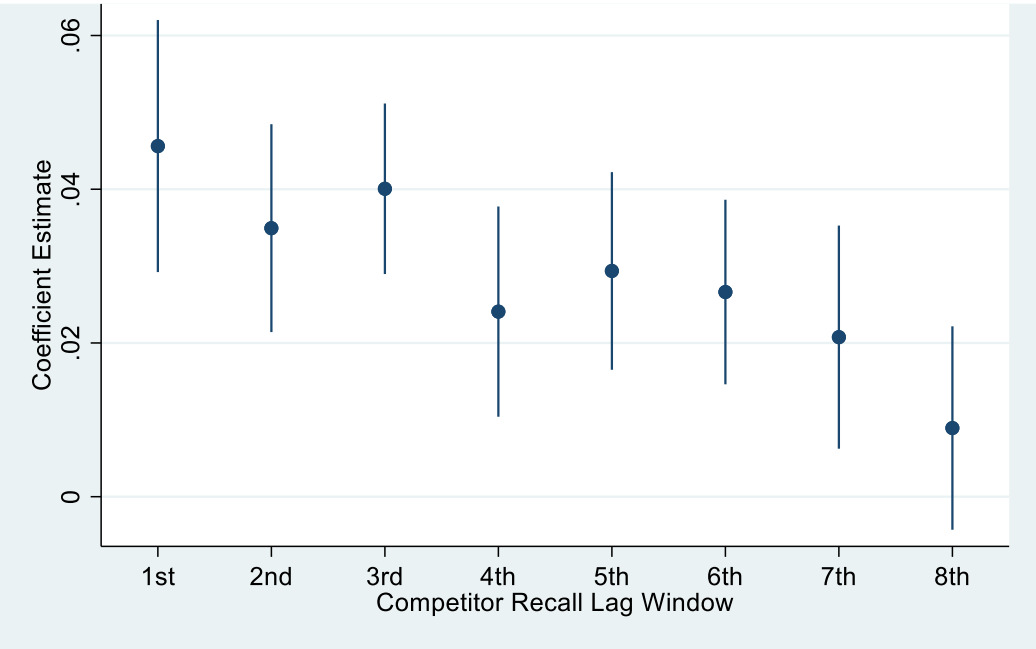
FDA, 2025. Manufacturer and User Facility Device Experience (MAUDE) Database [WWW Document]. URL https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

Haunschild, P.R., Rhee, M., 2004. The role of volition in organizational learning: The case of automotive product recalls. Management Science 50, 1545–1560.

Hobbins, K., 2023. FDA Facing Increased Scrutiny Over Medical Device Recalls [WWW Document]. URL https://www.mddionline.com/regulatory-quality/fda-facing-increased-scrutiny-over-medical-device-recalls (accessed 11.14.24).
Kadakia, K.T., Dhruva, S.S., Caraballo, C., Ross, J.S., Krumholz, H.M., 2023. Use of Recalled Devices in New Device Authorizations Under the US Food and Drug Administration's 510(k) Pathway and Risk of Subsequent Recalls. JAMA 329, 136. https://doi.org/10.1001/jama.2022.23279
Krieger, J.L., 2021. Trials and terminations: Learning from competitors' R&D failures. Management Science 67, 5525–5548.
Krumholz, H.M., Ross, J.S., Presler, A.H., Egilman, D.S., 2007. What have we learnt from Vioxx? BMJ 334, 120–123.
Mukherjee, U.K., Sinha, K.K., 2018. Product Recall Decisions in Medical Device Supply Chains: A Big Data Analytic Approach to Evaluating Judgment Bias. Production and Operations Management 27, 1816–1833. https://doi.org/10.1111/poms.12696
Nazarian, R., 2009. Developing Medical Devices in a Consumer-Driven Market [WWW Document]. Medical Device & Diagnostic Industry. URL https://www.mddionline.com/design-engineering/developing-medical-devices-in-a-consumer-driven-market (accessed 1.16.25).
Sall, B., 2008. FDA medical device regulation, in: Pisano, D.J., Mantus, D.S. (Eds.), FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics. CRC Press, pp. 69–108.
Shah, R., Ball, G.P., Netessine, S., 2017. Plant Operations and Product Recalls in the Automotive Industry: An Empirical Investigation. Management Science 63, 2439–2459. https://doi.org/10.1287/mnsc.2016.2456
Stern, A.D., 2017. Innovation under regulatory uncertainty: Evidence from medical technology. Journal of Public Economics 145, 181–200.
Thirumalai, S., Sinha, K.K., 2011. Product recalls in the medical device industry: An empirical exploration of the sources and financial consequences. Management Science 57, 376–392.
U.S. Food and Drug Administration, 2025a. Class 1 Device Recall [WWW Document]. URL https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=27672 (accessed 1.6.25).
U.S. Food and Drug Administration, 2025b. Class 2 Device Recall [WWW Document]. URL https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=28008 (accessed 1.6.25).
U.S. Food and Drug Administration, 2025c. Class 3 Device Recall VIA Microcatheter [WWW Document]. URL https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=187704 (accessed 1.6.25).
U.S. Food and Drug Administration, 2024. Medical Device Recalls [WWW Document]. URL https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls (accessed 12.11.24).
U.S. Food and Drug Administration, 2023. Medtronic Recalls Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) with Glassed Feedthrough for Risk of Low or No Energy Output During High Voltage Therapy [WWW Document]. URL https://www.fda.gov/medical-devices/medical-device-

recalls/medtronic-recalls-implantable-cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy (accessed 11.14.24).
U.S. Food and Drug Administration, 2020. Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities [WWW Document]. URL https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities (accessed 1.16.25).
Wizemann, T., 2010. Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report. National Academies Press, Washington, D.C. https://doi.org/10.17226/12960
Wooldridge, J.M., 2010. Econometric analysis of cross section and panel data, 2nd ed. ed. MIT Press, Cambridge, Mass.
Wowak, A.J., Mannor, M.J., Wowak, K.D., 2015. Throwing caution to the wind: The effect of CEO stock option pay on the incidence of product safety problems: CEO Stock Option Pay and Product Safety Problems. Strat. Mgmt. J. 36, 1082–1092. https://doi.org/10.1002/smj.2277
Wowak, K.D., Ball, G.P., Post, C., Ketchen Jr, D.J., 2021. The influence of female directors on product recall decisions. Manufacturing & Service Operations Management 23, 895–913.
Zipp, R., 2022. Patient death prompts another recall of Medtronic's HVAD System. MedTech Dive.

## Figure 1: Competitor Recall Window Lags




Notes: (1) Figure uses the estimation results in Appendix Table A1. (2) All variables are held at their respective means. (3) Coefficient estimates and standard errors are reported for Competitor Recalls lagged over successive six-month windows. For example, the 1st lag represents the most prior six-month window, the 2nd lag represents the second prior six-month window, and so on.

## Table 1: Descriptive Statistics

| VARIABLE | OBS | MEAN | ST DEV | MIN | MAX |
|---|---|---|---|---|---|
| New Product Submissions | 138,863 | 0.084 | 0.341 | 0.000 | 13.000 |
| Product Age | 138,863 | 52.173 | 19.267 | 0.000 | 80.000 |
| Product Classification I | 138,863 | 0.067 | 0.249 | 0.000 | 1.000 |
| Product Classification II | 138,863 | 0.931 | 0.253 | 0.000 | 1.000 |
| Product Classification III | 138,863 | 0.002 | 0.049 | 0.000 | 1.000 |
| Firm Public | 138,863 | 0.198 | 0.398 | 0.000 | 1.000 |
| Firm Experience | 138,863 | 6.526 | 5.638 | 0.000 | 30.000 |
| Firm Products | 138,863 | 8.263 | 17.111 | 0.000 | 118.000 |
| Firm Recalls | 138,863 | 0.014 | 0.177 | 0.000 | 28.000 |
| Competitor Recalls | 138,863 | 0.271 | 1.558 | 0.000 | 44.000 |
| Competitor Number | 138,863 | 40.718 | 47.774 | 0.000 | 237.000 |

Notes: (1) Variables are in raw form (i.e., no transformations). (2) Descriptive statistics are calculated from observations in the analysis sample. (3) Product Age, Firm Public, Firm Experience, Firm Products, Firm Recalls, Competitor Recalls, and Competitor Number are lagged. (4) Inclusion in the analysis sample requires: (a) at least one recall occurs in product code over sample timeframe and (b) at least one competitor firm submission occurs in product code over sample timeframe.

## Table 2: Main Estimation Results

| | (1) | (2) | (3) | (4) |
|---|---|---|---|---|
| Product Age | -0.205*** | -0.303*** | -0.195*** | -0.293*** |
| | -0.036 | -0.037 | -0.036 | -0.038 |
| Product Classification II | 0.362** | 0.374** | 0.374** | 0.390** |
| | -0.129 | -0.129 | -0.128 | -0.129 |
| Product Classification III | -0.132 | -0.234 | -0.027 | -0.032 |
| | -0.291 | -0.302 | -0.288 | -0.28 |
| Firm Public | 0.419*** | 0.430*** | 0.424*** | 0.435*** |
| | -0.089 | -0.089 | -0.091 | -0.09 |
| Firm Experience | 0.104*** | 0.096*** | 0.098*** | 0.088*** |
| | -0.024 | -0.023 | -0.024 | -0.024 |
| Firm Products | -0.692*** | -0.684*** | -0.695*** | -0.687*** |
| | -0.072 | -0.071 | -0.072 | -0.071 |
| Firm Recalls | 0.161** | 0.135* | | |
| | -0.054 | -0.054 | | |
| Competitor Recalls | 0.073*** | 0.242*** | | |
| | -0.007 | -0.027 | | |
| Competitor Number | | 0.244*** | | |
| | | -0.026 | | |
| Competitor Recalls X Competitor Number | | -0.040*** | | |
| | | -0.006 | | |
| No MAUDE Firm Recalls | | | 0.141 | 0.143 |
| | | | -0.086 | -0.091 |
| No MAUDE Competitor Recalls | | | 0.213*** | 0.645*** |
| | | | -0.021 | -0.09 |
| Competitor Number | | | | 0.247*** |
| | | | | -0.027 |
| No MAUDE Competitor Recalls X Competitor Number | | | | -0.103*** |
| | | | | -0.02 |
| Constant | -1.409*** | -1.726*** | -1.456*** | -1.784*** |
| | -0.314 | -0.313 | -0.314 | -0.315 |
| Fixed Effects | RMS F Y | RMS F Y | RMS F Y | RMS F Y |
| Observations | 138863 | 138863 | 138863 | 138863 |
| Adjusted R-squared | 0.089 | 0.093 | 0.087 | 0.092 |

Notes: (1) Negative binomial model regression estimation with half-year interval and lag structures. (2) Dependent variable is count of firm New Product Submissions. (3) All models include regulatory medical specialty (RMS), firm (F), and year (Y) fixed effects. (4) Firm Recalls and Competitor Recalls are Class I or Class II. No MAUDE Recalls are Class I and II Firm Recalls and Competitor Recalls that have no MAUDE associated with the recall. (5) Product Age, Firm Public, Firm Experience, Firm Products, Firm Recalls, Competitor Recalls, and Competitor Number are lagged. (6) Product Age, Firm Experience, Firm Products, and Competitor Number are logged. (7) Inclusion in the analysis sample requires: (a) at least one recall occurs in product code over sample timeframe and (b) at least one competitor firm submission occurs in product code over sample timeframe.
Standard errors in parentheses, + p<0.10, *p<0.05, **p<0.01, ***p<0.001