Disclosure and Innovation*

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Abstract

This paper studies how the disclosure of product quality information impacts innovation. In the United States, medical device firms are required to report product malfunctions and injuries to the FDA and to a public adverse events regulatory database. However, historically, firms could choose to exclude certain adverse events from the public database, opting instead to report them to a private FDA database. Beginning in 2019, this private data became accessible to the public. We analyze how the inability of incumbents to withhold negative product quality information (the "disclosure effect") and resulting shift in learning opportunities for entrants (the "learning effect") shifted the rate and direction of subsequent medical innovation. Additionally, we consider spillovers effects across product markets and firms.

JEL Classifications: O310; D830; L640
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Extended Abstract

Firms' innovation choices depend on available information. This necessity generates a tension. On the one hand, successful innovation requires being able to learn from others, including the directions of their efforts and both positive and negative outcomes. Yet, on the other hand, profiting from innovation requires some control over information emanating from one's own effort (Teece, 1986). The patent system attempts to remedy this tension for technological information by mandating disclosure of patented technologies but guaranteeing time-limited exclusivity of use. An active literature in strategy and economics continues to grapple with the relationship between disclosure and innovation (Chondrakis et al., 2021; Baruffaldi et al., 2023; Furman et al., 2021; Kankanhalli et al., n.d.; Kim and Valentine, 2021; Lück et al., 2020; Gross, 2022).

In this paper, we examine how the elimination of a channel through which innovating firms could withhold adverse product event information affects subsequent innovation. We theorize two potential channels through which such effects could materialize. First, firm choosing subsequent innovation effort, since they are no longer able to withhold any potential future negative product information, may decrease their innovative effort in the affected product markets. We call this channel the "disclosure effect." We expect this channel to decrease innovation in product markets most exposed to information withholding pre-shock. We also expect the disclosure effect to be strongest in incumbent firms, who were the firms able to withhold adverse events pre-shock. A second channel through which inability to withhold negative product information could affect innovation is via a "learning effect". That is, firms may change their innovation choices because they have more information post-shock about the negatives relating to particular products made by other firms. Again, this should decrease innovation in affected product markets, but here we would expect this effect to be most salient for entrant firms.

We investigate this relationship using data from the U.S. medical device industry, focusing

on innovations first marketed in the time window from 2000 to 2023. We identify a exogenous decrease in firms' ability to withhold negative product information using the public release and simultaneous discontinuation of the Alternative Summary Report (ASR) data, a selected set of medical device adverse events that were not publicly disclosed, in June 2019. Our core datasets include the ASR data, which allows us to identify product markets exposed to the shock, the publicly disclosed adverse events data, MAUDE (Manufacturer and User Facility Device Experience), and, to track innovation, the Premarket Approvals data (PMA) and 510(k) Premarket notification datasets, which collectively track all new medical devices approved or cleared for marketing by the FDA. We use both FDA datasets and data available from Evaluate Medtech to capture innovation information.

The ASR data were released in June 2019 as a result of a Kaiser Health News (KHN) report in March 2019, which made the existence of this database public knowledge. The ASR was started in 1999 ostensibly as a way to relieve administrative burden of the FDA owing to high volumes of adverse events. As a response to the KHN report, the FDA posted all of the ASR data and eliminated the program. By the time it was eliminated, ASR applied to 102 product codes, compared to over 4,000 in MAUDE, and included over 5.8 million reports to from its initiation in 1999 until its termination in June 2019, compared with the 8.2 million events in the public database MAUDE over the same time period (Galasso and Luo, 2024). One example of a product code in ASR is medical staplers. Figure 1 details the number of adverse events in MAUDE (public) versus ASR (private) for 2000-2023.

We include in our sample the set of firm-product markets with at least one adverse event (captured in MAUDE or ASR) prior to 2019. Our core treatment measure is at the product market level, where we classify a product market as having "High Exposure" if it had at least one adverse event in the ASR database, which we further disaggregate into focal firm ASR adverse event versus other firm. Our final dataset includes 936 firms and 3349 product markets, and 16,796 firm-product markets. Our unit of observation is the firm-product market-year. Our analytical sample is 345,670 observations. We observe (Table 1) that on

average 8 percent of firm-product market-years have High Exposure and 5 percent have at least one new medical device approval.

To examine how the ASR shock affected innovation, we implement a DID specification which compares firm-product markets with High Exposure to those without any adverse events in ASR before and after the ASR release in 2019. Our main regressions are OLS and include firm-product market and year fixed effects and firm-product market clustered standard errors.

We find that the ASR release is associated with a decline in approved medical devices. Column 1 in Table 2 shows that among affected firm-product markets, there is a 0.02 percentage point (or a 47 percent) decrease in the likelihood of any medical device approval. Columns 2 and 3 show that these effects are larger when the adverse event(s) in ASR belong to the focal firm. We further estimated an event study version of this result. Providing support for our identification strategy, Figure 2 shows that the likelihood of any medical device associated any given firm-product market declines following the ASR's public release.

Beyond direct effects on treated product markets, we also investigate if there are spillover effects to related product markets. To do so, we used data on predicate devices.[1] If devices in one product market serve as predicates for the other—that is, if the devices are "substantially equivalent" enough in technology or design per the FDA to serve as the basis for regulatory clearance of a device across product classes—we consider a product market as related. Using this measure, Table 3 documents the presence of meaningful spillover effects: Column 1 shows that the use of adverse events in ASR in different, but technologically similar product markets can lead firms to lower their level of innovation. Further, we expect that negative effects would be strongest when the focal firm has had no experience in the related product

[1]The US FDA regulates medical devices and categorizes them into three classes: *Class I* are low-risk devices, mainly subject to basic controls and typically not subject to FDA notification before marketing; *Class II* are medium-risk devices, often requiring a Pre-Market Notification process (known as 510(k)), in which manufacturers need to show that their device is substantially equivalent to a device that is already on the market; and *Class III* are high-risk devices which have to undergo a more stringent Pre-Market Approval (PMA) process, i.e., clinical trials to prove safety and effectiveness. Most devices are Class II, where manufacturers are required to demonstrate that their proposed device is "substantially equivalent" to a previously approved device, known as a "predicate" device.

market, as the release of information within ASR would less likely to be known ex-ante. Column 2 confirms this expectation: spillover effects are less negative when the firm has had at least one approval in the linked product market.

The decline in medical device approvals following ASR's public release could result from two effects: the inability of incumbents to withhold negative product quality information (the "disclosure effect") and resulting shift in learning opportunities for entrants (the "learning effect"). To investigate these, we categorize firms into by their pre-shock, those will relatively little experience ("entrants") and those with more device experience ("incumbents"), as proxied by the 90th percentile of medical device approvals in the focal product market prior to 2019 (or approximately 4 approvals). Figure 3 presents coefficients from regressions that are fully saturated with controls (for detailed estimates, see Table 4). The figure indicates that the impact of ASR's public release is noticeably different for the two firm types: entrants experience little change in the likelihood of a medical device approval, while incumbents are significantly more likely to lower their approvals. These findings are consistent with the view that firm concerns about disclosing negative information (which may dampen current and future demand) may lead firms to withhold investment in additional approvals.

In the next iteration of our ongoing work on this project, we plan to bring increased rigour to our existing sets of analysis, using a more carefully constructed control group (i.e., better accounting for any selection into treatment) and exploring different sources of variation in exposure to treatment, as well as providing additional tests of the disclosure and learning effects of the ASR shock on innovation in medical devices.

In sum, we find that firms decrease their innovative efforts after they can no longer expect to withhold negative information. Even an associated public release of negative information, and the potential learning effects of such disclosure, does not seem to counteract the overall negative effects on innovation in exposed product markets. Our research thus contributes to the larger literature on the relationship between disclosure, and in particular the ability to withhold negative information, and innovation.

References

Baruffaldi, Stefano, Markus Simeth, and David Wehrheim, "Asymmetric Information and R&D Disclosure: Evidence from Scientific Publications," *Management Science*, March 2023. Publisher: INFORMS.

Chondrakis, George, Carlos J. Serrano, and Rosemarie H. Ziedonis, "Information disclosure and the market for acquiring technology companies," *Strategic Management Journal*, 2021, *42* (5), 1024–1053.

Furman, Jeffrey L., Markus Nagler, and Martin Watzinger, "Disclosure and Subsequent Innovation: Evidence from the Patent Depository Library Program," *American Economic Journal: Economic Policy*, November 2021, *13* (4), 239–270.

Galasso, Alberto and Hong Luo, "Product Liability Litigation and Innovation: Evidence from Medical Devices," March 2024.

Gross, Daniel P., "The Hidden Costs of Securing Innovation: The Manifold Impacts of Compulsory Invention Secrecy," *Management Science*, June 2022. Publisher: INFORMS.

Kankanhalli, Gaurav, Alan Kwan, and Kenneth Merkley, "The Paradox of Innovation Non-Disclosure: Evidence from Licensing Contracts," *American Economic Journal: Applied Economics.*

Kim, Jinhwan and Kristen Valentine, "The innovation consequences of mandatory patent disclosures," *Journal of Accounting and Economics*, April 2021, *71* (2), 101381.

Lück, Sonja, Benjamin Balsmeier, Florian Seliger, and Lee Fleming, "Early Disclosure of Invention and Reduced Duplication: An Empirical Test," *Management Science*, June 2020, *66* (6), 2677–2685. Publisher: INFORMS.

Teece, David, "Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy," *Research Policy*, December 1986, *15* (6), 285–305.

1 Figures and Tables

Figure 1: Differences in ASR and MAUDE: Stapler Example

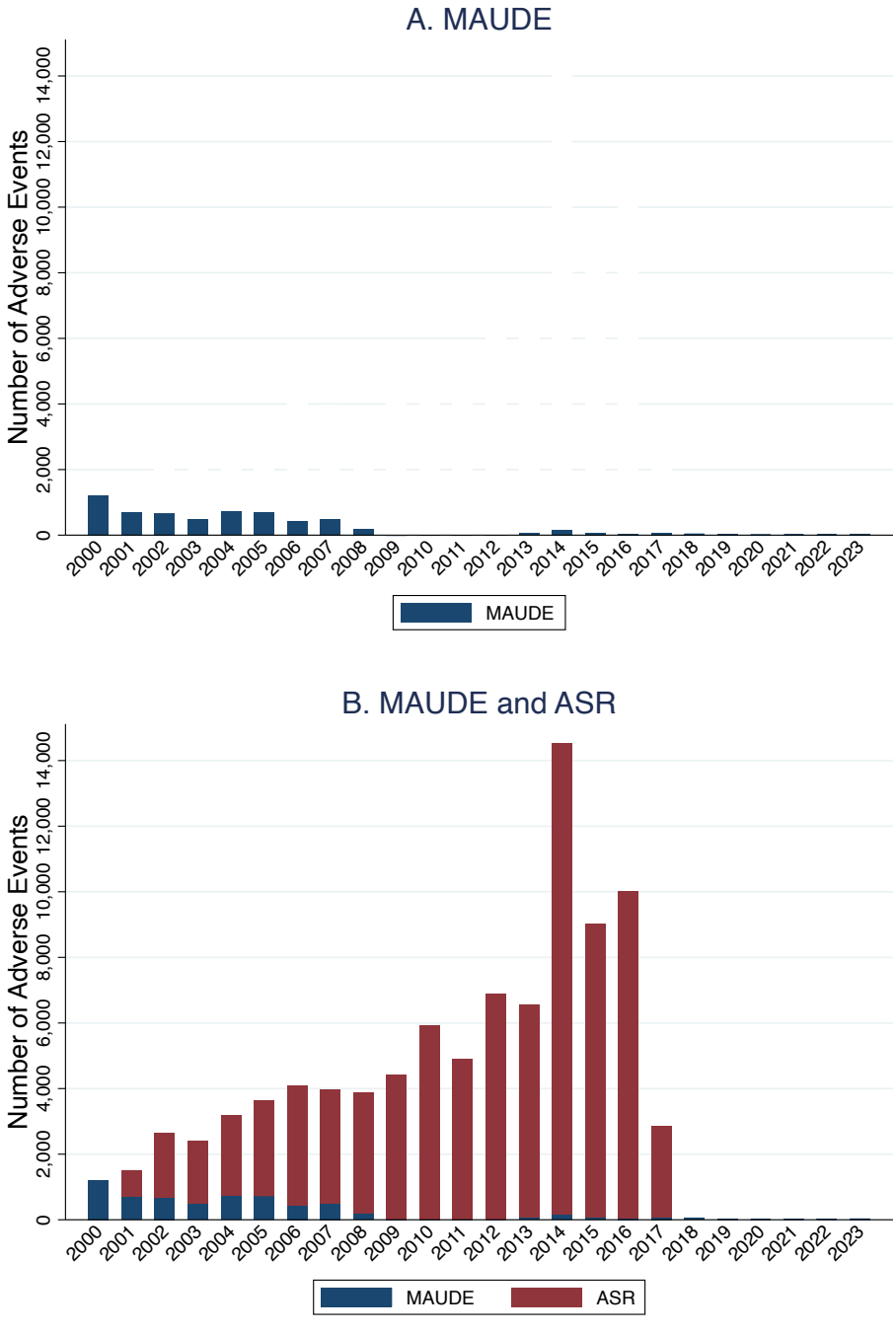


Table 1: Summary Statistics: Firm-Product Market-Year Level

	mean	sd	min	max
High Exposure	0.08	0.28	0	1
High Exposure (Focal Firm)	0.01	0.10	0	1
High Exposure (Non-Focal Firm)	0.07	0.26	0	1
Any Application	0.05	0.21	0	1
Nb. Application	0.07	0.39	0	20
Year	2013.11	6.04	2003	2023

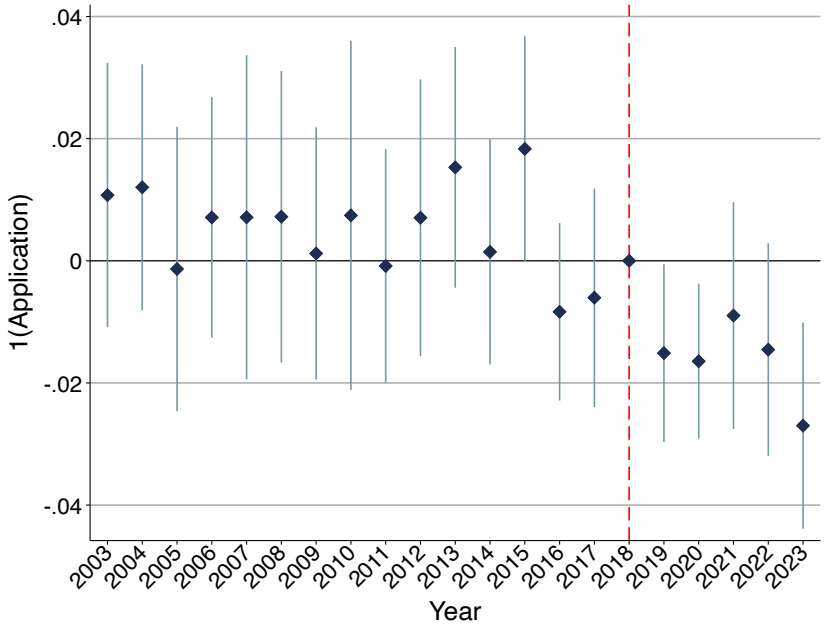
Note: Observations at the firm-market-year level.

Table 2: Impact of ASR Release on Medical Device Approvals

	(1)	(2)	(3)
VARIABLES	1(App)	1(App)	1(App)
Post x High Exposure	-0.0212***		
	(0.00597)		
Post x High Exposure (Focal Firm)		-0.0359***	
		(0.0124)	
Post x High Exposure (Non-Focal Firm)			-0.0187***
			(0.00584)
Observations	345,760	345,760	345,760
R-squared	0.308	0.308	0.308
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.0455	0.0455	0.0455

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Figure 2: Impact of ASR Release on Medical Device Approvals



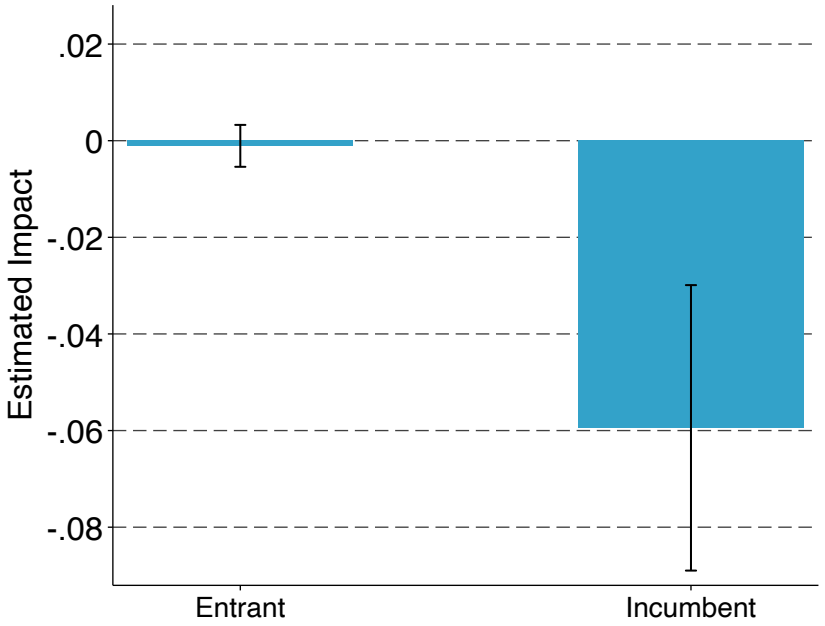
Note: Controls include Firm-Market FE, Year FE. SE clustered at the Firm-Market level.

Table 3: Impact of ASR Release on Medical Device Approvals, ASR Linked by Predicate

VARIABLES	(1) 1(App)	(2) 1(App)
Post x Any ASR in Linked PC	-0.0450***	-0.121***
	(0.00517)	(0.0329)
Post x Any ASR in Linked Market x Any Firm Exp in Linked Market		0.0765**
		(0.0321)
Observations	345,760	345,760
R-squared	0.309	0.309
Year FE	YES	YES
Firm-PC FE	YES	YES
Mean of Dep. Var.	0.0455	0.0455

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Figure 3: Impact of ASR Release: Heterogeneity by Firm Type



Note: Controls include Firm-Market FE, Year FE. SE clustered at the Firm and PC level.

Table 4: Impact of ASR Release: Heterogeneity by Firm Type

VARIABLES	(1) Entrant	(2) Incumbent
Post x High ASR Exposure	-0.00209	-0.0574***
	(0.00195)	(0.0129)
Observations	374,748	62,541
R-squared	0.080	0.196
Year FE	YES	YES
Firm-PC FE	YES	YES
Cluster SE	FIRM-PC	FIRM-PC
Mean of Dep. Var.	0.0125	0.244

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1