ONLINE APPENDIX

Product Liability Litigation and Innovation: Evidence from Medical Devices

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A. Theoretical model

Our modeling approach follows Waldman (1993) and considers a monopoly producer in a market that lasts two periods. We first present the basic model consistent with Waldman (1993) and then extend it by adding considerations of product liability litigation.

A.1. The Basic Model

In the first period, the firm sells products of type A. The products are perfectly durable and provide utility to consumers in periods 1 and 2. In the second period, the firm decides whether to introduce a new version of the product, which we refer to as type B. Each unit of the product is produced at marginal cost c. There are two groups of consumers. Consumers of group 1 are present in the market in periods 1 and 2. Consumers of group 2 are present in the market only in the second period. Each group has a size of N. Consuming technology $k = A, B$ in period $t = 1, 2$ gives consumers utility $V_k + N_k^t$, where the term N_k^t captures network effects linked to the total number of individuals using product k in period t. These network externalities are not necessary to derive our results, but we include them in the model for consistency with Waldman's framework. As does Waldman (1993), we assume that the firm can perfectly price discriminate and that there is no discounting.

In this setting, if the firm sells product A to all N consumers of group 1 in period 1, the following surplus is generated in the first period: $(V_A + N - c)N$. Still following Waldman (1993), we assume that all individuals of group 1 consume in the first period and focus on the decision to introduce the new version of the product in period 2. We assume that the firm can offer a lower price to group 1 consumers if they trade in their version of product A and purchase version B.

Consider first the case in which the firm chooses not to offer product B and simply continues to sell product A in the second period. If all N consumers of group 2 buy the product, the firm generates the following second-period surplus by trading with group 2: $(V_A + 2N - c)N$. Under the assumption of perfect price discrimination, this formula also captures the second-period profits the firm generated in the absence of product upgrades.[1]

Consider then the case in which the firm switches to product B. Waldman (1993) shows that this generates second-period profits from group 1 equal to $(V_B - V_A + N - c)N$. To see this, notice that in the second period, group 1 consumers obtain gross utility equal to $V_B + 2N$ if they purchase B and $V_A + N$ if they keep consuming A. This implies that the maximum price, p, that the firm can charge to induce them to switch is

[1] Waldman (1993) shows that these profits are consistent with a Perfectly Coalition Proof Nash equilibrium. Notice that trading to consumers of group 2 also increases the utility of group 1 but this does not translate into a second-period profit flow as there are no transactions with these consumers in period 2.

obtained by solving $V_B + 2N - p = V_A + N$ which yields $p = V_B - V_A + N$. The profits obtained from group 2 consumers by purchasing product B are $(V_B + 2N - c)N$.[2]

The above analysis leads to the following condition for keeping the initial product on the market:

$$V_A > V_B + (N - c)/2. \tag{1}$$

Notice that the inequality is more likely to be satisfied if $V_A - V_B > 0$ (i.e., the alternative version of the product is strictly inferior) and if $N - c < 0$ (the network effects are small relative to the production costs).

A.2. Adding Product Liability Litigation

We now extend the basic model to consider the case in which the firm, when deciding to offer a new version of the product, faces product liability lawsuits against the old product. Such litigation adds several additional considerations, which may influence the likelihood of new product introduction in different directions.

We first consider two effects that would increase the likelihood of introducing the new product. The first is that keeping the old product A on the market would result in greater litigation costs than introducing the new product B (under the assumption that B is safer than A). Specifically, we assume that the baseline litigation cost is L, which the firm needs to pay regardless of product switching. Switching to product B does not add additional costs, but keeping product A on the market results in a total litigation cost of $L + \rho L2N$. Intuitively, we can think of the extra term $\rho L2N$ as the total variable cost of litigation in that each of the $2N$ consumers of the old product may join the litigation with probability ρ and incur a cost of L.[3] The second effect is a reduction in the perceived value of the old product, which becomes $V_A - \Delta$. The term Δ captures consumers' lowered willingness to pay because they know that the product may cause them harm.

With these two effects, the condition required to keep product A on the market becomes:

$$(V_A - \Delta + 2N - c)N - L(1 + \rho 2N) > (V_B - V_A + \Delta + N - c)N + (V_B + 2N - c)N - L, \tag{2}$$

which is simplified to:

$$V_A > V_B + (N - c)/2 + \Delta + L\rho. \tag{3}$$

Notice that compared to equation (1), litigation increases the likelihood of introducing product B through

[2]Notice that in both cases the computation relies on the assumption that consumers expect all other consumers to switch to B. This is also consistent with the Perfectly Coalition Proof equilibrium concept.

[3]Here, we implicitly assume that before the litigation, the firm expects a litigation cost for the old product lower than $\rho L2N$. Otherwise, the firm would have introduced the safer product in the first place. This is plausible as the litigation event per se may increase the firm's perception of the safety profile of its old product. Alternatively, the litigation may make the court more likely to hand out tougher judgments.

two channels. First, as captured by Δ, litigation increases consumers' value for product B relative to product A. Second, as captured by $L\rho$, introducing the new product protects the firm from an increase in the scope of litigation and the associated costs.

The above analysis assumes that product B is safer than product A without extra R&D investment. This may not be the case. Assuming that extra investment is necessary to make product B safer and that the investment is R. Adding R to the right-hand side of equation (2), the condition for keeping the old product on the market becomes:

$$V_A > V_B + (N-c)/2 + \Delta + L\rho - \frac{R}{2N}. \tag{4}$$

Comparing (1) and (4) shows that, in this more generalized extension, the effect of product liability litigation on innovation is ambiguous. Specifically, the likelihood of new product introduction increases when $2N(\Delta + L\rho) > R$ and decreases otherwise. On the one hand, litigation may increase the relative profitability of new products because consumers perceive them as safer and because the new products provide greater protection against additional liability litigation. These benefits need to be balanced against the costs associated with developing a safer version of the product.

B. Data on Mergers and Acquisitions

A complication in linking data on the various variables (e.g., new product applications) to our sample firms comes from the fact that mergers and acquisitions are common in the medical device industry. Furthermore the firm names that show up in the FDA databases (e.g., the applicant of a new device) are often those of the acquired firms even after their acquisitions. For our analysis, we want to count an acquired firm's new product applications as those by the parent firm during the years in which the parent firm owns it. This requires information on the ownership period, which starts from the year of the acquisition. Less frequently, a firm may divest an independent entity or sell it to another firm. For these cases, the spin-off year is the end of an ownership period.

We went through the following three steps to identify firms acquired and spun off by our sample firms and the ownership spells:

1. We first identified the names of firms that were acquired by our sample firms during the sample period. This information was drawn from three different sources: the WRDS Company Subsidiary Data file, Refinitiv (formerly Thomson Financial) M&A data, and the FDA establishment registration

databases.[4] Excluding subsidiaries that bear their parents' names (e.g., Abbott Molecular for Abbott), these databases yielded 4,363 unique subsidiary names associated with our sample firms. The vast majority of these names are alternative spellings or misspellings of the same firms rather than distinct firms.

2. Because finding the information on the starting and ending years of an ownership period requires manual work, we restricted the subsidiary names for further cleaning to a subset of the relatively important ones. We define the importance using the number of times these names show up in the various FDA databases (e.g., whether a subsidiary has applied for a PMA application). Specifically, using a fuzzy matching algorithm, we matched the subsidiary names to four FDA databases—the two application databases (510(k) and PMA) and the two adverse event databases (MAUDE and ASR)—separately. Because there are relatively few unique firms in the PMA and the ASR databases, we kept a subsidiary name for further cleaning provided it was matched to a name in these databases with a similarity score greater than 0.85. Because many more entity names exist in the MAUDE and 510(k) databases, we first dropped names that are not the most active (i.e., the number of times the name shows up in the database is below the 75th percentile). We kept subsidiary names for further cleaning if they were matched to at least one name in the MAUDE or the 510(k) database with a similarity score greater than 0.85. This step yielded 420 unique subsidiary names for further cleaning. Note that many of these are still different spellings of the same firms.

3. For each of the 420 names, we did two things: first, we manually identified the acquisition and spin-off dates using the WRDS Company Subsidiary Data file, the Refinive M&A database, as well as various publicly available news sources. Second, we standardized the spellings of the subsidiary names. Ultimately, we ended up with 254 unique firms that were acquired or spun off by our 45 sample (parent) firms.

Apart from firms acquired by our sample firms, we also manually collected two additional sets of ownership relationships. One is the ownership relationships among the subsidiary firms in our sample. The other is the ownership relationships among the parent firms in our sample. We also collected information on the founding years of firms in our sample. With all of this information in hand, we accounted for these ownership relationships as we created our analysis panel dataset at the parent firm-product code-year level.

[4]The FDA databases contain information on the owner-operators of all registered establishments (which include a firm's subsidiaries as well as related entities such as importers or manufacturers). The two databases that we used are the "Owner Operator" and "Registration" datasets, which are available at https://www.fda.gov/medical-devices/device-registration-and-listing/establishment-registration-and-medical-device-listing-files-download.

Finally, we wanted to note that apart from acquisitions, a firm may also have independent subsidiaries that are recorded as the relevant entity names in the FDA databases. These subsidiaries often bear their parent companies' names and are much easier to identify within the FDA databases. We allocated their applications (and other variables such as adverse events) to the parent firms.

References

Waldman, Michael (1993) "A new perspective on planned obsolescence," *Quarterly Journal of Economics* 108: 273-283

Table A1. Robustness Checks

	(1)	(2)	(3)	(4)	(5)	(6)
	Applications	Application Dummy	Application Dummy	Application Dummy	Exit	Application Dummy
Estimation method	Poisson	OLS	OLS	OLS	OLS	OLS
Litigation	-0.504**		-0.134***	-0.158***	-0.022	-0.133*
	(0.215)		(0.035)	(0.040)	(0.046)	(0.070)
log(Adverse Events + 1)	0.160***	0.010***	0.009***	0.010***	-0.054***	0.001
	(0.014)	(0.002)	(0.002)	(0.002)	(0.002)	(0.003)
log(Cases Filed + 1)		-0.024***				
		(0.008)				
FDA Avg Approval Time			-0.002***			
			(0.001)			
Litigation X Won				0.050		
				(0.067)		
Litigation X Lost				-0.047		
				(0.086)		
Observations	54118	86753	86753	86753	86753	35925

Notes: Robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. All regressions include firm-code and year effects. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Applications = the total number of applications submitted by the firm in a product code in a year. Exit = 1 if at least five years of inactivity subsequent to the last filing. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Cases Filed = the number of new cases filed against the defendant firms in the litigated product code in a given year. FDA Avg Approval Time = the average number of months the FDA takes to approve an application submitted in a product code in a given year. This variable is replaced with zero when no applications are filed in this code-year. A dummy indicating that no applications are filed is also included in this regression. Won = 1 starting from the first year in which the defendant firms won a case, Lost = 1 starting from the first year in which the defendant firms lost a case, and the two variables are not mutually exclusive. Column 6 drops firm-codes that have ever experienced an acquisition.

Table A2. Controlling for Firm-Technology Area-Specific Time Trends

	(1) Application Dummy	(2) Application Dummy	(3) Application Dummy	(4) Application Dummy
Litigation	-0.145***	-0.138***	-0.119***	-0.068*
	(0.039)	(0.041)	(0.044)	(0.038)
Firm-technology-year effects	16 tech areas	73 tech areas	370 tech areas	937 tech areas
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Observations	84633	80376	64966	40579

Notes: OLS regressions with robust standard errors clustered at the firm-code level. *significant at 10% ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Column 1 defines tech areas by the first three digits of the CFR classification scheme, Column 2 defines tech areas by the first four digits of the CFR classification scheme, Column 3 defines tech areas by the first five digits of the CFR classification scheme, and Column 4 defines tech areas by the finest level (all six digits) of the CFR classification scheme.

Table A3: Dynamic Analysis

	(1)	(2)	(3)	(4)	(5)
	Application Dummy	Application Dummy	Application Dummy	Application Dummy	Application Dummy
Litigation	-0.159***	-0.159***	-0.159***	-0.124***	-0.173**
	(0.041)	(0.042)	(0.041)	(0.047)	(0.069)
After Litigation	-0.050		-0.044	-0.043	-0.051
	(0.058)		(0107)	(0.059)	(0.199)
After Litigation X Length			-0.001		
			(0.016)		
After Litigation Year 1		-0.126**			
		(0.061)			
After Litigation Year 2		-0.055			
		(0.073)			
After Litigation Year 3+		-0.005			
		(0.078)			
Year 1 Before End of Litigation				-0.064	-0.019
				(0.048)	(0.099)
Year 2 Before End of Litigation				0.028	-0.151
				(0.039)	(0.120)
Litigation spells included	all	all	all	less than 7 years	more than 7 years
Observations	86753	86753	86753	86365	86187

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. All regressions include firm-code and year effects and control for log(Adverse Events + 1). Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. After Litigation = 1 for years after litigation is concluded. In Column 2, dummy variable After Litigation Year X captures the Xth year after the end of the litigation spell. These "After Litigation Year X" dummies are mutually exclusive of each other, as well as the Litigation dummy. In Columns 3 and 4, dummy variable Year X Before End of Litigation captures xth year before the end of the litigation spell. These two dummies are mutually exclusive of one another, but are additional effect on top of the Litigation dummy. Length = duration of litigation spell in years.

Table A4: Drivers of the Number of Hidden Reports

	(1) Hidden Reports	(2) Hidden Reports	(3) Hidden Reports
Adverse Events	0.889***	0.895***	0.005
	(0.094)	(0.090)	(0.004)
Serious Events	-1.632***	-1.715***	-0.005
	(0.371)	(0.394)	(0.005)
log(Recalls + 1)	-0.061***	-0.063*	0.000
	(0.023)	(0.033)	(0.000)
Firm-code effects	YES	YES	YES
Year effects	YES	YES	YES
Sample	2003-2018 non 12 ASR codes	2003-2018 non 12 ASR codes, more-aware firms	2003-2018 non 12 ASR codes, less-aware firms
Observations	60150	39449	20701

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Hidden Reports = the total number of adverse events reported in the ASR database that are associated with a firm's devices in a product code and a year. Adverse Events = the total number of adverse events associated with a firm's devices in a product code and a year (in thousands). Serious Events = the total number of adverse events involving injuries and deaths associated with a firm's devices in a product code and a year (in thousands). Recalls = the number of Class I and Class II recalls by a firm in a product code in a year. More-aware firms = 1 if the firm operated, during 1995-1999, in the original 12 codes selected by the FDA as the agency initiated the ASR program. Less-aware firms = 1 if the firm didn't operate, during 1995-1999, in the original 12 codes selected by the FDA as the agency initiated the ASR program.

Table A5: Instrumental Variable Regressions

	(1) Application Dummy	(2) Application Dummy	(3) Application Dummy
Litigation (instrumented)	-3.408* (1.814)	-0.724** (0.323)	-1.177* (0.628)
log(Adverse Events + 1)	0.022* (0.012)	0.005* (0.003)	0.018* (0.010)
log(Recalls + 1)	0.027* (0.016)	0.010 (0.007)	0.013** (0.006)
Firm-code effects	YES	YES	YES
Year effects	YES	YES	YES
Instruments	log(Adverse Events/Public Events)	Aware*log(Adverse Events + 1), Aware*log(Serious Events + 1)	PMA*After2008
First stage F-stat	23.596	66.121	28.425
Sample	2003-2018, excluding origional 12 ASR codes	2003-2018, excluding origional 12 ASR codes	PMA codes and high-risk 510(k) codes
Observations	59869	59869	12968

Notes: 2SLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Public Events = the total number of adverse events reported in the MAUDE database that are associated with a firm's devices in a product code and a year. Serious Events = the total number of adverse events involving deaths or injuries associated with a firm's devices in a product code and a year. Aware = 1 if the firm operated, during 1995-1999, in the original 12 codes selected by the FDA as the agency initiated the ASR program. After 2008 = 1 for years after 2008. PMA = 1 if the product code is subject to the Premarket Approval review requirement. Recalls = the number of Class I and Class II recalls by a firm in a product code in a year. High-risk 510(k) are 510(k) product codes with more than 1,000 adverse reports filed during the entire sample period.

Table A6: Litigation and Patenting

	(1)	(2)	(3)	(4)
	Patent Application Dummy	Patent Applications	Safety Patent Application Dummy	Safety Patent Applications
Litigation in Subclass	0.114***	0.628***	0.021*	0.057*
	(0.023)	(0.147)	(0.011)	(0.031)
log(Patent Applications)			0.109***	0.150***
			(0.002)	(0.005)
Year effects	YES	YES	YES	YES
Firm-subclass effects	YES	YES	YES	YES
Observations	255304	255304	255304	255304

Notes: Robust standard errors clustered at the firm-patent technology class level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Patent Application Dummy = 1 if the firm submits at least one patent application in a patent class in a given year. Patent Applications = the number of patent applications filed by the firm in the patent class in a given year. Litigation in Subclass = 1 if there is active litigation against the firm in a year involving the focal patent class. Safety Patent Application Dummy = if the firm applies for at least one safety-related patent application in a patent class and year. We classify a patent as safety-related if its title or abstract includes keywords about either safety (e.g., safe, reliable, integrity) or problems (e.g., error, failure, problem, vulnerability). Safety Patent Applications = the total number of safety-related patent applications by a firm in a patent class in a year. Columns 3 and 4 include control for total patent applications in the year-subclass.