Online Appendix

Appendix 1. Recall Event: Window and Severity

While the 180-day window prior to device application captures the most recent recall activity with meaningful variation across firms, we assess the robustness of Hypothesis 2 using alternative recall windows. Specifically, we re-estimate the models using recall events occurring within 270 days and one year prior to the device application. The results remain consistent with the main findings, as reported in Tables A1.1 and A1.2.

Table A1.1. Interaction Between FDA Lobbying and an Alternative Recall Event Window (270 days) Predicting Time to Approval

	Model 1			Model 2		
Variable	T.R.	S.E.	P-value	T.R.	S.E.	P-value
Lobbying the FDA	0.857*	(0.05)	0.014	0.871*	(0.06)	0.033
Recall event (within 270 days)	0.995	(0.04)	0.891	0.993	(0.04)	0.853
Breakthrough innovation	0.998	(0.00)	0.584	1.023*	(0.01)	0.038
Lobbying the FDA X Recall event (within 270 days)	1.127*	(0.07)	0.044	1.129*	(0.07)	0.039
Lobbying the FDA X Breakthrough innovation				0.973**	(0.01)	0.004
Control Variables Included						
lnsigma	0.786***	(0.01)	0.000	0.786***	(0.01)	0.000
kappa	1.286***	(0.06)	0.000	1.283***	(0.06)	0.000
Constant	80.021***	(11.39)	0.000	80.548***	(11.47)	0.000
Year Effect	Y			Y		
Log-likelihood	-6821.36			-6818.19		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Table A1.2. Interaction Between FDA Lobbying and an Alternative Recall Event Window (1 year) Predicting Time to Approval

	Model 1			Model 2		
Variable	T.R.	S.E.	P-value	T.R.	S.E.	P-value
Lobbying the FDA	0.853*	(0.06)	0.015	0.866*	(0.06)	0.031
Recall event (within 1 year)	0.991	(0.04)	0.831	0.990	(0.04)	0.800
Breakthrough innovation	0.998	(0.00)	0.503	1.023*	(0.01)	0.037
Lobbying the FDA X Recall event (within 1 year)	1.132+	(0.07)	0.051	1.137*	(0.07)	0.041
Lobbying the FDA X Breakthrough innovation				0.972**	(0.01)	0.003
Control Variables Included						
lnsigma	0.786***	(0.01)	0.000	0.786***	(0.01)	0.000
kappa	1.285***	(0.06)	0.000	1.282***	(0.06)	0.000
Constant	79.989***	(11.40)	0.000	80.514***	(11.49)	0.000
Year Effect	Y			Y		
Log-likelihood	-6821.35			-6818.05		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

We further examined whether the moderating effect of recall events varies by FDA severity classification. FDA classifies recalls into three categories based on health risk: Class I (most severe, involving a reasonable probability of serious adverse health consequences or death), Class II (moderate, involving temporary or medically reversible consequences), and Class III (least severe, violating FDA

regulations but unlikely to cause health consequences). Class II recalls account for the majority of medical device recalls in our sample, followed by Class III, with Class I recalls relatively rare.

The results in Table A1.3 reveal that the moderating effect varies by severity in a pattern that is informative for the underlying mechanism. The Lobbying X Class I Recall interaction is not statistically significant (T.R. = 0.958, p = 0.626), the Lobbying X Class II interaction is marginally significant (T.R. = 1.106, p = 0.059), and the Lobbying X Class III interaction is highly significant and largest in magnitude (T.R. = 1.439, p < 0.001).

Table A1.3. Interaction Between FDA Lobbying and Recall Event Severity Predicting Time to Approval

	Model 1			Model 2			Model 3		
Variable	T.R.	S.E.	P-value	T.R.	S.E.	P-value	T.R.	S.E.	P-value
Independent variables									
Lobbying the FDA	0.919+	(0.04)	0.053	0.873*	(0.05)	0.015	0.885*	(0.04)	0.013
Recall event (Class I)	0.923	(0.07)	0.275						
Recall event (Class II)				1.019	(0.03)	0.553			
Recall event (Class III)							0.942	(0.06)	0.345
Interactions									
Lobbying the FDA X Recall event (Class I)	0.958	(0.08)	0.626						
Lobbying the FDA X Recall event (Class II)				1.106+	(0.06)	0.059			
Lobbying the FDA X Recall event (Class III)							1.439***	(0.15)	0.000
Control Variables Included									
lnsigma	0.786***	(0.01)	0.000	0.786***	(0.01)	0.000	0.786***	(0.01)	0.000
kappa	1.293***	(0.06)	0.000	1.289***	(0.06)	0.000	1.283***	(0.06)	0.000
Constant	81.160***	(11.63)	0.000	80.309***	(11.39)	0.000	80.535***	(11.64)	0.000
Year Effect	Y			Y			Y		
Log-likelihood	-6822.81			-6820.99			-6817.86		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

This result initially appears counterintuitive, since one might expect the most severe recalls to produce the strongest moderating effect. We interpret this in two ways that are consistent with our theory. First, as shown in Table A1.4, Class I recalls occur in only 3.24% of device-quarter observations in our sample, which limits statistical power to detect interaction effects even when the true effect may be substantial. Second, and more substantively, our mechanism does not rest on the absolute severity of the underlying harm but on the visibility of the recall as a signal that earlier engagement may have failed to surface foreseeable risks. In particular, Class II recalls are substantially more common than Class I recalls, generating recurring signals that may shape regulators' interpretations of firms' prior lobbying activities. From a reputation-management standpoint, the accumulation of moderate-severity recalls may provide more consistent signals for reevaluating the credibility of a firm's prior engagement than rare but highly severe events. For Class III recalls, although these are less severe, their significant positive moderating effect suggests that even lower-risk compliance problems may negatively influence regulators' perceptions when they recur, as they can indicate broader concerns about organizational quality and oversight. This interpretation aligns with the broader logic of our theory. Regulators are not simply weighing recalls by clinical severity. They are using recall events as reputational cues that prompt reassessment of whether prior interactions provided reliable assurance about a firm's vigilance. Frequent or visible recalls, even when individually less severe, may carry greater interpretive weight in this reassessment process than rare catastrophic events.

Table A1.4. Frequency of Recall Events by Recall Class

Variable	1 (Event)	%	0 (No Event)	%	Total
Class 1 Recall	401	3.24	11,991	96.8	12,392
Class 2 Recall	4,184	33.8	8,208	66.2	12,392
Class 3 Recall	552	4.45	11,840	95.6	12,392

Appendix 2. Innovation Leadership: Alternative Measurements

In the main analysis, we measure innovation leadership using a firm's top 1% breakthrough patents, identified based on forward patent citations within the industry. As a robustness check, we re-estimated the models using alternative thresholds of the top 3% and top 5% of cited patents. The results remain consistent with our primary findings for Hypothesis 3, as reported in Table A2.1. As an alternative measure of innovation leadership, we code the number of Prix Galien Product Awards that a focal device firm has received prior to the submission. The results using this alternative measure remain consistent with our primary findings for Hypothesis 3, as shown in Table A2.2.

Table A2.1. Interaction Between FDA Lobbying and Alternative Breakthrough Innovation Cutoffs Predicting Time to Approval

	Model 1			Model 2		
Variables	T.R.	S.E.	P-value	T.R.	S.E.	P-value
Lobbying the FDA	0.945	(0.04)	0.206	0.956	(0.04)	0.315
Breakthrough Innovation (3%)	1.010*	(0.00)	0.017			
Lobbying the FDA X Breakthrough Innovation (3%)	0.988***	(0.00)	0.000			
Breakthrough Innovation (5%)				1.007+	(0.00)	0.072
Lobbying the FDA X Breakthrough Innovation (5%)				0.991**	(0.00)	0.008
Control Variables Included						
lnsigma	0.786***	(0.01)	0.000	0.786***	(0.01)	0.000
kappa	1.287***	(0.06)	0.000	1.286***	(0.06)	0.000
Constant	81.265***	(11.66)	0.000	81.452***	(11.69)	0.000
Year Effect	Y			Y		
Log-likelihood	-6819.76			-6819.93		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Table A2.2. Interaction Between FDA Lobbying and an Alternative Measure of Innovation Leadership (Cumulative Number of Prix Galien Product Awards) Predicting Time to Approval

	Model 1		
Variables	T.R.	S.E.	P-value
Lobbying the FDA	0.987	(0.05)	0.812
Cumulative number of PG awards	0.992	(0.01)	0.564
Lobbying the FDA X Cumulative number of PG awards	0.939*	(0.03)	0.024
Control Variables Included			
lnsigma	0.692***	(0.02)	0.000
kappa	1.557***	(0.11)	0.000
Constant	164.312***	(28.29)	0.000
Year Effect	Y		
Log-likelihood	-2755.17		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Additionally, we tested an alternative proxy for innovation using the FDA's De Novo classification, which establishes a regulatory pathway for novel medical devices that lack a valid predicate. The FDA introduced this program in 2010 and explicitly frames De Novo classification as a risk-based regulatory determination. This is theoretically distinct from our patent-based innovation leadership measure, which captures externally recognized technological impact rather than a regulatory risk classification. Examining whether De Novo activity produces the same moderating pattern provides a useful contrast to our primary measure. Because relatively few devices enter the De Novo pathway, we

constructed a firm-year count of the cumulative number of De Novo classified devices for each firm and estimated the model on the 2010 to 2022 subsample.

Table A2.3 below reports the interaction between FDA lobbying and cumulative De Novo classifications on time to approval. In contrast to our primary findings using the patent-based measure, De Novo classifications are associated with significantly longer approval times. This divergence is consistent with our theoretical argument. De Novo classification is an FDA risk designation that signals regulatory uncertainty rather than externally validated technological accomplishment. It therefore operates through the regulatory-scrutiny channel rather than the reputational-credibility channel that underlies our innovation leadership construct. Whereas patent-based innovation leadership functions as a positive reputational cue that reinforces regulators' confidence and accelerates review, De Novo status flags a firm that tends to submit more risky applications, which heightens precautionary scrutiny and lengthens review. The contrast supports the discriminant validity of our innovation leadership measure: the accelerating effect we document is specific to reputational signals of technological accomplishment and does not extend to regulatory markers of novelty or risk.

The FDA also introduced the Breakthrough Devices Program in 2018. Restricting the sample to the period in which the program operated (2018 to 2022) substantially reduces the sample to 1,340 device-quarter observations from 79 firms. Within this restricted sample, the interaction between FDA lobbying and Breakthrough Device Designation could not be estimated.

Table A2.3. Interaction Between FDA Lobbying and an Alternative Measure of Innovation Leadership (Cumulative Number of De Novo Classifications) Predicting Time to Approval

		Model 1	
Variables	T.R.	S.E.	P-value
Lobbying the FDA	0.933	(0.05)	0.231
Cumulative number of De Novo Classification	0.843	(0.05)	0.001
Lobbying the FDA X Cumulative number of De Novo Classification	1.138*	(0.06)	0.021
Control Variables Included			
lnsigma	0.716***	(0.02)	0.000
kappa	1.524***	(0.10)	0.000
Constant	146.681***	(25.03)	0.000
Year Effect	Y		
Log-likelihood	-3797.97		

Note. Device-quarter observations=7,846; 149 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Appendix 3. FDA Committee Membership: Controlling for Trust but not Reputation

We theorize that lobbying the FDA shapes trust within the regulator-firm relationship and that subsequent reputational shocks can affirm or violate that trust through betrayal aversion and the halo tax. Because innovation leadership is an audience-visible cue operating outside the dyadic regulator-firm relationship, we conducted additional tests to confirm that relational trust cues do not account for our results. We use FDA committee membership as a proxy for dyadic trust, since it captures direct, sustained engagement between a firm and the regulator less directly tied to broad audience evaluations than recalls or innovation awards. Although this variable is already included as a control in our main models, we re-estimated our specifications with it interacted with FDA lobbying. The logic is straightforward: if the H2 and H3 moderating effects were driven by dyadic trust rather than audience-level cues, modeling the FDA lobbying X FDA committee-membership interaction should absorb explanatory power and attenuate our focal interactions.

The results, reported in Table A3, do not support this alternative explanation. The Lobbying X Breakthrough Innovation interaction remains stable and significant across all three specifications (T.R. = 0.973, p = 0.003, Model 1; T.R. = 0.972, p = 0.003, Model 2; T.R. = 0.971, p = 0.004, Model 3), and the Lobbying X Recall Event interaction remains significant when the committee-membership interaction is included (Model 3). The Lobbying × FDA Committee Membership interaction is only marginally significant and does not displace either focal interaction. Our findings show that the H2 and H3 interactions retain their magnitude and significance even after explicitly modeling the dyadic-trust interaction. This pattern supports our theoretical claim that these effects operate through audience-visible reputational cues rather than solely through the private trust embedded in the regulator-firm relationship.

Table A3. Interaction Between FDA Lobbying and Innovation Leadership, Controlling the Interaction of FDA Lobbying and FDA Committee Membership

	Model 1			Model 2			Model 3		
Variable	T.R.	S.E.	P-value	T.R.	S.E.	P-value	T.R.	S.E.	P-value
Independent variables									
Lobbying the FDA	0.934	(0.04)	0.122	0.979	(0.05)	0.675	0.923	(0.06)	0.193
Recall event	1.036	(0.03)	0.260	1.035	(0.03)	0.282	1.006	(0.03)	0.851
Breakthrough innovation	1.022*	(0.01)	0.040	1.023*	(0.01)	0.041	1.024*	(0.01)	0.039
FDA committee membership	0.981	(0.05)	0.712	1.034	(0.06)	0.581	1.033	(0.06)	0.580
Interactions									
Lobbying the FDA X Recall event							1.125*	(0.06)	0.031
Lobbying the FDA X Breakthrough innovation	0.973**	(0.01)	0.003	0.972**	(0.01)	0.003	0.971**	(0.01)	0.004
Lobbying the FDA X FDA committee membership				0.871+	(0.07)	0.096	0.867+	(0.07)	0.092
Control Variables Included									
lnsigma	0.786***	(0.01)	0.000	0.785***	(0.01)	0.000	0.785***	(0.01)	0.000
kappa	1.290***	(0.06)	0.000	1.289***	(0.06)	0.000	1.282***	(0.06)	0.000
Constant	81.384***	(11.65)	0.000	82.482***	(11.95)	0.000	81.670***	(11.76)	0.000
Year Effect	Y			Y			Y		
Log-likelihood	-6819.84			-6818.00			-6815.76		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Appendix 4. Linear 2SLS Estimates and IV Diagnostics

Standard post-hoc IV diagnostics (e.g., Kleibergen-Paap, Cragg-Donald, Anderson-Rubin) are derived under the assumption of linear second-stage estimation and are not available for the non-linear AFT control-function specification reported in Table 3. To provide direct evidence on instrument strength and relevance, we re-estimated the IV analysis using a linear 2SLS specification at the firm-year level with the full set of post-hoc IV diagnostics.

Table A4 below reports the second-stage 2SLS estimates with IV diagnostics. The second-stage coefficient indicates that lobbying the FDA is associated with approval approximately 38.67 days earlier ($p < 0.01$), consistent in direction with our main AFT results. In other words, a one-unit increase in lobbying (from 0 to 1, since lobbying is binary) is associated with approval that is 38.67 days earlier.

Also, the instrument is strong and relevant: the first-stage F statistic (30.62) exceeds the Stock-Yogo 10% maximal IV size critical value (16.38; Stock & Yogo, 2002), the Kleibergen-Paap rk LM statistic rejects underidentification ($\chi^2 = 13.48$, $p < 0.001$), and the Cragg-Donald Wald F (688.11) and Kleibergen-Paap rk Wald F (30.62) statistics both exceed conventional thresholds. The weak-instrument-robust Anderson-Rubin test rejects the null ($\chi^2 = 5.60$, $p = 0.018$), and the endogeneity test confirms that lobbying is endogenous ($\chi^2 = 6.63$, $p = 0.010$).

We retain the AFT control-function estimates as our preferred specification in the main text because the duration structure of the outcome is appropriate for our research question. The linear 2SLS estimates and diagnostics reported here provide supporting evidence that the instrument is strong.

Table A4. Second-Stage 2SLS Estimates and Diagnostic Tests Predicting Time to Approval

Variable	Coef.	S.E.
(Instrumented) Lobbying the FDA	-38.67**	(13.96)
Control Variables Included		
Constant	83.11***	(18.31)
Diagnostic tests		
First-stage F statistic	30.62	
Stock-Yogo 10% maximal IV size critical value	16.38	
Kleibergen-Paap rk LM statistic (underidentification)	13.48 ($p < 0.001$)	
Cragg-Donald Wald F statistic (weak identification)	688.11	
Kleibergen-Paap rk Wald F statistic (weak identification)	30.62	
Anderson-Rubin Wald test	Chi-sq = 5.60 ($p = 0.018$)	
Stock-Wright LM S statistic	Chi-sq = 7.67 ($p = 0.006$)	
Endogeneity test	Chi-sq = 6.63 ($p = 0.010$)	

Note. Firm-year observations=5,720; 224 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Appendix 5. Sample Window and Firm Locations

Pandemic-period robustness tests. One important consideration was to account for the potential impact of COVID-19 on the device approval process, particularly during 2020-2021. We first exclude observations from 2020–2021 and re-estimate all models to assess whether the results are influenced by pandemic-related disruptions. The results remain consistent with our primary findings, indicating that the observed effects are not driven by pandemic-period anomalies. Second, we estimate the models using only pandemic-period observations (2020-2021), treating COVID-19 as a distinct institutional context. Further, rather than restricting the sample period, we construct a binary indicator for the pandemic period (2020–2021) and estimate models that include interactions between FDA lobbying and this indicator to test whether the effect of lobbying on approval time differs during the pandemic. These analyses do not yield statistically significant differences in approval time.

To better understand how the pandemic affected firms' regulatory strategies, we conduct two-sample t-tests comparing firms' propensity to lobby the FDA before versus during the pandemic. The results indicate that there was a statistically significant decline in lobbying targeting the FDA during the pandemic, as shown in Table A5. The mean lobbying indicator decreases from 0.191 in the pre-pandemic period to 0.117 during the pandemic, a difference of 7.4 percentage points ($t = 6.27$, $p < 0.001$). This suggests that while the pandemic did not meaningfully alter the effect of lobbying on approval time, it significantly constrained firms' engagement in lobbying activities.

Patent citation window. We accounted for the five-year citation window used to identify breakthrough patents in our patent-based innovation leadership variable. Although the sample includes device applications from 2002 to 2021, patent data were collected through 2022, which means that patents granted after 2017 do not have a full five-year citation period and instead have only one- to four-year citation counts. To ensure consistent measurement, we analyzed the models excluding observations from 2018–2021. The results remain consistent with the primary findings.

Colocation with the FDA. Finally, to account for the potential effect of geographic proximity to the FDA, we include a control indicating whether a firm is headquartered in Maryland (coded as 1 and 0 otherwise). Results remain consistent with the primary findings.

Table A5. Comparison of Key Variables Before and During the COVID-19 Pandemic

Variable	Pre-Pandemic Mean (N = 17,821)	Pandemic Mean (N = 1,150)	Mean Difference	t-statistic	p-value
Time to Approval	66.22	61.99	4.23	1.60	0.110
Lobbying the FDA	0.191	0.117	0.074	6.27	< 0.001
Recall Event	0.346	0.383	−0.037	−2.56	0.011
Innovation Leadership	0.642	0.408	0.234	2.23	0.026

Appendix 6. Device Specialty Area

Regulatory scrutiny and risk profiles may vary across device categories. To explore this heterogeneity, we estimate models that interact FDA lobbying with device specialty indicators. The results show statistically significant variation across specialties. In several areas, such as Microbiology, Obstetrics/Gynecology, Physical Medicine, and General & Plastic Surgery, lobbying is associated with significantly faster approval times, whereas in Clinical Toxicology devices, lobbying is associated with significantly longer approval times. These patterns suggest that the influence of lobbying on approval speed differs across specialty areas. Therefore, by controlling for device specialty areas, we account for systematic heterogeneity in regulatory scrutiny across specialties, reducing the likelihood that specialty-specific factors drive the observed effects. The results are reported in Table A6.

Table A6. Interaction Between FDA Lobbying and Device Specialty Areas Predicting Time to Approval

	Model 1		
Variables	T.R.	S.E.	P-value
Independent variables			
Lobbying the FDA	1.110	(0.14)	0.399
Device category: Clinical chemistry	0.712**	(0.09)	0.008
Device category: Cardiovascular	0.728***	(0.07)	0.001
Device category: Dental	0.893	(0.12)	0.384
Device category: Ear, nose, & throat	0.743	(0.16)	0.158
Device category: Gastroenterology & Urology	0.756**	(0.07)	0.004
Device category: Hematology	0.998	(0.34)	0.995
Device category: General Hospital	0.772*	(0.09)	0.020
Device category: Immunology	1.500**	(0.19)	0.002
Device category: Microbiology	0.870	(0.09)	0.173
Device category: Neurology	0.829+	(0.09)	0.076
Device category: Obstetrics/Gynecology	1.137	(0.17)	0.392
Device category: Ophthalmic	0.887	(0.16)	0.507
Device category: Orthopedic	0.778**	(0.07)	0.003
Device category: Physical medicine	0.886	(0.12)	0.388
Device category: Radiology	0.524***	(0.06)	0.000
Device category: General & Plastic surgery	0.723**	(0.08)	0.002
Device category: Clinical toxicology	0.836	(0.24)	0.542
Interactions			
Lobbying the FDA X Clinical chemistry	1.262	(0.19)	0.127
Lobbying the FDA X Cardiovascular	0.783+	(0.10)	0.057
Lobbying the FDA X Dental	1.315	(0.24)	0.134
Lobbying the FDA X Ear, nose, & throat	1.021	(0.32)	0.948
Lobbying the FDA X Gastroenterology & Urology	0.818	(0.13)	0.199
Lobbying the FDA X Hematology	1.588	(0.74)	0.319
Lobbying the FDA X General Hospital	0.960	(0.15)	0.798
Lobbying the FDA X Immunology	0.821	(0.24)	0.499
Lobbying the FDA X Microbiology	0.676*	(0.11)	0.019
Lobbying the FDA X Neurology	0.737	(0.21)	0.293
Lobbying the FDA X Obstetrics/Gynecology	0.450*	(0.17)	0.037
Lobbying the FDA X Ophthalmic	1.000	(0.00)	.
Lobbying the FDA X Orthopedic	0.878	(0.12)	0.339
Lobbying the FDA X Physical medicine	0.243***	(0.08)	0.000
Lobbying the FDA X Radiology	0.952	(0.13)	0.718
Lobbying the FDA X General & Plastic surgery	0.630*	(0.12)	0.014
Lobbying the FDA X Clinical toxicology	1.931*	(0.62)	0.040
Control Variables Included			
lnsigma	0.783***	(0.01)	0.000
kappa	1.283***	(0.06)	0.000
Constant	78.132***	(11.33)	0.000
Observations	12,392		
Year Effect	Y		

Note. Device-quarter observations=12,392; 225 firms; Firm clustered standard errors in parentheses (two-tailed test). *** p<0.001, ** p<0.01, * p<0.05, + p<0.10.

Appendix 7. Interview descriptions
Recruitment Message:

Good afternoon,

We are conducting academic research about how the FDA evaluates medical device companies, particularly in the context of product recalls and subsequent engagement by those firms.

I'm reaching out to see if you would be willing to speak with me about how the FDA approaches the medical device review process, how interactions with companies are handled—both before and after recalls—and how corporate outreach or advocacy efforts are interpreted by FDA officials.

Your insights would be incredibly valuable to this research. The conversation would remain strictly confidential, and any information you provide will be anonymized and used solely for academic purposes. I'd also be happy to share the interview questions in advance for your review.

Participation is entirely voluntary, and you are free to skip any questions or end the interview at any time.

Please let me know if you'd be open to a brief conversation. I'm happy to schedule at your convenience.

Interview Questions (former regulators):

1. Can you describe your experience working with the FDA's medical device review and approval process? What roles have you played in that process?
2. How would you describe the FDA's role in the medical device review process? How is that role communicated externally to firms? How does the FDA communicate this role internally?
3. From your experience, how do companies typically approach the FDA during the review process? What kinds of strategies or interactions are common?
4. Have you had experience with companies or industry groups engaging the FDA through advocacy or outreach efforts? How are these interactions typically perceived internally?
5. From your perspective, what are companies typically trying to achieve when they engage with the FDA after a product issue or in the context of a regulatory challenge?
6. Can you walk me through your experience with medical device recalls? In your view, do recalls affect how the FDA engages with or perceives a company over time?
7. Is there anyone else that you can think of that we could talk to?

Interview Questions (industry lobbyists):

1. Can you briefly describe your role and how you have been involved in the FDA medical device approval process?
2. When medical device companies lobby the FDA, what does that typically look like in practice—where do these interactions occur, and who is usually involved in the conversations?
3. What kinds of information are shared in lobbying interactions beyond what appears in the formal device application—for example, what gets discussed with agency staff in these meetings?
4. From your perspective, what do regulators get out of these lobbying interactions—what is the value to them, if any?
5. How would you describe the balance between information provision and relationship-building in these meetings?
6. To what extent do trust and reputation, either of the firm or of the lobbyist, matter for getting meetings and for how these conversations unfold?
7. How, if at all, do adverse events such as product recalls change the tone or content of lobbying conversations with regulators, compared to more routine interactions?

Interview Analysis

We recorded each interview and analyzed the transcripts using an inductive approach. After each interview, we prepared detailed notes, which we reviewed multiple times to identify patterns in how respondents described lobbying, recalls, firm reputation, and decision timing. Three themes were consistent across the interviews. First, respondents described FDA engagement as ongoing problem solving rather than a discrete attempt to influence a single application. Industry respondents emphasized access, explanation, and the commercial cost of delay, while former regulators emphasized whether engagement helped clarify the review path and resolve uncertainty. Second, respondents described recalls as cues that can change how firms are viewed during later review, particularly when adverse events raise questions about quality systems, responsiveness, or risk-management capacity. Third, the interviews complicate a simple account in which lobbying uniformly accelerates review. Several respondents described engagement as useful when it clarifies uncertainty, but potentially counterproductive when it appears to pressure the agency or minimize safety concerns. We use these interviews as illustrative evidence that helps interpret the approval-time results, not as a stand-alone qualitative test of the theory.