Information and Market Adjustment After Entry: Evidence from FDA Accelerated Approval

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Abstract

When products enter the market before their quality is fully known, demand is shaped by incomplete information and may adjust as new evidence resolves that uncertainty. I study how prescription drug utilization responds to this information using the FDA's Accelerated Approval pathway, where drugs can be used while confirmatory evidence on clinical benefit is still being generated. I construct a new product-level dataset linking Accelerated Approval products to the direction and publication timing of confirmatory evidence and subsequent regulatory outcomes, and merge it with national quarterly Medicaid utilization from 2008Q1 through 2022Q4. Using staggered event studies, I find that unfavorable confirmatory evidence is followed by a substantial decline in utilization: log utilization falls by 0.48 log points on average over the first five quarters and by 0.77 log points over the first nine, equivalent to roughly 38% and 54% on the exponential scale. The decline remains large when I restrict the sample to periods before each product's recorded final regulatory resolution, indicating that the pattern is not driven by post-resolution utilization. Favorable evidence is associated with higher utilization in the baseline specification, but the increase begins before formal publication and is not present in the pre-resolution sample. The results suggest that unfavorable post-approval evidence can induce meaningful market adjustment before final regulatory resolution. This strengthens the case for timely confirmatory trials, transparent dissemination of their results, and prompt regulatory action when warranted.

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1 Introduction

In prescription drug markets, treatment decisions can be made before all uncertainty about a drug's clinical value has been resolved. This is important because new evidence may arrive after a drug is already being prescribed, changing the information available to physicians, patients, and payers even though the product itself has not changed. In this paper, I study how drug utilization responds when this new clinical evidence becomes available after approval.

I use the FDA Accelerated Approval (AA) pathway as the setting for the analysis. Under this pathway, an indication can be approved using a surrogate or intermediate endpoint that is reasonably likely to predict clinical benefit, while the clinical benefit itself is verified later through confirmatory trials. The program therefore gives patients earlier access to treatment, but part of the uncertainty that would otherwise be resolved before approval remains after the drug is already in use.

This creates a useful distinction between the information generated by the confirmatory trial and the regulatory action that follows it. Once the new evidence becomes public, physicians, patients, and payers can respond even if the FDA has not yet reached its final regulatory decision. FDA can later convert the indication to traditional approval, change the indication, or withdraw approval. I ask whether utilization responds to the new evidence during this period, before the recorded final regulatory outcome. If it does, confirmatory trials matter not only because they inform the regulator, but also because they can change treatment choices while the product remains on the market.

To study this question, I construct a new product-level dataset for drugs linked to the Accelerated Approval pathway. For each linked product, I record the Accelerated Approval date, whether the relevant confirmatory evidence is favorable or unfavorable, the formal journal-publication date, and the subsequent final regulatory outcome and date when observed. I merge these records with national quarterly Medicaid prescription utilization from 2008Q1 through 2022Q4. The resulting panel lets me observe utilization around the information event while keeping the later regulatory outcome separate.

For the empirical analysis, I use the quarter of formal publication as a common date at which the confirmatory evidence is publicly disseminated. Publication occurs at different times across products, so I estimate separate staggered event studies for favorable and unfavorable evidence. The specification includes product fixed effects, calendar-quarter fixed effects, and flexible controls for time since Accelerated Approval. These controls help separate the publication event from the normal lifecycle of a drug, since confirmatory results are often published several years after approval.

A simple learning framework helps organize the expected response. Accelerated Approval is granted only after the available evidence makes clinical benefit reasonably likely, so the market enters the confirmatory period with a relatively optimistic prior. A confirmatory trial that verifies benefit may therefore confirm what was already expected, while failure to verify benefit is more likely to be a large negative surprise. This gives a direct reason to expect the market response to depend on the direction of the evidence.

I find the clearest response following unfavorable confirmatory evidence. In the main specification, log Medicaid utilization falls by 0.48 log points on average over event quarters 0–4 and by 0.77 over event quarters 0–8. The decline develops over several quarters after publication, while the pre-publication path is comparatively stable, although the individual leads are noisy and the number of treated unfavorable products is small.

The baseline estimates for favorable evidence are positive: the pooled coefficient is 0.39

over event quarters 0–4 and 0.35 over event quarters 0–8. However, utilization is already increasing before formal publication, and the favorable association is not present in the pre-resolution sample—which removes each product's recorded final-resolution quarter and all later observations—where the corresponding coefficients are 0.02 and −0.25. I therefore interpret the favorable estimates as an association around favorable evidence and subsequent regulatory conversion rather than as a clean response to information before final resolution. Because the favorable and unfavorable models use different products, the difference in magnitudes is not a formal test of asymmetric updating.

I also examine whether the main results depend on observations after the FDA's recorded final regulatory resolution. When I remove each product's final-resolution quarter and all later observations, the unfavorable coefficients remain large at −0.41 over quarters 0–4 and −0.61 over quarters 0–8, while the favorable coefficients attenuate to the null. This restriction changes the products that continue to identify treatment, so I use it as a robustness comparison rather than as a mechanical decomposition of information and regulation.

This paper is related to the literature on information and learning in pharmaceutical demand. Existing work shows that scientific evidence, treatment experience, marketing, and professional networks can affect prescribing and drug diffusion (Azoulay, 2002; Coscelli and Shum, 2004; Crawford and Shum, 2005; Chintagunta et al., 2009; Ching and Ishihara, 2010; Agha and Molitor, 2018; Dubois and Tunçel, 2021; Vakratsas and Wang, 2024). I study a different source of information: evidence generated after approval under an explicit regulatory requirement. The setting allows me to observe a quality signal that is directly tied to uncertainty remaining when the drug is already being used.

The paper also relates to research on pharmaceutical regulation and Accelerated Approval. Prior work studies surrogate endpoints, the timing and completion of confirmatory trials, and the consequences of those trials for conversion or withdrawal (Budish et al., 2015; Wallach et al., 2018; Beakes-Read et al., 2022; Omae et al., 2022; Deshmukh et al., 2023; Shahzad et al., 2023; Tibau et al., 2025; Gyawali et al., 2021; Liu et al., 2024). A related literature documents the importance of Accelerated Approval drugs for public insurance spending and use (Sachs et al., 2021; Skydel et al., 2022). I add a market-response margin to this literature by studying whether utilization changes when the post-approval evidence itself becomes public. The new linked dataset makes this possible by bringing the confirmatory evidence, its publication date, subsequent regulatory resolution, and national Medicaid utilization into one panel.

The rest of the paper is organized as follows. Section 2 discusses the Accelerated Approval pathway and the timing of confirmatory evidence and regulatory resolution. Section 3 describes the confirmatory-evidence dataset and Medicaid utilization data. Section 4 presents the motivating data patterns. Section 5 develops the learning framework. Section 6 presents the empirical strategy. Section 7 discusses the results and robustness exercises, and Section 8 concludes.

2 Institutional Background

Accelerated Approval and Remaining Clinical Uncertainty The FDA established Accelerated Approval in 1992 to provide earlier access to therapies for serious conditions when there is an unmet medical need. Traditional and accelerated approval both require evidence of effectiveness, but the evidence can be based on different endpoints. Traditional approval generally relies on a direct measure of clinical benefit or a validated surrogate endpoint,

while Accelerated Approval can rely on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit (FDA, 2026).

The main difference for this paper is the timing of the remaining uncertainty. A product can be prescribed after Accelerated Approval even though the final clinical benefit that matters for patients has not yet been fully verified. Earlier access can be valuable for serious or life-threatening conditions, but physicians, patients, payers, and the regulator continue to receive new information after approval. Figure 1 summarizes this process and shows how confirmatory evidence and final regulatory resolution can occur at different points in time.

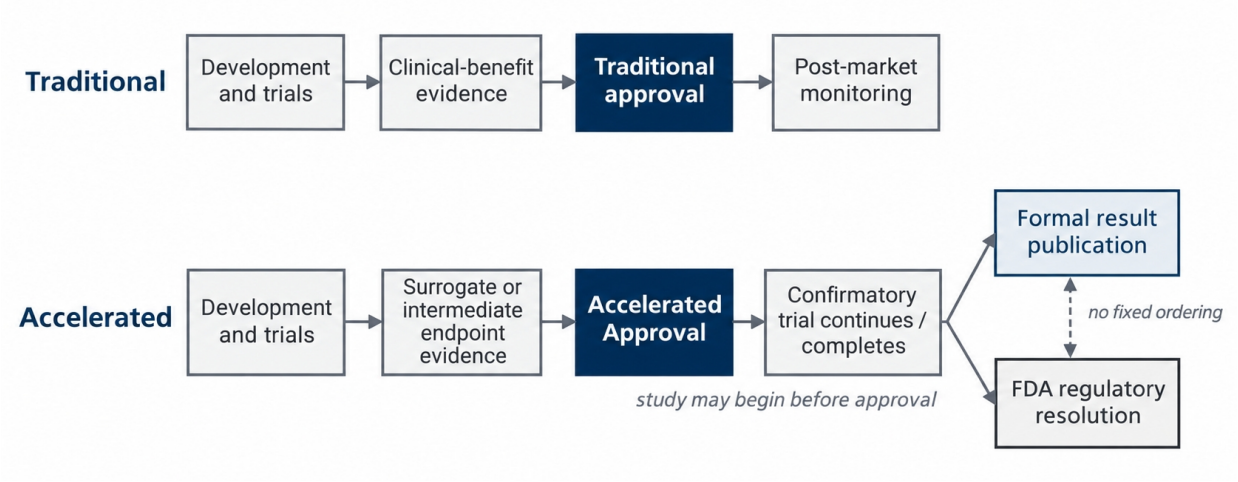


Figure 1. Accelerated Approval, Confirmatory Evidence, and Regulatory Resolution

Notes: The figure is an original schematic. Traditional approval is shown as following clinical-benefit evidence. Accelerated Approval can be based on a surrogate or intermediate clinical endpoint reasonably likely to predict clinical benefit, while the confirmatory study continues or is completed. A confirmatory study may begin before Accelerated Approval. Formal result publication and FDA regulatory resolution are distinct events and need not occur in a fixed order. See FDA (2026, 2025).

Confirmatory Trials as Post-Approval Information Sponsors receiving Accelerated Approval are required to conduct confirmatory studies intended to verify and describe the anticipated clinical benefit. These studies can begin before approval and continue after the product is already being used. Current law allows FDA, when appropriate, to require a confirmatory study to be underway before approval or within a specified period afterward, and FDA's 2025 draft guidance explains how the agency evaluates whether a trial is sufficiently underway (FDA, 2025).

The same confirmatory trial has two roles. For the FDA, it provides evidence used to decide whether the anticipated benefit has been verified. For physicians, patients, and payers, it provides new information about the product while treatment decisions are still being made. A favorable result can confirm the case for continued use, while an unfavorable result can lower the expected benefit of treatment. This means utilization may respond to the information before the final regulatory decision is completed.

Accelerated Approval is granted at the indication level, but the utilization data in this paper are observed at the product level. A product may have other approved indications when a confirmatory result is published. The outcome therefore measures total Medicaid utilization of the product rather than utilization only for the accelerated indication. I return to this limitation in Section 3.

From Clinical Evidence to Regulatory Resolution If confirmatory evidence verifies benefit, FDA can terminate the post-approval requirement and the indication can move to traditional approval. If the evidence fails to verify benefit, or if the required study is not completed with due diligence, FDA can initiate procedures that may lead to withdrawal or a change in the approved indication (FDA, 2026). These steps do not necessarily occur at the same time as the publication of the clinical evidence.

Makena is a useful example. Makena received Accelerated Approval in 2011, its required confirmatory study failed to verify clinical benefit, FDA proposed withdrawal in 2020, and the final withdrawal decision was issued in April 2023 (Aaron et al., 2022; FDA, 2023). During this period, the evidence available to physicians and payers had changed even though the final regulatory status had not yet been resolved. This is the type of interval in which an information response can occur.

Figure 2 shows the timing for selected products in the constructed data. Each line starts at Accelerated Approval and marks the formal publication of the confirmatory evidence and the recorded final regulatory resolution when observed. The distance between these dates varies substantially across products, and the ordering is not fixed. In some cases publication precedes final resolution by years; in others a recorded regulatory action occurs before formal journal publication. Treating these events as one date would therefore remove variation that is important for the empirical question.

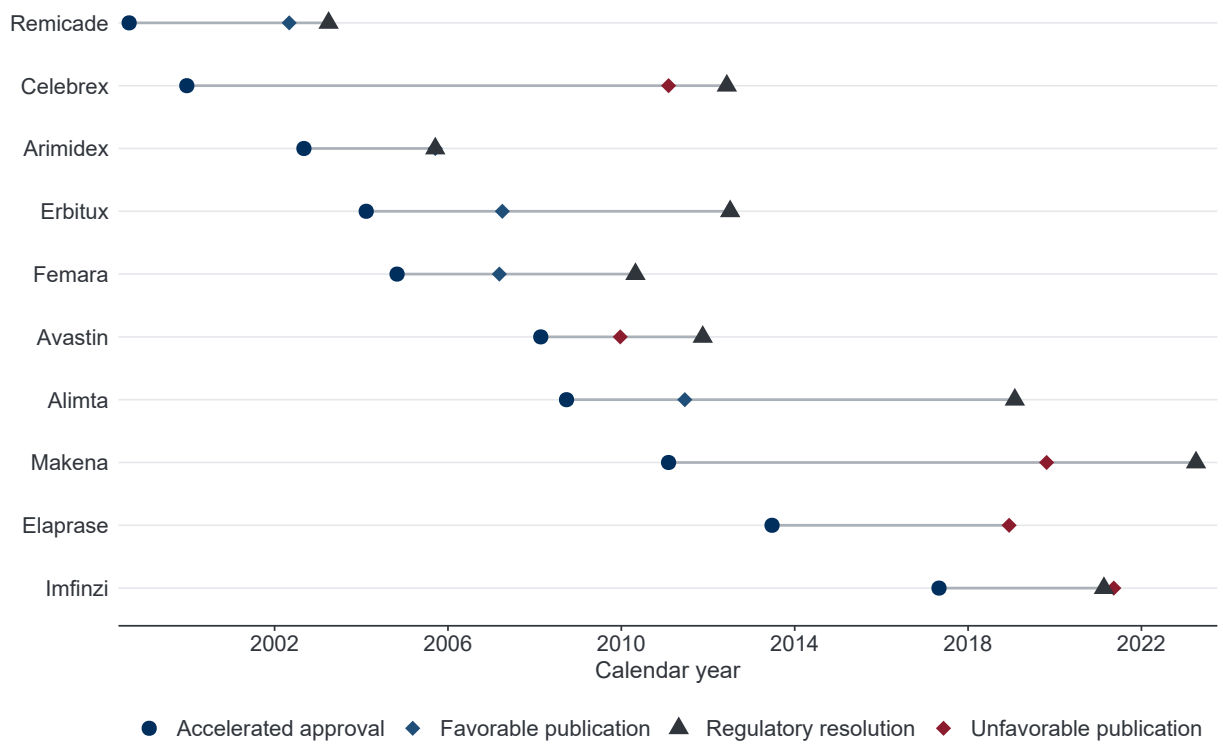


Figure 2. Timing of Accelerated Approval, Formal Publication, and Regulatory Resolution

Notes: The figure shows up to five high-utilization favorable-result products and five high-utilization unfavorable-result products. Lines begin at Accelerated Approval and extend through the later observed formal-publication or regulatory-resolution date. Publication and regulatory-resolution markers can overlap when the dates coincide. The figure illustrates institutional timing; selected products need not all contribute treated observations to the 2008Q1–2022Q4 estimation sample.

For this paper, the distinction is straightforward. Confirmatory trials produce evidence

that the FDA later uses in its regulatory decision, but the same evidence may also change treatment choices while the product remains in use. The empirical analysis asks whether this second response is visible in Medicaid utilization and whether it remains when observations after the recorded final regulatory outcome are removed.

3 Data

I combine information from the Accelerated Approval pathway with national Medicaid prescription utilization. Because no standard dataset contains the confirmatory result, its publication date, the later regulatory outcome, and a utilization identifier in one file, I first construct a product-level event dataset and then link it to quarterly utilization.

New Product-Level Confirmatory-Evidence Dataset I begin with FDA/CDER records on products and indications receiving Accelerated Approval. For each linked product, I manually collect the associated confirmatory-trial information, including the Accelerated Approval date, the confirmatory trial when identified, whether the relevant evidence verifies the anticipated clinical benefit, the formal journal-publication date, and the subsequent final regulatory outcome and date when observed. I then reconcile product names across FDA records, trial records, publications, and the identifiers used in the Medicaid data.

In the final panel, a "product" is the proprietary product name used to match these sources. I sum Medicaid utilization across the NDC records assigned to that proprietary name and across states. This mapping is necessary because FDA records are generally organized at the indication level while Medicaid utilization is observed at the product/NDC level. As a result, the outcome captures total Medicaid use of the product, including use outside the accelerated indication when such use exists.

I classify the confirmatory evidence as favorable when it verifies the relevant clinical benefit and as unfavorable when it does not. Products without a recorded confirmatory-result publication are kept in a separate no-result group. The sign of the evidence is based on the confirmatory result rather than the eventual FDA outcome. Conversion and withdrawal are recorded separately, since defining the information event using the later regulatory decision would mechanically combine the two events I want to distinguish.

The broader linked utilization data contain 126 products: 75 with favorable confirmatory evidence, 25 with unfavorable evidence, and 26 with no recorded confirmatory-result publication. Table 1 summarizes these products by Accelerated Approval year and recorded regulatory status. Most of the linked products received Accelerated Approval after 2010. Among products with favorable evidence, 60 are recorded as converted to traditional approval, while 19 of the products with unfavorable evidence are recorded as withdrawn. These counts describe the linked sample and show the close institutional relationship between the direction of the confirmatory evidence and the eventual regulatory outcome.

Formal Publication as the Information Event The empirical event date is the quarter in which the confirmatory result is formally published in a journal. I use publication because it can be dated using a common rule across products and because it is distinct from the later final regulatory outcome. It gives me a reproducible date at which the clinical result is available to the broader medical community.

Table 1. Accelerated Approval Products in the Linked Utilization Data

	Approval Year				Regulatory Status		
Result Type	1996–00	2001–10	2011–20	2021–23	Converted	Withdrawn	No Action Not Converted
Favorable Result	4	20	44	7	60	0	15
Unfavorable Result	4	4	13	4	0	19	6
No Result	1	1	12	12	0	0	26
Total	9	25	69	23	60	19	47

Notes: The table describes the 126 products in the broader linked utilization data. "No Result" means that no confirmatory-result publication is recorded in the constructed event file. Regulatory status is the product-level status recorded in that file. The main 2008Q1–2022Q4 estimation panel contains 120 products.

Formal publication is not necessarily the first time information about a trial becomes public. Sponsor announcements, conference presentations, ClinicalTrials.gov postings, advisory-committee materials, or FDA communications can occur earlier. I therefore do not interpret the publication coefficient as the response to a completely unanticipated news shock. Among the 100 products with a recorded confirmatory-result publication in the broader linked file, 79 also have a recorded final regulatory-resolution date and 14 have that resolution dated before journal publication. Appendix Table A5 and Figure A6 summarize these timing differences.

Medicaid Utilization I use the State Drug Utilization Data reported under the Medicaid Drug Rebate Program. States report quarterly utilization for covered outpatient drugs paid for by Medicaid, including National Drug Codes, product names, prescription counts, units reimbursed, and reimbursement amounts (CMS, 2026). I aggregate these records to the national product-quarter level because the confirmatory evidence is a national product-level information event rather than a state-specific treatment.

The main outcome is

$$y_{it} = \log(1 + \text{Prescriptions}_{it}),$$

where i indexes products and t indexes calendar quarters. This transformation reduces the influence of the highly skewed upper tail while retaining product-quarters with zero recorded utilization. The historical aggregated file does not retain the original state/NDC suppression flags, so I cannot always distinguish a true zero from underlying suppressed low-volume cells. Approximately 29% of product-quarters have zero recorded prescriptions. I therefore do not interpret zero versus positive utilization as a clean extensive margin. More generally, because the outcome is log-plus-one and includes zeros, I treat the regression coefficient as the primary estimand; $100[\exp(\widehat{\beta}) - 1]$ is only a descriptive scale conversion (Chen and Roth, 2024).

The SDUD data do not identify the prescribing physician, patient, or indication for which a prescription was written. As a result, the estimates capture product-level utilization around the confirmatory-information event and can reflect changes in physician prescribing, patient demand, payer management, treatment persistence, or substitution. They should not be interpreted as direct estimates of physician beliefs or as indication-specific treatment effects.

Analysis Sample and Descriptive Statistics The main estimation window is 2008Q1–2022Q4 and contains 3,466 product-quarter observations for 120 products. The six linked products outside this window are in the no-result group. Table 2 summarizes utilization in

the estimation panel. The favorable group contains 75 products and 2,518 product-quarters, while the unfavorable group contains 25 products and 705 product-quarters. Mean prescription counts are much larger than medians, particularly for unfavorable-result products, indicating a highly skewed distribution. The no-result products are lower-volume on average and have a median of zero in the estimation window.

Confirmatory evidence also tends to arrive several years after initial approval. Formal publication occurs, on average, about 42 months after Accelerated Approval for favorable-result products and 59 months after Accelerated Approval for unfavorable-result products. Among products with a recorded final regulatory date, final resolution occurs an average of 11.4 months after publication for favorable evidence and 27.1 months after publication for unfavorable evidence. These averages depend on the dates that are observed, but they illustrate that the information and regulatory process can continue for a substantial period after approval.

Table 2. Descriptive Statistics: National Product-Quarter Panel, 2008–2022

Result Type	Products	Prod.-Qtrs.	Mean Rx	Median Rx	Mean Months AA to Pub.	Mean Gap (Months) Final Resolution − Pub.
Favorable	75	2,518	956.1	107	41.9	11.4
Unfavorable	25	705	5,319.7	60	59.0	27.1
No Result	20	243	27.7	0	–	–

Notes: Prescription counts are national quarterly Medicaid prescription counts in the constructed panel. The final-resolution gap is calculated only for products with a recorded final regulatory-resolution date; negative values indicate final recorded resolution before formal publication. Recorded publication need not be the first information date, as discussed in the text.

4 Motivating Data Patterns

Before moving to the event-study estimates, I look at three features of the raw utilization data that matter for the empirical design. First, utilization changes substantially over calendar time. Second, there are large differences in utilization across products. Appendix Figures A1 and A2 show these two patterns. Favorable- and unfavorable-result products both move considerably over time, while products with no recorded result are generally lower-volume and include many product-quarters with no recorded Medicaid prescriptions. Mean utilization is also much larger than median utilization, particularly in the unfavorable group. These patterns make a simple comparison of utilization levels across result groups difficult to interpret and motivate the use of product and calendar-quarter fixed effects.

The third issue is the product lifecycle. Confirmatory results are often published several years after Accelerated Approval, so publication can occur when a product is already diffusing, maturing, or beginning to decline for other reasons. Figure 3 plots the raw within-product change in log utilization relative to the quarter before publication. Utilization for favorable-result products begins increasing before formal publication. For unfavorable-result products, the decline is more visible after publication, although the raw pre-period is noisy. These are unadjusted patterns and combine lifecycle changes, calendar shocks, cohort composition, and the information event itself.

These patterns motivate the controls used below. I include product fixed effects, calendar-quarter fixed effects, flexible controls for time since Accelerated Approval, and a staggered

event-study design that uses within-product changes around publication. They also make clear why I interpret the favorable and unfavorable results differently: the unfavorable response is more closely aligned with publication, while favorable utilization is already moving beforehand.

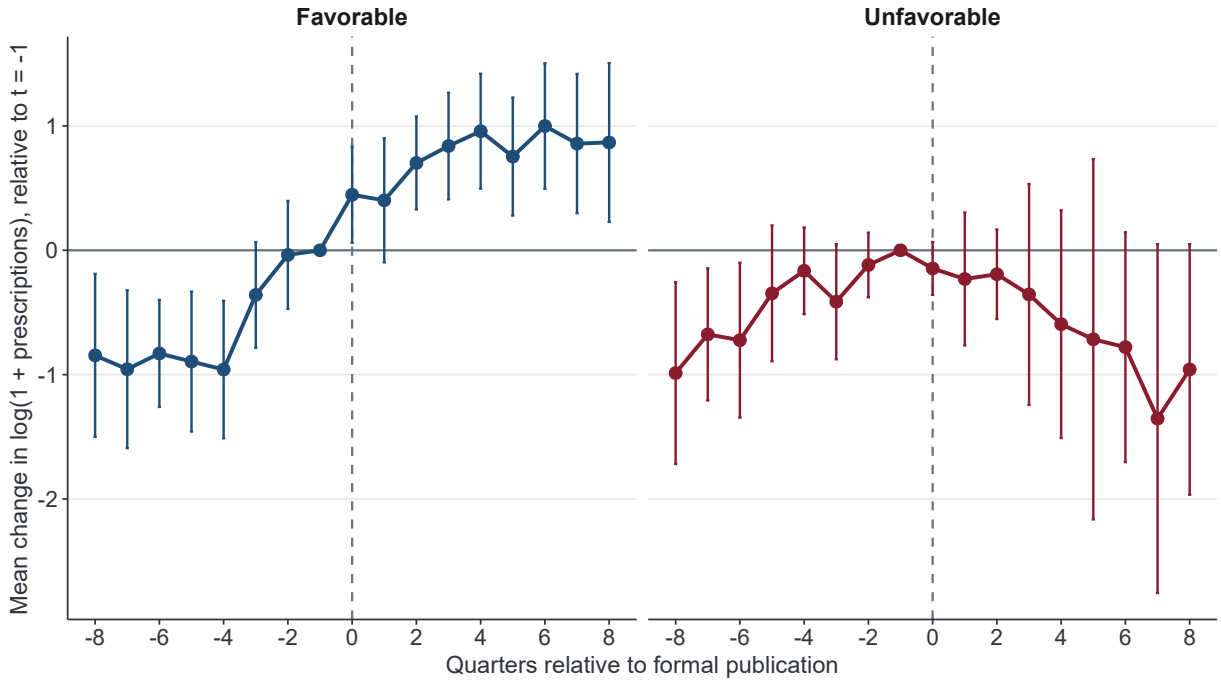


Figure 3. Descriptive Utilization Patterns Around Formal Publication

Notes: Product-level log utilization is normalized to event quarter -1 and then averaged by event time. Bars show 95% confidence intervals. These are unadjusted averages and do not control for calendar time, treatment cohort, or time since Accelerated Approval.

5 Conceptual Framework

I use a simple learning framework to organize how confirmatory evidence can affect utilization after approval. The framework is not intended to be a structural demand model. Its purpose is to make clear what changes when a new clinical signal arrives and what patterns I should expect to see in utilization.

Beliefs about Clinical Benefit Let θ_i denote the true clinical benefit of product i for the relevant use. At the time of Accelerated Approval, θ_i is not fully known. Let I_{i0} denote the public information available at that point, including the evidence supporting approval and the surrogate or intermediate endpoint. Market participants start with prior mean

$$\mu_{i0} = E[\theta_i \mid I_{i0}]$$

and prior variance σ^2_{i0}. A confirmatory trial then produces a new signal

$$s_i = \theta_i + \varepsilon_i, \qquad \varepsilon_i \sim N(0, \tau_i^2),$$

so that under normal learning the posterior mean is

$$\mu_{i1} = \mu_{i0} + \kappa_i(s_i - \mu_{i0}), \qquad \kappa_i = \frac{\sigma_{i0}^2}{\sigma_{i0}^2 + \tau_i^2}.$$

The relevant surprise is therefore $s_i - \mu_{i0}$, and the size of the belief revision also depends on how informative the new evidence is through κ_i.

Accelerated Approval affects the prior in an important way. Approval requires evidence that makes clinical benefit reasonably likely, so the prior entering the confirmatory period is already favorable. A confirmatory result that verifies benefit may simply confirm what was expected. In contrast, failure to verify benefit is more naturally a negative surprise relative to that prior. Holding the precision of the signal and the responsiveness of demand fixed, this gives a straightforward reason for the belief revision to be larger following unfavorable evidence.

From Beliefs to Utilization Let aggregate utilization be $Q_i = D_i(\mu_i, X_i)$, where X_i contains other determinants of use and D_i is increasing in expected clinical benefit. Around the pre-signal information set,

$$\Delta \log Q_i \approx \eta_i \kappa_i (s_i - \mu_{i0}), \qquad \eta_i = \frac{\partial \log D_i}{\partial \mu_i} > 0.$$

A negative surprise lowers expected clinical benefit and tends to reduce use, while a positive surprise tends to increase it. The response should be larger when the evidence is more informative, when the surprise relative to the prior is larger, or when utilization is more responsive to perceived clinical quality.

There is no reason for the adjustment to occur in one quarter. Let m_e denote the share of relevant market participants who have incorporated the new evidence by event quarter e, with m_e weakly increasing after dissemination. Aggregate use can then be written as

$$Q_{ie} = (1 - m_e) D_i(\mu_{i0}, X_{ie}) + m_e D_i(\mu_{i1}, X_{ie}).$$

Even when the result becomes public at a particular date, utilization can adjust gradually as information spreads, existing patients remain on treatment, and guidelines or payer decisions change.

Empirical Implications The framework gives three implications for the empirical analysis. First, utilization should move with the surprise in clinical quality relative to prior beliefs. Because Accelerated Approval begins with a favorable prior, failure to verify benefit should generally imply a negative revision, while verification may produce a smaller update if it mostly confirms what was already expected. Second, larger or more informative belief revisions should produce larger utilization responses. I cannot separately identify signal precision or the accelerated indication's share of total product use in the current data, so I treat this as a mechanism rather than a tested heterogeneity result. Third, if information spreads gradually, the utilization response should build over several quarters rather than appear only in the publication quarter.

Whether utilization changes before final regulatory resolution is not implied by this learning model. I examine that timing separately by comparing the publication-centered estimates with estimates from a sample censored at each product's recorded final regulatory-resolution date.

6 Empirical Strategy

Treatment Timing and Comparison Groups I define treatment using the quarter in which the relevant confirmatory evidence is formally published. Let i index products and t index calendar quarters, and let G_i denote the publication quarter for product i when publication occurs within the estimation window. For products with no publication event during the window, $G_i = \infty$.

I estimate favorable and unfavorable evidence separately. In the favorable analysis I exclude unfavorable-result products, and in the unfavorable analysis I exclude favorable-result products. In each case, the comparison group consists of no-result products and products whose relevant publication occurs after 2022Q4. I also exclude products whose publication occurs before or at their first usable observation because they do not provide a pre-publication period.

Because publication occurs in different quarters across products, a standard two-way fixed-effects event study can make comparisons across already-treated and later-treated cohorts that are difficult to interpret when treatment effects vary over time or across cohorts (Goodman-Bacon, 2021; de Chaisemartin and D'Haultfoeuille, 2020). I therefore use the interaction-weighted estimator of Sun and Abraham (2021), which estimates cohort-specific event-time effects and then aggregates across the cohorts contributing to each event time.

Event-Study Specification The estimating equation is

$$y_{it} = \alpha_i + \lambda_t + \Gamma(a_{it}) + \sum_{g<\infty} \sum_{e \neq -1} \delta_{g,e} \mathbf{1}\{G_i = g\} \mathbf{1}\{t - g = e\} + \varepsilon_{it}, \tag{1}$$

where α_i are product fixed effects, λ_t are calendar-quarter fixed effects, and $\Gamma(a_{it})$ is a flexible set of indicators for time since Accelerated Approval. The quarter immediately before publication, $e = -1$, is omitted. Event times at or below -9 and at or above 9 are pooled into tails.

For each displayed event time e, the Sun–Abraham estimate is

$$\delta_e = \sum_{g<\infty} w_{g,e} \delta_{g,e},$$

where $w_{g,e}$ is the cohort-share weight among the publication cohorts that contribute to event time e. In practical terms, the coefficient measures how utilization changes at a given distance from publication relative to the quarter before publication, after accounting for permanent product differences, common calendar shocks, and the post-AA lifecycle. Standard errors are clustered by product, which is the level at which the publication event varies.

The time-since-AA controls use bins for pre-AA observations, quarters 0–3, 4–7, 8–11, 12–15, 16–19, 20–23, 24–31, 32–39, and 40 or more quarters after Accelerated Approval. I allow this lifecycle to be nonlinear because utilization can change substantially as products diffuse and mature. The baseline keeps pre-AA observations because Accelerated Approval is indication-specific and some proprietary products already have Medicaid utilization for other indications before the accelerated indication is approved. I also report a post-AA-only specification to check that pre-AA history, including quarters before launch for low-volume no-result products, is not driving the estimates.

For the dynamic event studies, I report event times -8 through 8, with -1 omitted. For the headline estimates, I re-estimate the model after pooling event quarters 0–4 or 0–8 into a

single relative-time category. These coefficients are average interaction-weighted effects over the listed windows; they are not arithmetic averages of the plotted event-time coefficients and they are not cumulative effects.

Identification and Interpretation The identifying assumption is that, absent publication of the relevant confirmatory result, treated products would have followed utilization paths comparable to the comparison group after conditioning on product fixed effects, calendar-quarter fixed effects, and time since Accelerated Approval. One concern is that other product-specific information or market events can occur near publication. Formal publication is consistently dated across products, but sponsor announcements, conference presentations, registry postings, or FDA communications may occur earlier. For this reason, I interpret the event study as utilization around a common dissemination date rather than as the response to a completely unanticipated publication shock.

A second concern is that publication can occur close to the later regulatory outcome. I address this by removing observations at and after the recorded final regulatory-resolution quarter in a robustness exercise. This restriction changes which products continue to contribute treated observations after publication, so I do not interpret it as a mechanical decomposition of information from regulation.

The favorable estimation sample contains 2,176 product-quarter observations for 82 products, including 54 products treated within the estimation window and 28 comparison products. Of the 75 favorable-result products in the panel, 13 are already treated at the beginning of their usable estimation window and 8 publish after 2022Q4. The unfavorable sample contains 903 product-quarter observations for 43 products, including 21 treated products and 22 comparison products; 2 unfavorable products are already treated and 2 publish after 2022Q4. The relatively small number of treated unfavorable products means the product-clustered standard errors should be read with caution. Appendix Table A4 reports the composition of the main and restricted samples.

The outcome is product-level Medicaid utilization. The estimates do not separately identify physician learning, patient demand, payer response, indication-specific use, substitution to competing drugs, or welfare. I use the learning framework to organize the information channel, but the reduced-form estimates capture the combined market response observed in the utilization data.

7 Results and Discussion

Main Market Response Table 3 reports the average post-publication response over the first five and first nine quarters. I treat the regression coefficient in log points as the primary estimand.

The main result is the decline following unfavorable confirmatory evidence. When a confirmatory trial fails to verify the anticipated clinical benefit, utilization falls after the result is published. The pooled coefficient is -0.477 over event quarters 0–4 (SE 0.145, $p = 0.002$) and -0.767 over event quarters 0–8 (SE 0.173, $p < 0.001$). The larger estimate over the longer window shows that the decline continues to develop after publication rather than occurring only in the publication quarter.

For favorable evidence, the baseline coefficients are positive. The pooled estimate is 0.386 over event quarters 0–4 (SE 0.153, $p = 0.014$) and 0.348 over event quarters 0–8 (SE 0.176,

Table 3. Utilization Response to Confirmatory Evidence

Evidence	Window	Estimate	SE	p-value	Product-Quarters / Products
Favorable	0 to 4	0.386	0.153	0.014	2,176 / 82
Favorable	0 to 8	0.348	0.176	0.051	2,176 / 82
Unfavorable	0 to 4	−0.477	0.145	0.002	903 / 43
Unfavorable	0 to 8	−0.767	0.173	< 0.001	903 / 43

Notes: Outcome is log(1 + national quarterly Medicaid prescriptions). All models include product and calendar-quarter fixed effects and flexible quarters-since-AA bins. Standard errors are clustered by product. The reported windows are average effects over the listed event quarters, not cumulative effects.

$p = 0.051$). However, utilization is already increasing before formal publication. Moreover, given the favorable prior embedded in Accelerated Approval, a result that verifies benefit does not necessarily represent a positive surprise relative to what the market already expected. I therefore treat the favorable estimates as an association around favorable evidence rather than as a clean publication-induced response.

The two sets of estimates come from different products, so comparing their magnitudes is not a formal test of asymmetric updating.

How the Response Develops Over Time Figures 4 and 5 report the quarter-by-quarter estimates, and Appendix Tables A2 and A3 list the corresponding coefficients. These dynamics are useful because the pooled windows do not show whether adjustment happens immediately or builds over time.

For favorable evidence, the publication-quarter coefficient is positive but imprecise. The estimate is 0.313 at event time 2 ($p = 0.057$), 0.517 at event time 3 ($p = 0.012$), and 0.505 at event time 4 ($p = 0.026$). The increase in the baseline specification develops over several quarters rather than appearing as a one-quarter jump. At the same time, the pre-publication movement makes it difficult to interpret this path as a clean diffusion response beginning at publication.

For unfavorable evidence, the timing is more closely aligned with publication. The publication-quarter estimate is −0.101 ($p = 0.593$), followed by −0.323 at event time 1 ($p = 0.019$), −0.482 at event time 2 ($p = 0.046$), −0.759 at event time 3 ($p = 0.026$), and −1.000 at event time 4 ($p = 0.005$). The coefficients become more negative later in the window. This gradual decline is consistent with information taking time to diffuse, existing patients remaining on treatment, or guideline and payer responses occurring with a lag. The aggregate Medicaid data do not allow me to separate these mechanisms.

Pre-Publication Dynamics Appendix Table A1 reports the pooled pre-event estimates. For unfavorable evidence, the pooled coefficient over event quarters −8 through −2 is 0.024 (SE 0.145, $p = 0.869$), and none of the individual displayed leads is statistically significant at the 5% level. The coefficients are still noisy, including a noticeable movement between event times −4 and −3, so I do not take the pre-period as proof of exact parallel trends. It is, however, considerably more stable than the favorable path.

For favorable evidence, the pooled pre-period coefficient is −0.285 (SE 0.176, $p = 0.109$), while the coefficients at event times −5 and −4 are statistically different from zero. One explanation is that favorable trial information can reach the market before journal publica-

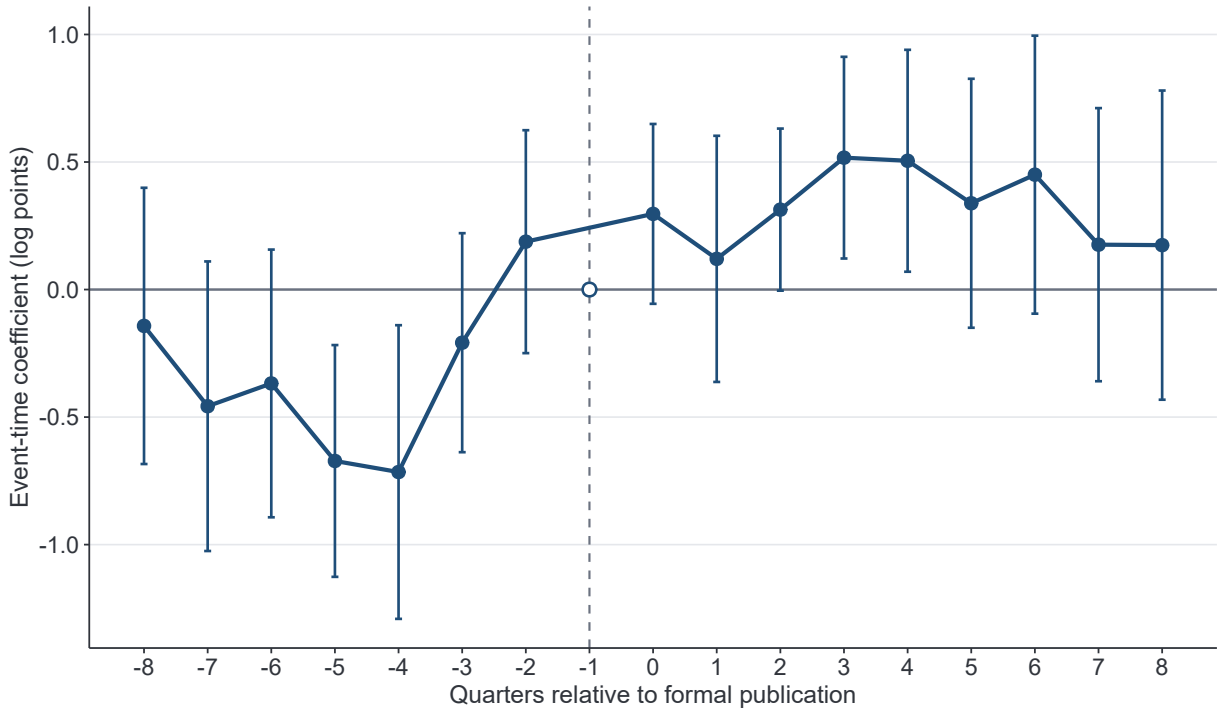


Figure 4. Dynamic Utilization Response to Favorable Confirmatory Evidence

Notes: Sun–Abraham event-study estimates with product and calendar-quarter fixed effects and flexible lifecycle controls. Event time −1 is the omitted reference period and is shown as an open marker at zero. Bars show 95% confidence intervals; standard errors are clustered by product.

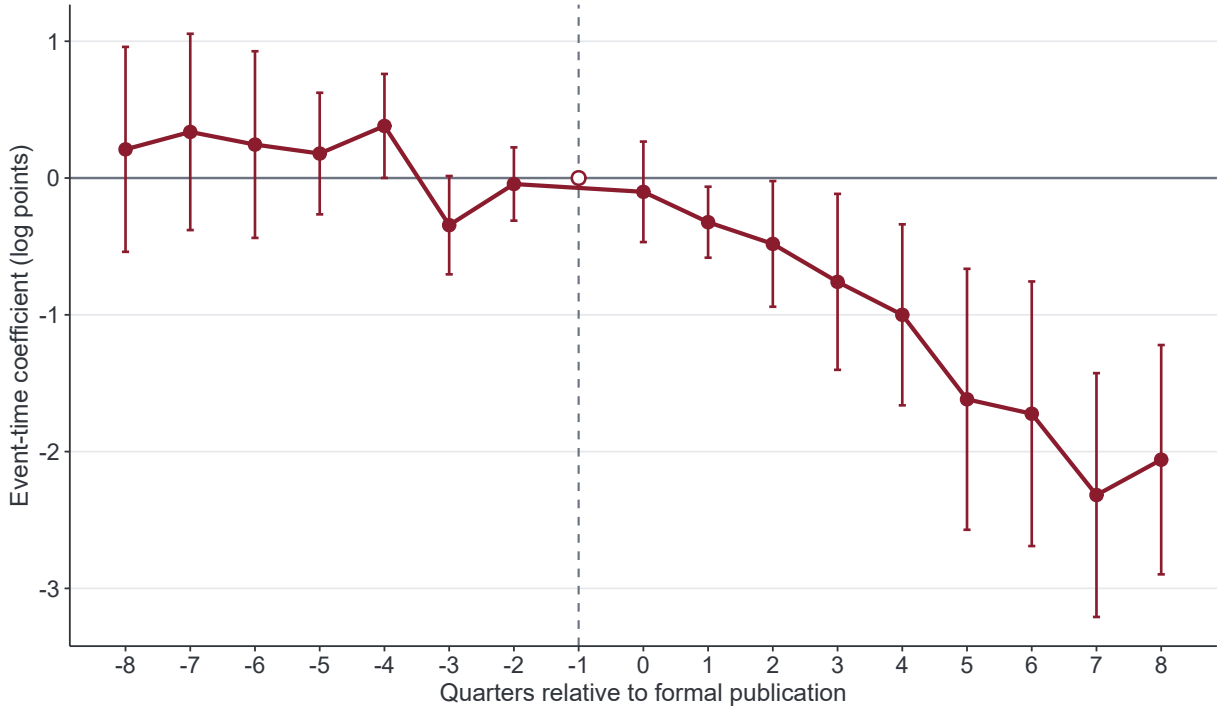


Figure 5. Dynamic Utilization Response to Unfavorable Confirmatory Evidence

Notes: Sun–Abraham event-study estimates with product and calendar-quarter fixed effects and flexible lifecycle controls. Event time −1 is the omitted reference period and is shown as an open marker at zero. Bars show 95% confidence intervals; standard errors are clustered by product.

tion through conference presentations, sponsor announcements, or other channels. Product-specific lifecycle changes may also matter. For this reason, I interpret the favorable result as higher utilization around the broader dissemination of favorable evidence rather than as a response that begins exactly at the publication date.

Robustness and Alternative Interpretations I first check whether the event-study patterns are being driven by product history before Accelerated Approval. When I restrict the panel to observations on or after Accelerated Approval, the pooled coefficients remain close to the baseline: 0.377 and 0.350 for favorable evidence, and −0.569 and −0.793 for unfavorable evidence over the 0–4 and 0–8 windows. Appendix Figures A3 and A4 show the corresponding dynamic estimates. Thus, the main patterns are not generated by pre-AA observations.

The second check focuses on the timing of the final regulatory outcome. A decline following unfavorable evidence could partly reflect the FDA's final action rather than a response to the evidence itself. I therefore remove each product's recorded final regulatory-resolution quarter and all later observations. This is conservative in the sense that every post-resolution quarter is removed, but it also changes the identifying sample because only products whose publication occurs sufficiently before final resolution continue to contribute later post-publication observations. The treated count falls from 54 to 35 for favorable evidence and from 21 to 15 for unfavorable evidence, while the comparison groups rise from 28 to 46 and from 22 to 27.

Table 4. Robustness of the Post-Publication Utilization Response

Specification	Window	Estimate	SE	p-value	Product-Quarters / Products
Favorable: Post-AA Only	0 to 4	0.377	0.152	0.015	2,051 / 81
Favorable: Post-AA Only	0 to 8	0.350	0.172	0.046	2,051 / 81
Favorable: Pre-Resolution	0 to 4	0.016	0.138	0.909	1,150 / 81
Favorable: Pre-Resolution	0 to 8	−0.247	0.156	0.117	1,150 / 81
Unfavorable: Post-AA Only	0 to 4	−0.569	0.115	< 0.001	831 / 42
Unfavorable: Post-AA Only	0 to 8	−0.793	0.099	< 0.001	831 / 42
Unfavorable: Pre-Resolution	0 to 4	−0.409	0.152	0.010	663 / 42
Unfavorable: Pre-Resolution	0 to 8	−0.613	0.157	< 0.001	663 / 42
Unfavorable: Excluding Celebrex	0 to 4	−0.494	0.121	< 0.001	843 / 42
Unfavorable: Excluding Celebrex	0 to 8	−0.837	0.160	< 0.001	843 / 42

Notes: Specifications are otherwise identical to Table 3. The post-AA-only sample removes observations before the Accelerated Approval quarter. The pre-resolution sample additionally removes the recorded final regulatory-resolution quarter and all later observations. A treated product whose publication is no longer observed before its retained endpoint does not identify a post-publication/pre-resolution effect. The Celebrex specification excludes Celebrex from the unfavorable-result sample.

For unfavorable evidence, the decline remains large in this pre-resolution sample. The pooled coefficient is −0.409 over quarters 0–4 (SE 0.152, $p = 0.010$) and −0.613 over quarters 0–8 (SE 0.157, $p < 0.001$). Thus, for the products that remain treated in this exercise, the decline is already visible in observations before the recorded final regulatory-resolution quarter.

The favorable result does not survive the same restriction. The pooled coefficient falls

to 0.016 over quarters 0–4 (SE 0.138, $p = 0.909$) and −0.247 over quarters 0–8 (SE 0.156, $p = 0.117$). The data therefore do not provide clear evidence of a favorable utilization response before recorded final regulatory resolution. One possible explanation is that the positive baseline association partly reflects changes occurring around later conversion to traditional approval or other contemporaneous product-level changes. Since the censoring also changes sample composition, I do not use this contrast to isolate any one mechanism.

I also exclude Celebrex from the unfavorable sample. Celebrex is atypical because its accelerated indication is narrow relative to the product's broader market and generic competition enters during the observed history. Excluding it does not change the unfavorable conclusion: the pooled coefficients are −0.494 over quarters 0–4 and −0.837 over quarters 0–8. Appendix Figure A5 shows a similar decline over event time.

There are several limitations to the interpretation. Formal publication is a standardized dissemination date rather than a verified earliest-information date, and the recorded final regulatory-resolution date can follow earlier FDA signals. Products are also linked by proprietary name, so prescriptions for generic versions are not assigned to the brand product. Generic entry around the event window can therefore lower measured brand utilization mechanically; the current specifications do not separately control for loss of exclusivity or biosimilar entry. Finally, the SDUD data do not identify utilization for the accelerated indication alone. Given these limitations, I interpret the evidence as a product-level utilization response, with the strongest result coming from the decline following unfavorable evidence.

Policy Implications Confirmatory trials matter not only for the FDA's later decision but also for the information available while a product remains in use. The results suggest that timely trial completion and transparent dissemination can allow treatment choices to adjust sooner when new evidence changes expected clinical benefit, while regulatory action remains necessary to resolve labeling, indication, and formal approval status when warranted.

8 Concluding Remarks

In this paper, I study how prescription drug utilization changes when new clinical evidence becomes available after a drug is already in use. The Accelerated Approval pathway provides a setting where this can be observed because approval can occur before clinical benefit is fully verified and confirmatory trials later produce additional evidence. I link these trial outcomes and publication dates to national Medicaid utilization and find a clear decline following unfavorable evidence.

In the baseline event study, log utilization falls by 0.48 log points on average over event quarters 0–4 and by 0.77 over event quarters 0–8 after unfavorable confirmatory evidence. The decline remains large when I restrict the sample to post-AA observations and when I remove observations at and after the recorded final regulatory resolution; in the latter sample, the corresponding coefficients are −0.41 and −0.61. Favorable evidence is associated with higher utilization in the baseline, but utilization starts increasing before publication and the association is not present in the pre-resolution sample. Taken together, the evidence supports a stronger conclusion for unfavorable news: failed confirmatory evidence is followed by substantial adjustment in product utilization before the recorded final regulatory outcome.

This market response does not replace the role of regulation. Confirmatory trials can affect treatment choices by generating new information, while the FDA still determines the

formal regulatory status of the indication. Timely trials and transparent dissemination can reduce the period in which treatment decisions rely on incomplete evidence, and prompt regulatory action remains important when the new evidence warrants it. With physician- or patient-level data, future work could separate changes in prescribing, payer response, treatment persistence, and substitution across therapies.

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Appendix

Additional Descriptive Figures Figures A1 and A2 report the calendar-time and cross-product descriptive patterns referenced in Section 4.

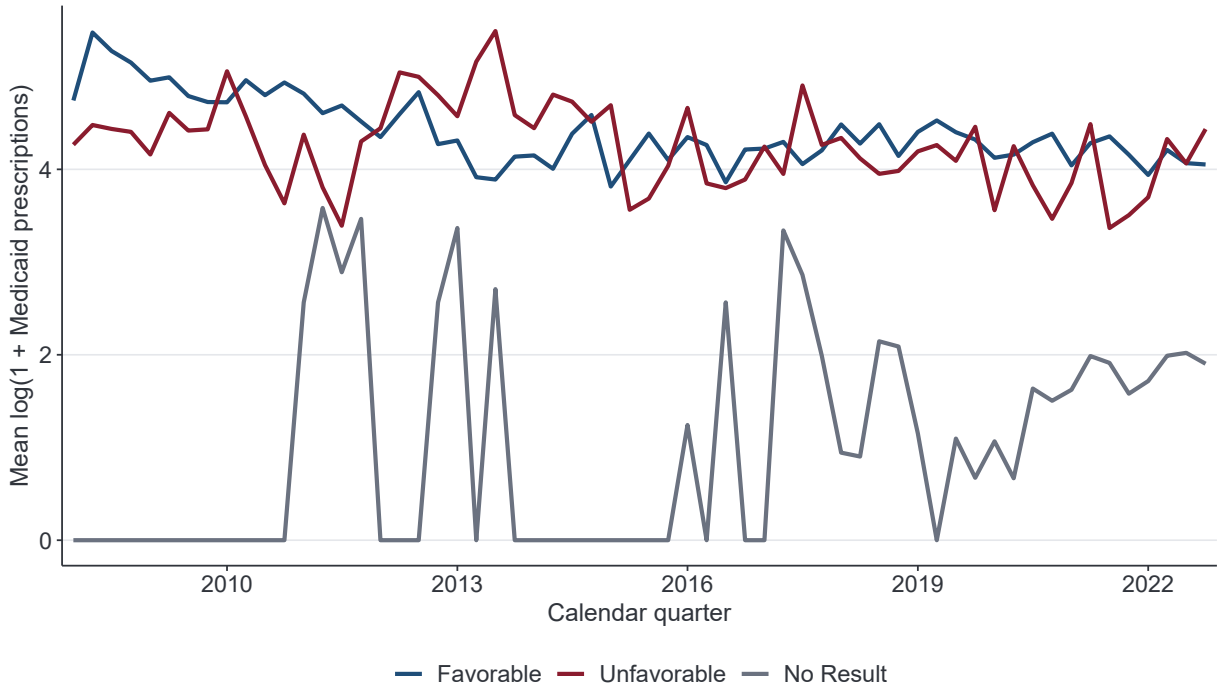


Figure A1. National Medicaid Utilization by Confirmatory-Result Type

Notes: Mean log(1+national Medicaid prescriptions) by calendar quarter and eventual confirmatory-result classification. The figure does not condition on treatment timing or time since Accelerated Approval.

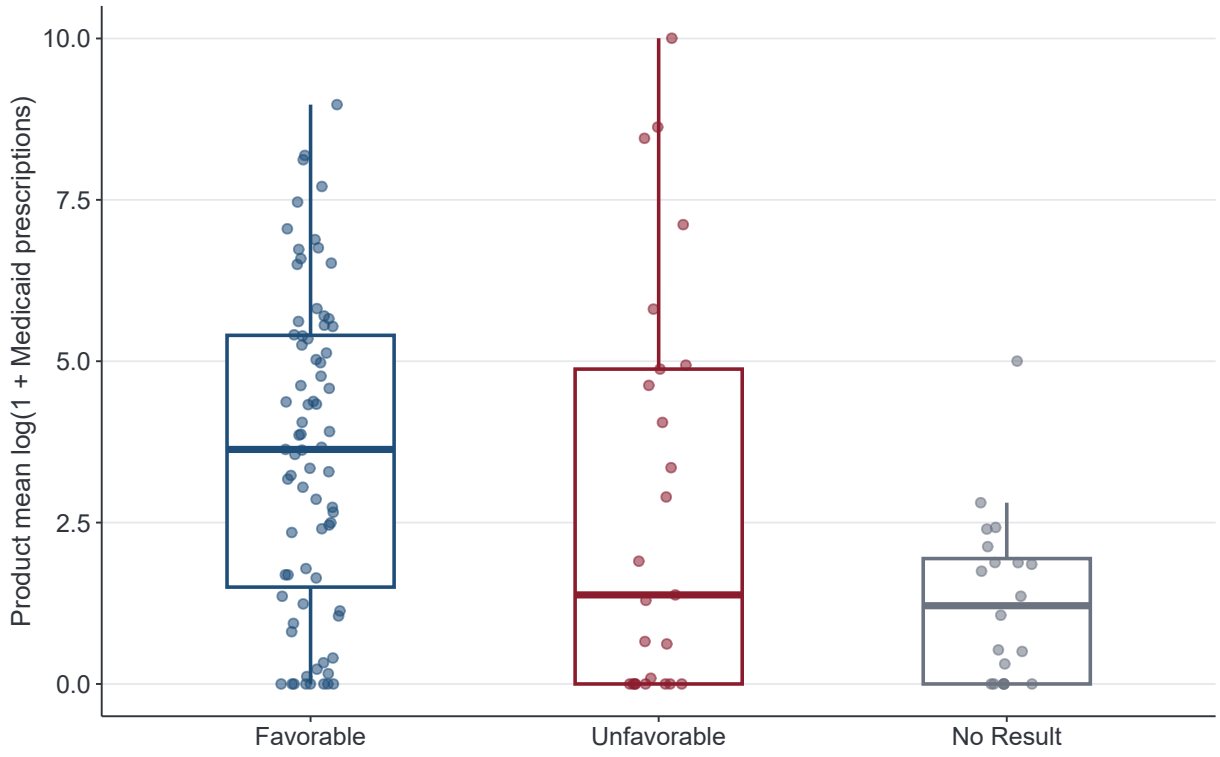


Figure A2. Cross-Product Heterogeneity in Medicaid Utilization

Notes: Each point is a product's mean log(1 + national Medicaid prescriptions) over the 2008Q1–2022Q4 panel. The figure summarizes cross-product dispersion.

Table A1. Pooled Pre-Event Diagnostics

Specification	Window	Estimate	SE	p-value
Favorable: Main	−8 to −2	−0.285	0.176	0.109
Unfavorable: Main	−8 to −2	0.024	0.145	0.869
Favorable: Post-AA Only	−8 to −2	−0.240	0.172	0.168
Unfavorable: Post-AA Only	−8 to −2	−0.052	0.132	0.696
Unfavorable: Excluding Celebrex	−8 to −2	−0.001	0.152	0.995

Table A2. Dynamic Event-Study Coefficients: Favorable Confirmatory Evidence

Event Time	Estimate	SE	p-value
−8	−0.143	0.276	0.607
−7	−0.457	0.290	0.118
−6	−0.368	0.268	0.173
−5	−0.672	0.232	0.005
−4	−0.715	0.294	0.017
−3	−0.208	0.219	0.344
−2	0.188	0.223	0.402
0	0.297	0.180	0.103
1	0.120	0.246	0.626
2	0.313	0.162	0.057
3	0.517	0.202	0.012
4	0.505	0.222	0.026
5	0.338	0.249	0.178
6	0.450	0.278	0.109
7	0.176	0.273	0.521
8	0.174	0.309	0.575

Notes: Event time −1 is the omitted reference period. Event times −8 through +8 are displayed separately. More distant tails (at or below −9 and at or above +9) are pooled in estimation but are not displayed. The specification includes product and calendar-quarter fixed effects and flexible lifecycle controls. Standard errors are clustered by product.

Table A3. Dynamic Event-Study Coefficients: Unfavorable Confirmatory Evidence

Event Time	Estimate	SE	p-value
−8	0.210	0.382	0.586
−7	0.337	0.366	0.362
−6	0.245	0.348	0.486
−5	0.179	0.227	0.434
−4	0.381	0.194	0.056
−3	−0.345	0.183	0.067
−2	−0.044	0.137	0.750
0	−0.101	0.187	0.593
1	−0.323	0.132	0.019
2	−0.482	0.234	0.046
3	−0.759	0.328	0.026
4	−1.000	0.338	0.005
5	−1.618	0.487	0.002
6	−1.723	0.493	0.001
7	−2.318	0.455	< 0.001
8	−2.059	0.428	< 0.001

Notes: Event time −1 is the omitted reference period. Event times −8 through +8 are displayed separately. More distant tails (at or below −9 and at or above +9) are pooled in estimation but are not displayed. The specification includes product and calendar-quarter fixed effects and flexible lifecycle controls. Standard errors are clustered by product.

Table A4. Analysis-Sample Composition

Specification	Prod.-Qtrs.	Products	Treated	Comparison
Favorable: Main	2,176	82	54	28
Unfavorable: Main	903	43	21	22
Unfavorable: Excluding Celebrex	843	42	20	22
Favorable: Post-AA Only	2,051	81	54	27
Unfavorable: Post-AA Only	831	42	21	21
Favorable: Pre-Resolution	1,150	81	35	46
Unfavorable: Pre-Resolution	663	42	15	27

Notes: In the main favorable sample, 13 of 75 favorable-result products are already treated at the beginning of their usable estimation window and are excluded; 8 publish after 2022Q4 and join 20 no-result products in the comparison cohort, yielding 54 treated and 28 comparison products. In the main unfavorable sample, 2 of 25 unfavorable-result products are already treated and 2 publish after 2022Q4, yielding 21 treated and 22 comparison products once the 20 no-result controls are included. The pre-resolution samples remove each product's recorded final regulatory-resolution quarter and all later observations; products whose publication is no longer observed before the retained endpoint do not identify a post-publication/pre-resolution effect.

Dynamic Robustness Figures The following figures report dynamic paths for the principal sample restrictions discussed in Table 4.

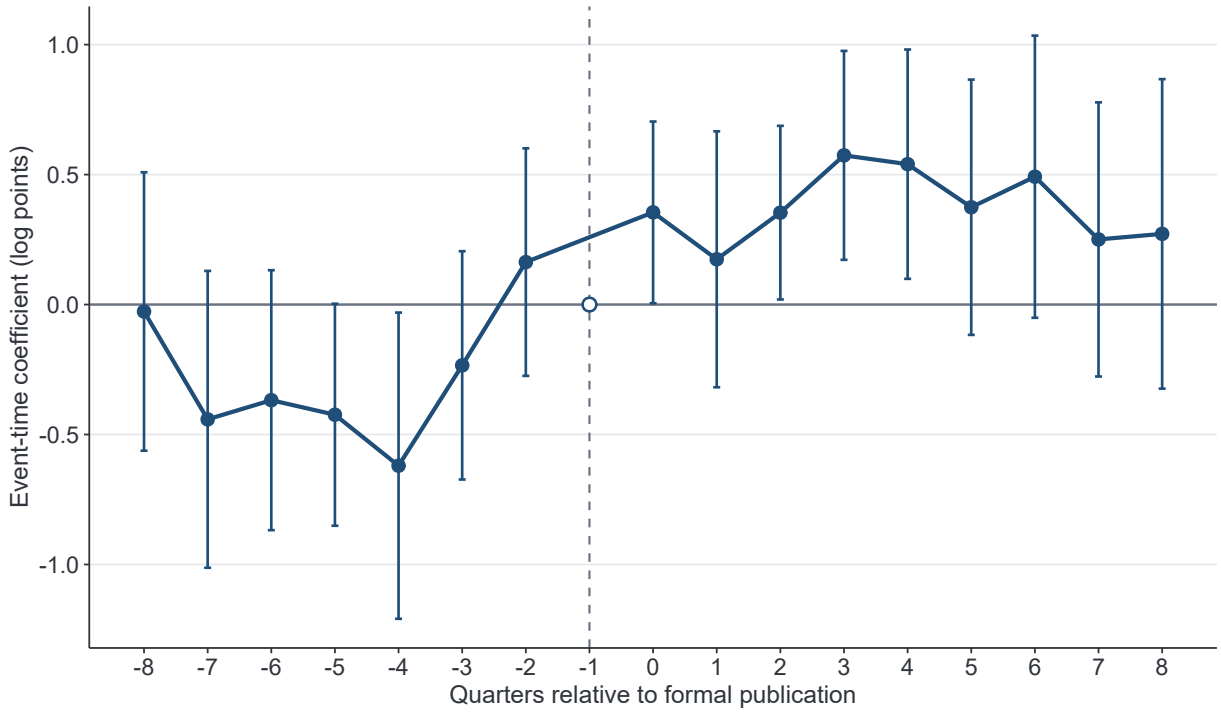


Figure A3. Favorable Evidence: Post-Accelerated-Approval Sample

Notes: Same specification as Figure 4, restricted to product-quarter observations on or after Accelerated Approval.

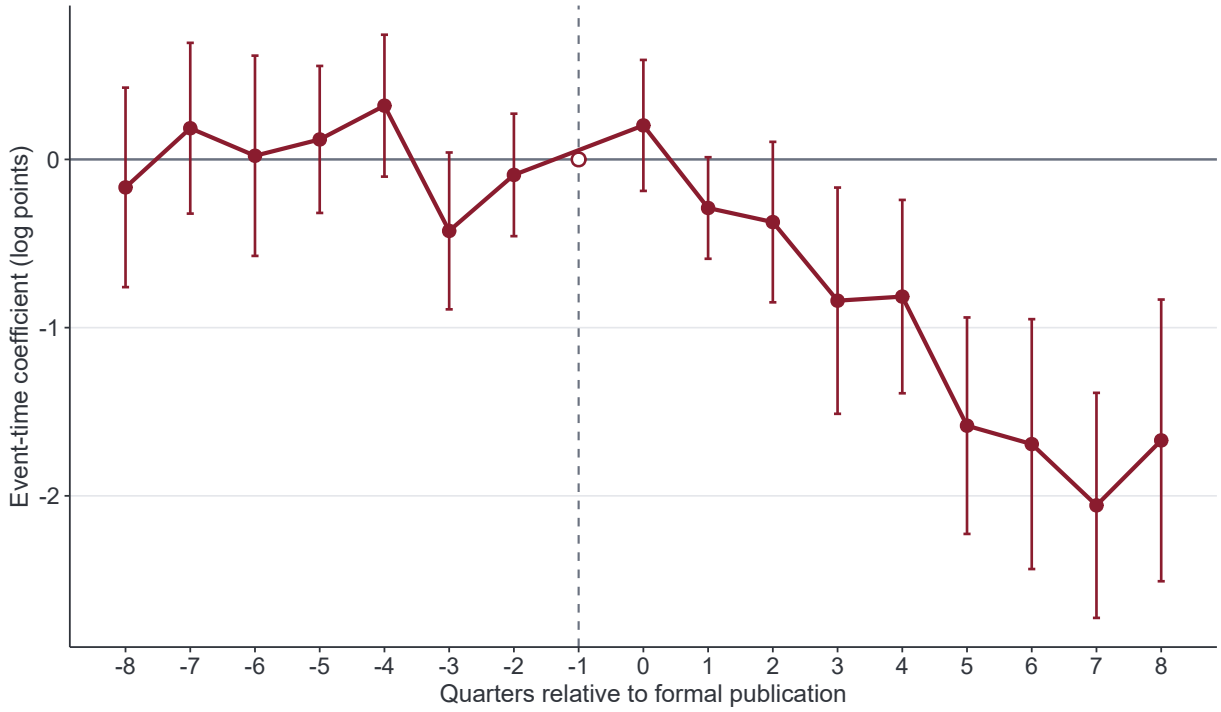


Figure A4. Unfavorable Evidence: Post-Accelerated-Approval Sample

Notes: Same specification as Figure 5, restricted to product-quarter observations on or after Accelerated Approval.

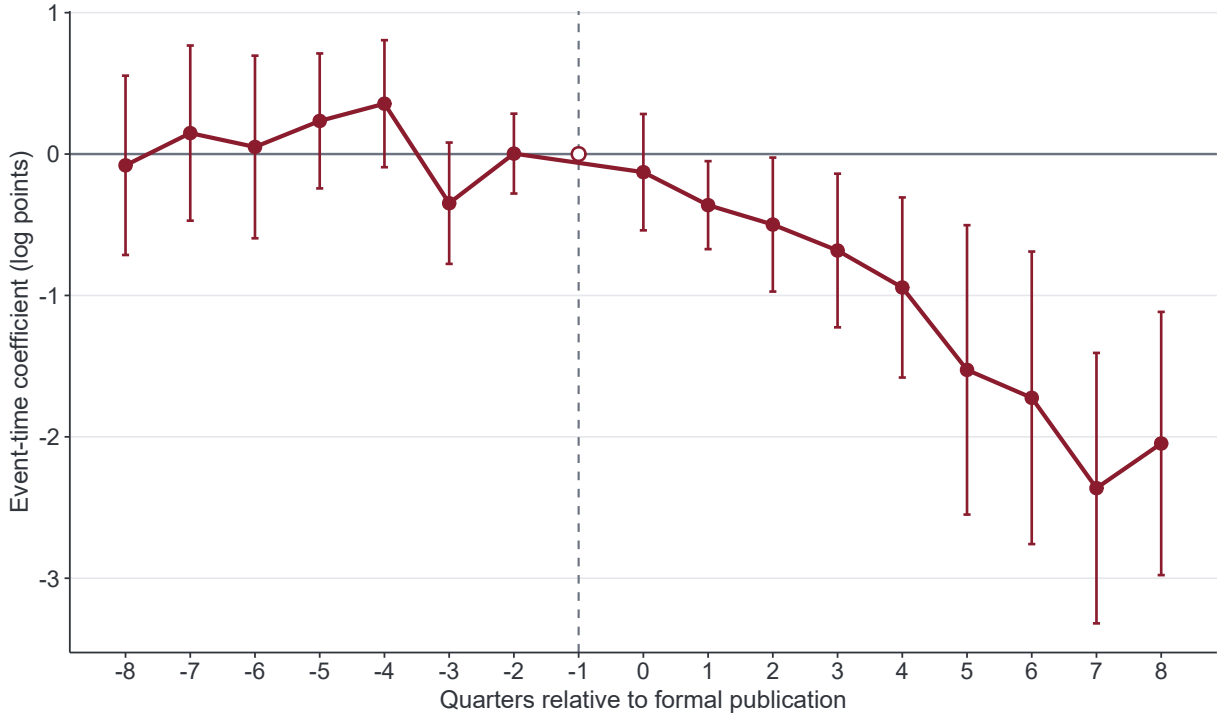


Figure A5. Unfavorable Evidence: Excluding Celebrex

Notes: Same specification as Figure 5, excluding Celebrex from the unfavorable-result sample.

Timing of Publication and Regulatory Resolution The timing audit below summarizes the gap between formal publication and recorded final regulatory resolution among products for which both dates are observed. It summarizes the observed timing and motivates the pre-resolution censoring exercise reported in Table 4.

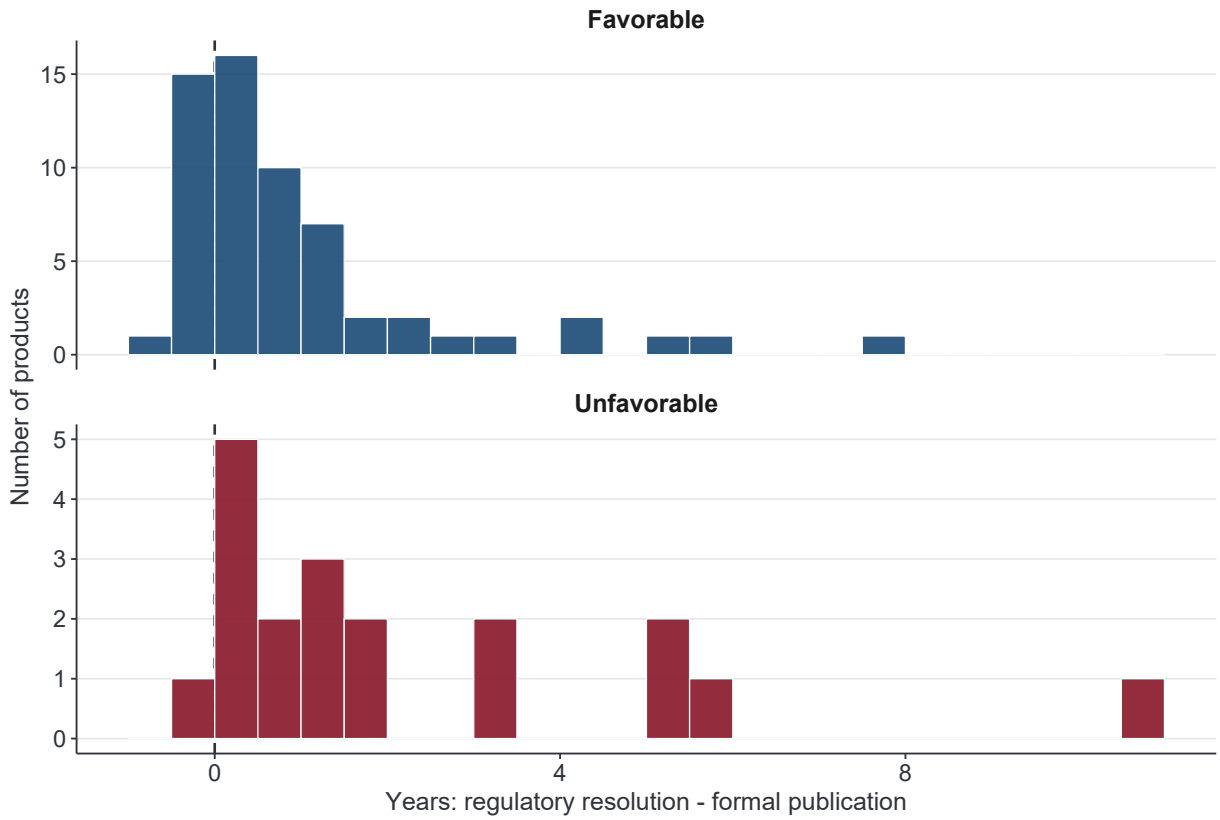


Figure A6. Timing of Final Regulatory Resolution Relative to Formal Publication

Notes: Negative values indicate recorded final regulatory resolution before formal journal publication. The figure uses products with a recorded confirmatory-result publication and both dates observed.

Table A5. Timing of Final Regulatory Resolution Relative to Formal Publication

Result	Recorded Publication	Final Resolution Date	Before Publication	Mean Gap (Months)	Median Gap (Months)
Favorable	75	60	13	11.45	4.27
Unfavorable	25	19	1	27.12	13.24
All Published	100	79	14	15.22	6.31

Notes: Mean and median months are calculated as recorded final regulatory-resolution date minus formal publication date among products with both dates observed. Negative product-level values indicate final regulatory resolution before formal publication.