

FDA Regulatory Milestones, Announcement Framing, and Biotechnology Stock Returns: Evidence on the Feasibility of an AI-Native Comparison, 2019-2026

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Abstract. This study measures how equity markets price binding FDA outcomes and the language sponsors use to announce them, and asks whether AI-native biotechnology firms are priced differently from traditional ones. Screening 33 AI-native drug developers against the 29,253 applications in the Drugs@FDA database returns 0 filings, so the intended comparison is infeasible at the approval margin; the comparison is therefore relocated to regulatory and clinical milestones. For 63 approval announcements by 56 listed sponsors, the cumulative average abnormal return over the two-day announcement window is 4.58%, significant under five test statistics with different failure modes. Pairing each sponsor release with the FDA label for the same drug shows that 99.2% of releases are more positive than the regulator's own text, and that sponsor tone is uncorrelated with the drug's regulatory safety profile. Announcement returns show no detectable relation to this excess optimism, although the confidence interval is too wide to exclude economically meaningful effects.

Keywords: Event study; FDA drug approval; textual analysis; announcement tone; artificial intelligence; biotechnology.

1. Introduction

Biotechnology equity valuation is concentrated on a small number of discrete, externally verified events. A regulatory decision by the U.S. Food and Drug Administration converts a probabilistic research asset into a marketable product or terminates it, and the decision is made by a third party on a statutory timetable that the firm does not control. That combination of exogeneity, verifiability and precise timing make drug approvals one of the cleanest settings in which to observe how new information enters prices, and a long line of event studies has exploited it [1-5]. The same literature has established that the announcement itself is a text authored by the firm, not by the regulator, and that firms exercise discretion over how a given outcome is framed [6].

A distinct body of capital flowed into biotechnology over the past decade on the claim that machine learning compresses discovery timelines, and the question of whether markets differentiate these firms at binding regulatory outcomes has not been examined. This study finds that the question cannot be answered at the approval margin, because the events do not exist. Matching 33 AI-native and computation-first drug developers, listed and private, against the complete Drugs@FDA application file returns 0 applications of any type, while six positive controls run through the identical query return between 4 and 35 applications each. The absence is therefore the property of the firm rather than of the matching procedure: as with the sample cut-off, none of the screened developers submitted a marketing application, let alone obtained approval. The return analysis that follows necessarily uses the narrower set of 10 of these firms that are listed on a US exchange and file with the Securities and Exchange Commission.

This study consequently adopts a two-arm design. A confirmatory arm estimates announcement returns and the incremental role of announcement language for 63 FDA approvals by listed traditional sponsors, where sample size and method are standard. An exploratory arm relocates the AI-native comparison to the regulatory and clinical milestones these firms do generate. Three results follow. Approval announcements earn a large and robustly significant positive abnormal return. Sponsor announcements are almost without exception more positive than the FDA's own label for the same drug, and the degree of optimism is unrelated to the drug's documented safety profile. Markets show

no detectable response to that optimism: the excess-tone measure has no cross-sectional explanatory power for announcement returns, on a sample too small to rule out an economically meaningful one.

2. Background and Related Work

Event-study inference in this setting rests on a standard toolkit [7, 8], with two adjustments that the drug-approval application makes mandatory. Announcement-induced variance inflates conventional test statistics, which motivates the standardized cross-sectional statistic of Boehmer, Musumeci and Poulsen [9]. Regulatory events also cluster in calendar time, inducing cross-sectional correlation in abnormal returns that biases test statistics upward unless corrected [10].

Empirical work on FDA events reports positive average reactions to approvals and larger negative reactions to failures, with effect sizes that scale inversely with firm size. Sharma and Lacey document that product-development outcomes map into firm value, with an asymmetry between successes and failures [1]. Rothenstein and co-authors find pronounced pre-announcement drift around oncology trial results but no detectable differential at FDA decisions themselves [2], and Hwang reports median abnormal returns near one percentage point for positive trial results among large firms [3]. Studies using comprehensive samples find much larger magnitudes for development-stage firms: Singh and co-authors report a two-day abnormal return of 6.3% for early-stage biotechnology sponsors, some 11 percentage points above the comparable figure for large pharmaceutical firms [4], and Cho, Singh and Lo document that biotechnology reactions to news are larger in both mean and dispersion than those of large pharmaceutical firms [5]. Evidence on regulatory designations is contested and appears to depend on which designation is studied. Miller reports a mean abnormal return of 3.4% on orphan-drug designation, with the point estimates concentrated in nano- and micro-capitalization firms, although the size-group estimates are not individually significant [11]; breakthrough-therapy designation has been examined separately and reaches a markedly less favourable assessment [12]. Hamill and co-authors show that a substantial part of the disagreement in this literature is attributable to event-day misspecification, since the administrative approval date frequently differs from the date the information reaches the market [13].

The language of corporate disclosure carries information beyond its quantitative content. Loughran and McDonald establish that finance-specific dictionaries are required for reliable tone measurement [14]; Huang, Teoh and Zhang show that the component of tone orthogonal to fundamentals is managed rather than incidental [15]; and transformer-based classifiers now outperform dictionary methods on financial text [16]. The pharmaceutical setting supplies unusually direct evidence of framing discretion: comparing complete response letters with the sponsor announcements that accompanied them, Lurie and co-authors find that sponsor releases reproduced only a small fraction of the regulator's stated concerns [6].

Evidence of AI-aided discovery is scarce and controversial. Jayatunga and co-authors reported from a consultancy advising the sector that Phase I success rates for AI-discovered molecules are well above historical norms, but Phase II rates are in line with the industry average; they described the sample as limited [17], and Khairil and co-authors characterized the field as a high-investment, low-validated-clinical-impact transitional period [18]. Where the fundamentals are unverified, the market has repeatedly priced technological narratives directly, as shown by the internet-era name change [19] and blockchain-related disclosure [20]. The question this paper attempts to address is whether AI-native drug developers are priced based on the narrative or on regulatory substance.

3. Data and Sample

The population of regulatory events is the set of novel drug approvals by the FDA Center for Drug Evaluation and Research from 2019 to 2025, and it includes the 339 approvals listed in the agency's own annual novel-approval files. Every record has an application number, the sponsor of record, receipt and approval dates, review designation, and expedited-programme flag.

Listed sponsors are retrieved using EDGAR full-text search and are not matched with the ticker directory. Name matching was tested and failed; only a small number of sponsors were found, and there were false positives among unrelated companies with similar names, an error that is carried over in the return series without a diagnostic signal. The procedure is to search the 8-K and 6-K filings in a window around each approval for the drug's proprietary name and keep the filer whose name is most similar to the FDA sponsor of record. A match is only accepted if the name similarity exceeds a certain threshold, and if more than one filer is returned, the leading candidate must be separated from the runner-up by a fixed margin; 133 of the 339 approvals are resolved under this rule, 36 fail it, and 170 are not returned at all. Ambiguous cases are not resolved manually; they are left as is. The two economically distinct groups are not separated by any mechanical rule; that is to say, corporate parents of the sponsor of record and counterparties with only royalty or licensing interests should not be assigned by inspection, as this would reintroduce the undetectable mapping error that the procedure aims to avoid. A separate exclusion list is kept for filers whose exposure to an approval is a royalty interest in that approval rather than in the asset itself; these companies announce drugs sponsored by others but have a different economic interest, and under the similarity rule, these filers have already been excluded, so no further approvals are removed by this list. Tickers for sponsors that have been acquired or delisted since are obtained from the exchange identifier in the firm's own press release and cannot be obtained through directory mapping.

The event date is the EDGAR filing date of the 8-K or 6-K, not the FDA approval date. The approval date is an administrative day that often precedes public disclosure, and using it is incorrect in a considerable number of cases [13]. There is a need for filing only when it is material; many large, diversified pharmaceutical companies do not submit a separate current report for each approval, so the resulting sample is concentrated in companies with significant approvals. After obtaining an identifiable ticker, parsing the FDA label and requiring sufficient price history, 63 events from 56 sponsors remain. Table 1 shows the construction.

The AI-native arm covers listed firms whose public identity rests on a named computational discovery platform. Because these firms generate no approvals, their events are regulatory designations, investigational-new-drug clearances and first dosing, topline trial readouts, and terminations or clinical holds, identified from the full 8-K and 6-K record of each firm and classified by pattern matching on the text of the attached press release. Filings bundled with quarterly results are excluded, because milestone language in a quarterly business update cannot be separated from the earnings information released at the same time; filings without an attached press release and repeat filings on the same day are also excluded. Of 214 candidate filings, 185 are excluded under these rules, leaving 29 milestone events, of which 25 have the price history required for estimation.

The two text corpora are built. The regulator's corpus is the "Highlights of Prescribing Information" section in the approved label; this includes the boxed warning, contraindications, warnings and precautions, and adverse reactions, and must be in the format stipulated by regulations. The firm-side corpus is the announcement text that the sponsor filed with the report. Documents are identified by the exhibit type in the filing header and not by file name. The two types of documents accepted are exhibits of type EX-99, which is the standard form for an attached press release, and the body of a Form 6-K, as foreign private issuers provide the release itself as the report rather than as an attachment. The body of Form 8-K is not admitted because it is a legal document of only a few hundred words, and its register is not the same as that of a press release; such filings provide return observation but no tone observation. The same admission rule is applied to both arms, as tone comparison across arms is not meaningful if the two sides are measured based on different genres of text. Boilerplate parts are not included in the final release before measurement; the forward-looking statements and company descriptions are standard template content that varies in length among companies and would otherwise dilute tone mechanically.

4. Method

Abnormal returns are estimated with the market model, using the SPDR S&P Biotech ETF as the benchmark. The equal-weighted biotechnology index is preferred to a capitalization-weighted alternative because the sample is concentrated in small and mid-capitalization firms. Parameters are estimated over the interval from 250 to 30 trading days before the event, which requires at least 120 valid observations and ends well before the approval decision date so that anticipatory volatility does not enter the estimation window. Returns are computed close to close from split- and dividend-adjusted prices.

Statistical inference uses five statistics with different failure modes. The conventional cross-sectional t-statistic assumes homoskedastic, uncorrelated abnormal returns. The Patell statistic standardizes residuals by their estimation-period standard error and accounts for prediction error. The Boehmer, Musumeci and Poulsen statistic is robust to event-induced variance [9]. The Kolari and Pynnönen adjustment corrects the preceding statistic for cross-sectional correlation among the abnormal returns entering the average [10]; the required average pairwise correlation is estimated from estimation-period abnormal returns and set to zero for event pairs whose event windows share no calendar date, since abnormal returns measured over disjoint intervals cannot be contemporaneously correlated. The Corrado rank statistic is a non-parametric alternative that does not rely on normality of daily returns. Agreement across all five is treated as the criterion for a reliable result.

Tone is measured with the Loughran and McDonald finance dictionary [14]. Net tone is the difference between positive and negative word counts divided by the total number of alphabetic tokens, expressed in percentage points, and the identical dictionary and denominator are applied to both corpora so that the two sides are commensurable.

A pair is the basic instrument for measurement. An announcement of a successful approval is generally in a positive mood and therefore shows little cross-sectional variation in raw sponsor language. Benchmarking each release with the regulator's own text for the same product shows that the difference depends on how far the sponsor's characterisation deviates from the regulatory record:

$$\text{ExcessTone}_i = \text{CompanyTone}_i - \text{FDATone}_i \quad (1)$$

The two sides are not commensurable in the strict sense: a press release and a label Highlights section differ in genre and length, and the label describes a product's standing safety profile rather than the approval event. Equation (1) is therefore a descriptive cross-text differential, not a decomposition that removes objective content from firm language, and it is interpreted as such throughout.

Validity of the regulator-side measure was verified before it was used, since a label-tone measure that is merely noise would leave equation (1) measuring noise as well, without any diagnostic signal. Two candidate texts were compared to a stratified pilot and then on the full corpus. Approval letters proved unusable, having little dispersion and essentially no association with the regulatory burden they describe, because their content is dominated by boilerplate post-marketing requirements. Label Highlights text passes the same test against an externally observable benchmark: across 332 labels, the 73 drugs carrying a boxed warning score 0.862 percentage points more negative than the 259 that do not, with $t = 5.69$ and a standardized effect size of 0.75. FDATone therefore tracks externally observable regulatory content rather than noise. The same check says nothing about the validity of sponsor tone, which has no comparable external benchmark.

Because the FDA publishes no text for designations, investigational-new-drug clearances or trial readouts, equation (1) is not computable for the exploration arm. The design anticipated using tone residualized on event-type indicators to compare arms, following the logic of abnormal tone in the disclosure literature [15]. That construction turns out to be degenerate here: event type separates the two arms perfectly, since every confirmatory-arm event is an approval and no exploratory-arm event is, so residual tone has mean zero within each arm by construction and carries no information about the contrast. Raw tone is therefore compared directly with the caveat that any difference confounds

firm type with event type. Cross-sectional models regress the two-day abnormal return on tone measures and objective event characteristics, with heteroskedasticity-robust standard errors. The specification was fixed before estimation and is reported as such, without further search over windows or controls.

5. Results

Table 1 reports sample construction for both arms. Of 339 novel approvals, 332 yield a machine-readable label (97.9%), 133 resolves to an SEC filer, and 63 survive all requirements. The retained approvals are weighted toward expedited products: 63.5% carry an orphan designation, 42.9% received priority review, 23.8% a breakthrough-therapy designation and 14.3% were approved under the accelerated pathway, while 22.2% carry a boxed warning.

Table 1. Sample construction.

Panel A: confirmatory arm	Events	Panel B: exploratory arm	Events
CDER novel approvals, 2019-2025	339	AI-native firms screened	10
With machine-readable label	332	Candidate milestone filings	214
Sponsor resolved to an SEC filer	133	Excluded by rule	185
Royalty counterparties excluded	0	Milestone events retained	29
With an identifiable ticker	108	With usable price history	25
Final event sample	63	Distinct firms	6
Distinct sponsors	56		

Table 2 shows cumulative average abnormal returns. In the two-day announcement window, the confirmatory sample reached 4.58%, had a median of 2.54%, and 63% of the events were positive. The conventional t-statistic is 2.95, the Patell statistic 8.24, the standardized cross-sectional statistic 3.18, its clustering-adjusted counterpart 3.17 and the rank statistic 3.09. Event-day clustering is insignificant in this sample, and the same-day pair share is 0.0015; thus, the clustering adjustment and the unadjusted statistic are almost the same. The mean is larger than the median in all windows, so the distribution is right-skewed and a few high positive scores pull up the average. Fig. 1 shows the cumulative path over the ten trading days on both sides of the filing. The path reached 8.69% by the filing date, and of this, 3.56 percentage points were added on that day alone; the rest accumulated in the previous sessions. The rise should not be assumed to be due to anticipatory trading alone. Only 34.9% of the filings appear on the approval date itself; 65.1% are released at least one trading day later, so for most events, the approval had already gone public before the event date, and part of the pre-event accumulation is the reaction to it. Anticipatory drift ahead of regulatory news has been mentioned separately in [2], but the current design cannot distinguish between the two channels; therefore, the announcement window is taken as the main result rather than a wide symmetric window. Lag also affects event identification: the procedure keeps the first current report in the window that mentions the drug, and upon inspection, it was found that among the longer lags, some matched filings were quarterly results, securities offerings or commercial-launch announcements that mentioned an already-granted approval rather than announcing it. Restricting the sample to the 43 events filed within two trading days of the approval date raises the two-day return to 5.93%, with a t-statistic of 2.93; thus, the full-sample estimate is the conservative one, and no result depends on the looser window.

Table 2. Cumulative average abnormal returns. Benchmark: SPDR S&P Biotech ETF; market model; estimation window (-250, -30). Panel A: FDA approval announcements by traditional sponsors. Panel B: regulatory and clinical milestone announcements by AI-native firms.

Window	n	CAAR (%)	Median (%)	Positive (%)	t	Patell	Z	BMP	K-P	Corrado
Panel A: traditional										
(0, 0)	63	3.56	1.01	65	2.41	9.17	2.44	2.43	3.29	
(0, +1)	63	4.58	2.54	63	2.95	8.24	3.18	3.17	3.09	
(-1, +1)	63	5.42	3.48	70	3.27	7.09	3.09	3.07	3.01	
(-2, +2)	63	6.28	5.70	67	2.82	5.84	3.23	3.21	2.16	
(-5, +5)	63	5.69	5.73	67	3.11	3.52	2.73	2.71	0.69	
Panel B: AI-native										
(0, 0)	25	4.52	1.98	68	1.83	5.88	1.83	1.83	2.66	
(0, +1)	25	4.88	1.84	68	2.07	4.46	2.08	2.09	2.27	
(-1, +1)	25	3.88	0.91	60	1.71	3.08	1.79	1.79	1.42	
(-2, +2)	25	5.69	2.44	56	2.37	3.45	2.74	2.63	2.41	
(-5, +5)	25	5.39	1.73	56	1.80	2.40	2.19	2.10	1.53	

The paired text measures behave as the design intends. Tone is available for 118 approvals, a set that overlaps the return sample without coinciding with it: 55 approvals have both tone and a usable return observation, 63 have tone but no price history, and 8 have returns but no admissible sponsor text. The descriptive tone results below use all 118 pairs; the cross-sectional regression uses the 55-observation intersection. Across 118 matched pairs, mean sponsor tone is -0.469% and mean label tone is -3.545%, giving a mean excess tone of 3.076 percentage points. The sponsor release is more positive than the regulator's text for the same drug in 117 of 118 pairs, or 99.2%, and the paired difference has a t-statistic of 20.26. Sponsor tone is statistically unrelated to label tone, with a correlation of 0.073: the language of an approval announcement carries no trace of how burdened the approved product's safety profile actually is. Excess tone is not a relabelling of either component, correlating 0.598 with sponsor tone and -0.755 with label tone. Fig. 2 shows the three distributions together with firm tone in the AI-native arm.

Table 3 reports the cross-sectional models. In the confirmatory arm the two-day abnormal return is regressed on excess tone, label tone and a boxed-warning indicator. The coefficient on excess tone is -0.16 with a robust standard error of 1.48, and the model explains a negligible share of the cross-sectional variation. The systematic optimism documented above is therefore large in the text and undetectable in prices. The estimate is not, however, a tight zero: the interval implied by that standard error spans roughly three percentage points of abnormal return in either direction per unit of excess tone, so effects of economic size cannot be ruled out on 55 observations.

Table 3. Cross-sectional models of the two-day abnormal return. Heteroskedasticity-robust standard errors in parentheses.

	Panel A: confirmatory		Panel B: pooled	
	Coefficient	(SE)	Coefficient	(SE)
Excess tone	-0.16	(1.48)		
Label tone	-1.53	(1.86)		
Boxed warning	-3.29	(4.93)		
Milestone event (AI-native arm)			-0.12	(2.83)
Residual tone			-0.17	(1.50)
Milestone x residual tone			-0.69	(2.29)
Constant	0.90	(3.37)	4.94	(1.62)
N	55		80	
R-squared	0.033		0.001	

The exploratory arm is reported without causal interpretation. Of the 513 current reports filed by the AI-native firms over their listed histories, 214 contain milestone language; the exclusion rules

leave 29 announcements, of which 25 for 6 firms have the price history an estimation window requires. Panel B of Table 2 reports the corresponding abnormal returns: 4.88% over the two-day window on 25 events, with a standardized cross-sectional statistic of 2.08 and a rank statistic of 2.27. The magnitude is close to the approval effect on Panel A, although the underlying events differ sharply in informational content: a designation or an early-phase readout does not establish marketability, whereas an approval does. Firm tone in the exploration arm averages 0.581% against -0.3% in the confirmatory arm, a Welch statistic of 4.13. That contrast cannot be attributed to firm type, because every confirmatory-arm event is an approval and no exploratory-arm event is; the comparison is between approval announcements and milestone announcements as much as between two kinds of firm. Panel B of Table 3 pools both arms, and its milestone indicator inherits the same collinearity: it is the milestone-versus-approval contrast rather than a firm-type effect. Neither it nor the interaction with tone is distinguishable from zero. Power is limited more severely than the event counts suggest, since the 25 exploratory events come from only 6 firms and are not independent within firm; treating events as independent, the design could detect standardized differences above 0.64, and the firm-level bound is looser still.

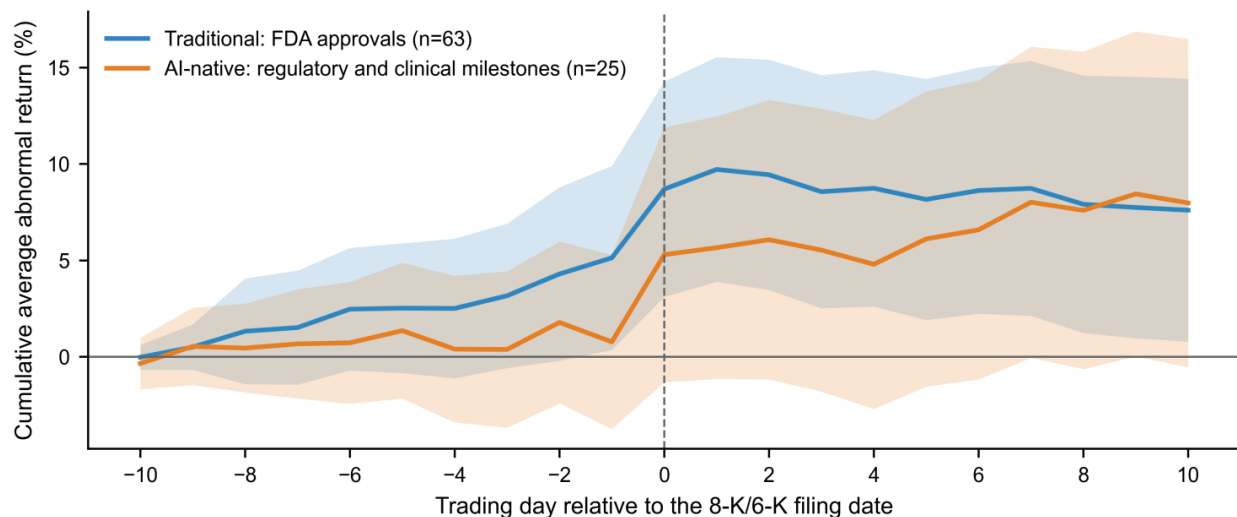


Fig 1. Cumulative average abnormal return around the filing date, by arm. Shaded areas are pointwise 95% bands computed from the cross-sectional standard error of daily abnormal returns; they assume independence across events and days and are indicative rather than simultaneous confidence regions.

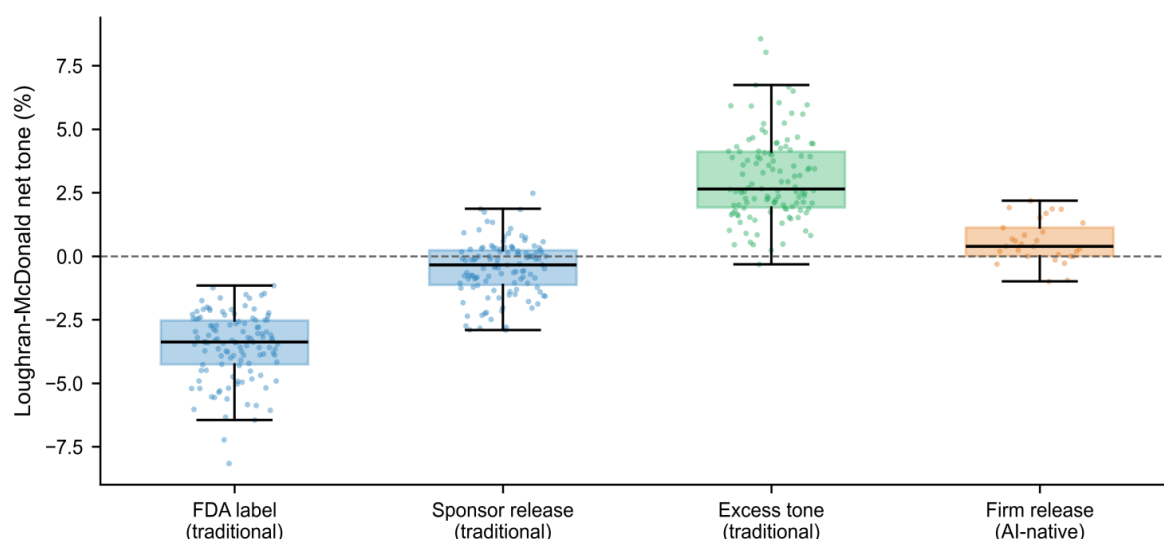


Fig 2. Distribution of Loughran-McDonald net tone for FDA labels, sponsor releases, the paired excess-tone measure, and AI-native firm releases.

6. Discussion and Limitations

Three limitations bound the interpretation. First, price data for delisted securities are not available from free sources, and 42 of 105 otherwise-usable approval events are lost for this reason, almost all of them sponsors acquired after the approval. The lost events are not a random subset. They resemble retained events on boxed warnings (21.4% against 22.2%) and orphan designation (52.4% against 63.5%) but are markedly richer in breakthrough-therapy designation (45.2% against 23.8%), accelerated approval (26.2% against 14.3%) and priority review (64.3% against 42.9%). Expedited designations mark products with larger commercial stakes and higher attention, and the designation literature reports positive point estimates for them [11], so the retained sample plausibly understates the true average reaction; the direction is an inference from sample composition rather than a tested claim, and the reported figure is best read as a conservative bound. A further 3 approvals with identifiable tickers drop out before the price screen, one because its label could not be parsed and the remainder because the matched filing predates the approval date and therefore cannot be the approval announcement; this is why the funnel in Table 1 runs from 108 to 105 before price availability is imposed.

Second, the requirement of a current report selects for firms whose value is concentrated in the approved product. Therefore, the estimates describe product-oriented sponsors and do not cover all the approvals. That restriction is where the announcement-language question has content, as a diversified sponsor has little to lose from how one approval is framed, but the resulting magnitudes should not be taken as population averages.

Third, the exploratory arm is small by construction, and its event identification is limited to what reaches EDGAR. Milestone events are present in current reports, so a designation that a company has only announced through its investor relations channel and has not filed a current report is outside the sample; announcements included with quarterly results are excluded because the milestone language cannot be separated from the earnings release. Only a small number of AI-native companies have been listed long enough to provide an estimation window. The results in that arm are consistent with either a real absence of a differential or insufficient power to detect one, and the paper does not specify which. The lack of approval for these companies is the binding constraint, and it will remain so until the first AI-designed molecule is approved.

7. Conclusion

Markets respond strongly and reliably to FDA approvals for sponsors whose value is concentrated in the approved product, with a two-day abnormal return of 4.58% that is significant under five test statistics with different failure modes. Firms announcing those approvals are almost universally more positive than the regulator writing about the same drug, and the extent of that optimism bears no relation to the drug's documented safety profile. No relation between that optimism and announcement returns is detectable in this sample, although the estimate is imprecise enough that a meaningful relation cannot be excluded.

The comparison that motivated this study cannot yet be run. AI-native drug developers have filed no marketing applications of any kind, so no approval-event sample exists for them, and the comparison must be relocated to earlier milestones where the regulator publishes no counterpart text and where the number of firms with sufficient listing history is small. Establishing that the comparison is currently infeasible, and quantifying how far it is from feasible, is a precondition for the study that will eventually be possible.

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