FDA approval announcements: attention-grabbing or event-day misspecification?

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HIGHLIGHTS

- The R&D sector is an important enabler of innovation to support growth.
- The attention-grabbing hypothesis provides a behavioural explanation for abnormal returns for FDA approval announcements for NYSE listed firms.
- We support event-day misspecification as an alternative explanation.
- Increases in shareholder wealth are driven by after-market-close announcements.

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ABSTRACT

The attention-grabbing hypothesis has been offered as a behavioural explanation for post-event abnormal returns for FDA drug approval announcements for NYSE listed firms. We show that when event-day mis-specification is accounted for the market reaction is centred on the event-day and that the increase in firm value is driven by after-market-close approval announcements.

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1. Introduction

The importance of R&D in driving innovation is well established in the endogenous growth literature (Coe and Helpman, 1995; Dungey and Volkov, 2018). Subsidies and patents are two of the main tools of R&D policy to support and protect the outputs from innovation (Perez-Sebastian, 2015). In this paper we focus our analysis on shareholder wealth effects for pharmaceuticals firms listed on the New York (NYSE) who were granted Food and Drug Administration (FDA) approval for new drug applications. Specifically, this paper investigates the impact of determining the exact timing of the market's reaction to FDA approval announcements and explores whether the attention-grabbing hypothesis provides an explanation for post-event abnormal returns reported (Hamill et al., 2013). Berkman and Truong (2009) show that post-event abnormal returns accompanying earnings announcements can be explained by mis-specification of the event day 0.

Barber and Odean (2008) examine the day following extreme returns to mitigate endogeneity. In an event study context, strict application of their model implies possible post-event abnormal returns on day +1. They point out that news items, such as FDA approvals, will catch the attention of some investors, while the extreme one-day returns — the previous day's big gainers and losers — will catch the attention of others. The result is that many investors may learn of the extreme returns/news after the market closes such that their first opportunity to respond is the next trading day. *Ex-ante*, adjusting for event day misspecification and observing a positive market reaction on day +1 supports the attention-grabbing hypothesis and should provide impetus to explore this issue further. In contrast, accounting for after-market-close announcements and observing a market reaction exclusively on day 0 provides clear evidence of the impact of event day misspecification and the need to make this adjustment when seeking to understand valuation effects accompanying FDA approval announcements, and for event studies in general.

2. Data

We identify original new drug approvals — including New Drug Applications (NDAs) — and biologic license applications (BLAs) from January 2009 to December 2015 from the US Food and Drug Administration (FDA) website. We note that drug approvals for sale in the US can be traded to another pharmaceutical company. Because the FDA monthly drug database only shows current information for the products listed (i.e. at December 2016)[1] we also match the drug approvals database with the applicant column in the "*CDER Drug and Biologic Calendar Year Approvals*" list provided every year to align the actual sponsor companies with the FDA drug announcements. In our sample all companies are listed on the New York Stock Exchange. To be included in the sample firms must have daily share price data available to conduct an event study from DataStream. We exclude any observations with contemporaneous news announcements +/- 3 days from the LexisNexis database. Table 1 provides a breakdown of the 233 approval announcements from 2009 to 2015.

[1] Note from FDA website, consulted December 2016.

Table 1
FDA approvals for NYSE listed pharmaceutical firms from 2009 to 2015

Year	Before market open	During market hours	After market close	No time stamps	Total by year
2009	0	2	21	12	35
2010	0	2	16	11	29
2011	1	7	15	10	33
2012	2	5	13	8	28
2013	2	4	15	9	30
2014	1	8	19	8	36
2015	0	13	22	7	42
Total	**6**	**41**	**121**	**65**	**233**

Notes: Before the market open for announcements released before 9:30 ET of the FDA announcement dates; during market hours for those announced from 9:30 to 16:00 ET; after the market close for FDA notifications occurred after 16:00 ET of the announcement dates or a couple of days after the FDA announcement dates.

We use PRNewswire and Business Wire to identify the announcement dates and timestamps from press releases issued by the firm being granted a new drug approval. The FDA's '*Policy and Procedures for Communicating Approval Information'*, the information dissemination process from the FDA to the firm, requires the regulatory project manager to promptly inform the application company of the FDA's decision before notifying the FDA Press Officer[2]. Therefore, there is a possibility that a firm's own announcement may precede an announcement on the FDA website and other online sources. To ensure the timing of a drug approval announcement is exact we also searched for press releases on the company's website. When timings from alternative sources conflicted, the earliest timestamp was used. We identified the precise timings for 168 approval announcements comprising 6 before market opening releases, 41 during market hours and 121 after-close announcements.

3. Methodology

An event study methodology is employed to estimate abnormal returns to FDA approval announcements for a 43-day test period from day -21 to +21 with the market model estimated from day -150 to -22 with the S&P 500 market index used as the market proxy. Scholes and Williams' (1977) procedure is adopted to adjust the beta to account for the possibility of asynchronous prices when calculating returns. We use Ruback's (1982) test to calculate the significance of cumulative abnormal returns over different holding periods. To ameliorate their influences, and to corroborate the results for the parametric event study, Corrado's (1989) non-parametric rank test is also employed as a robustness check.

4. Results

Table 2 panel A columns 1 and 2 report the results for the unadjusted sample which simply takes the approval date announced by the FDA and ignores the time of the announcement — which could be before-market-close (BMC), or after-market-close (AMC). As would be expected, given insider trading restrictions, and consistent with the empirical literature, the pre-event mean abnormal returns on day -1 and CARs over the holding periods (-10:-1) and (-5:-1) are statistically insignificant. The market reaction on day 0 is also

[2] See FDA's Policy and Procedures about Communicating Approval Information, consulted April 2017. https://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM082010.pdf

insignificant whereas the mean abnormal return of 0.44 of a percent on day 1 is significant with a *t*-statistic of 4.61. Ostensibly, this would support the attention-grabbing hypothesis. The economic importance of this economically and statistically significant day 1 mean abnormal return is evident from the post-event abnormal returns, i.e. the CAR holding periods (1:2) and (1:21) are also statistically significant but that for period (2:21) is insignificant.

Table 2
Shareholder wealth effects around FDA new drug approval announcements

	Unadjusted		*Event adjusted*		*Event and time stamp adjusted*	
	AR/MR[a] *N = 233*	*t-stat*	*AR/MR*[a] *N = 233*	*t-stat*	*AR/MR*[a] *N = 168*	*t-stat*
Panel A: Parametric tests						
	(1)	(2)	(3)	(4)	(5)	(6)
[-10, -1]	0.18	0.62	0.15	0.48	0.14	0.34
[-5, -1]	0.17	0.81	-0.08	-0.36	-0.19	-0.69
-1	-0.08	-0.89	0.06	0.57	0.05	0.40
0	-0.03	-0.36	0.42**	4.22	0.61**	4.90
1	0.44**	4.61	0.11	1.07	0.04	0.28
2	0.07	0.69	-0.06	-0.58	-0.09	-0.77
[1, 2]	0.50**	3.83	0.05	0.34	-0.06	-0.35
[1, 21]	0.97**	2.32	0.53	1.18	0.39	0.68
[2, 21]	0.53	1.30	0.43	0.97	0.35	0.63
Panel B: Corrado's Non-Parametric tests						
-1	-2.33	-0.68	2.42	0.73	2.03	0.49
0	-2.22	-0.64	2.13	0.64	4.54	1.11
1	6.58*	1.91	5.18	1.56	4.13	1.01

Notes: [a]AR is mean abnormal returns from the parametric events study, while MR is the mean rank from Corrado's (1989) non-parametric rank test. *denotes significant at the 5% level, ** denotes significance at the 1% level, or less. N is the sample size.

Columns 3 and 4 report the results when the sample is event-adjusted to identify day 0 as the day investors are able to trade on the information. Table 1 highlights that, for the total sample of 233 announcements, 121 took place AMC. The adjusted sample treats these AMC announcements as if they occurred on event day 0 given that the stock price cannot reflect this information until the following day. When the dataset is thusly re-centred, day 0 has a positive market reaction of 0.42 of a per cent with a *t*-statistic of 4.22 and day +1 becomes insignificant. Columns 5 and 6 report the results from this re-centred excluding the 65 announcements where a timestamp could not be identified. The market reaction on day 0 remains statistically significant with a mean abnormal return of 0.61 of a percent and accompanying *t*-statistic of 4.90.

From a firm valuation perspective these results support the hypothesis that FDA approval announcements are value relevant and convey new information to the market. From a theoretical perspective, the value of firms in the pharmaceutical sector can be viewed as a portfolio of real options (Hartman and Hassan, 2006) which recognises that R&D projects are a collection of bets with a low probability of paying off given the observed empirical

probability of success for new drug discoveries[3]. Pharmaceutical investors for a small number of blockbuster discoveries[4]. To evaluate the possibility that the market reaction reflects a few extreme observations we use Corrado's (1989) non-parametric rank test as a robustness check. The results in panel B of Table 2 show that, for the unadjusted sample, day +1 remains significant at the 5% level with a mean rank of 6.58. For both the event-adjusted sample and the event- and timestamp-adjusted sample, none of the days are statistically significant which indicates that the mean abnormal return of 0.61 of a percent reported in panel A is influenced significantly by a few large observations — an outcome consistent with the payoff from a portfolio of real options.

Table 3
Before and after market close analysis

	Before-market-close		*After-market-close*	
Days	*AR/MR*[a] *N=47*	*t-stat*	*AR/MR*[a] *N=121*	*t-stat*
Panel A: Parametric test				
-1	0.27	1.31	-0.03	-0.23
0	-0.18	-0.89	0.92**	6.23
1	-0.06	-0.32	0.07	0.50
Panel B: Corrado's Non-Parametric test				
-1	13.76*	1.86	-2.52	-0.51
0	-10.03	-1.36	10.20*	2.08
1	11.55	1.57	1.25	0.26

Notes: [a]AR is mean abnormal returns from the parametric events study, while MR is the mean rank from Corrado's (1989) non-parametric rank test. *denotes significant at the 5% level, ** denotes significance at the 1% level, or less. N is the sample size. The 47 BMC announcements comprise 6 before market open announcements and 41 during market hours.

Table 3 reports the results for the parametric event study and Corrado's nonparametric rank test for the BMC and AMC announcements. None of the BMC mean abnormal returns for days -1, 0 and +1 are statistically significant. Day -1 is significant at the 5% level for the rank test. The lack of consistency for the BMC sample provides strong support for an economically significant market reaction. In contrast, the AMC announcements are statistically significant for both tests with an economically significant market reaction of 0.92 of a percent that is significant at the 1% level. There is no evidence of market reaction on days -1 or + 1 for the parametric or non-parametric tests for the AMC sample.

7. Conclusion

We show that when an appropriate adjustment for timing is made, the positive market reaction to FDA approval announcements is centred on day 0 and is driven by after-market-close announcements. Our results are robust to the influence of outliers. This analysis supports event day misspecification as opposed to the attention-grabbing hypothesis as an explanation for shareholder wealth effects.

[3] One estimate is that approximately 5 out of 5000 new chemical entities progress to human clinical trials with only 1 likely to be granted FDA approval (Dedman *et al*., 2008).
[4] The FDA approval of the muscular dystrophy drug Eteplirsen 2016 increased the share price of Sarepta Therapeutics by 90%. "FDA Approves Sarepta's Muscular Dystrophy Drug", Wall Street Journal, 19th September 2016.

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