Check for updates

Received: 27 January 2020 | Revised: 6 September 2021 | Accepted: 19 January 2022

DOI: 10.1111/jbfa.12600

JBFA

ARTICLE

Informed options trading prior to FDA announcements

Marc J. M. Bohmann | **Vinay Patel**

Finance Discipline Group, University of Technology Sydney, Australia

Correspondence
Marc J. M. Bohmann, Finance Discipline Group, University of Technology Sydney, Australia.
Email: Marc.Bohmann@uts.edu.au

Abstract

We find that pre-announcement implied volatility spreads and options trading activity are abnormally elevated and can predict Food and Drug Administration (FDA) announcement date stock returns. The effect is more pronounced in firms with higher levels of information asymmetry and lower-quality corporate governance suggesting that some options traders are informed in advance of the details that affect the stock price impact of the FDA news. We provide the first examination of informed options trading prior to FDA announcements during a 21-year period. Our findings have implications for regulators, investors and relevant firms.

KEYWORDS
FDA, implied volatility, informed, options, trading

JEL CLASSIFICATION
G14

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.
© 2022 The Authors. *Journal of Business Finance & Accounting* published by John Wiley & Sons Ltd.

1 | INTRODUCTION

Insider trading relating to US Food and Drug Administration (FDA) news is prevalent as drug-related news is in the top five news events which has resulted in prosecuted insider trading filed by the US Securities and Exchange Commission (SEC; Ahern, 2020; Patel & Putnins, 2020).[1] SEC insider trading cases indicate that confidential information relating to FDA news is leaked in advance by company insiders, related stakeholders and regulatory staff. For example, Mentor Corporation (MNT) obtained approval from the FDA to market MemoryGel breast implants in November 2006. The FDA notified MNT of its decision prior to this news becoming public information. On the announcement date, MNT's stock price increased by 10% and was accompanied by large increases in trading volume.[2] An external printing firm that was subcontracted by MNT was notified of the FDA's decision so that marketing materials relating to the implants could be released quickly once this news was made public. Using this confidential information, the Chief Executive Officer (CEO) of the printing firm made four separate purchases of MNT call options across two brokerage accounts prior to the public announcement of the FDA approval resulting in illegal profits of approximately $80,000. The CEO of the printing firm also leaked this confidential information to a family member who traded MNT stocks. The litigation case indicates that the CEO of the printing firm was aware, or should have known, that the FDA's approval decision was price-sensitive non-public information.[3]

From the MNT SEC insider trading case, the CEO of the printing firm chose to trade options to take advantage of their inside information (not using stocks or other instruments), thereby utilizing the leverage inherent in options contracts to maximize their trading profits. SEC insider trading cases and a recent stream of literature provide evidence in support of options markets being an important venue for informed and insider trading. Easley et al. (1998) use a sequential trading model in which informed traders utilize options for sufficient levels of liquidity and leverage. Several studies find that options volume and order imbalance can predict future stock returns (e.g., Ge et al., 2016; Johnson & So, 2012; Pan & Poteshman, 2006). Numerous studies report evidence of abnormal options trading activity and implied volatility prior to a variety of major corporate news announcements (e.g., Cairney & Swisher, 2004; Chan et al., 2015; Govindaraj et al., 2020). In addition, a meaningful fraction of price discovery is found to occur in equity and futures options markets (e.g., Bohmann et al., 2019; Patel et al., 2020).

Given that finance theory predicts informed trading in options markets, SEC prosecution cases provide evidence of illegal insider trading prior to FDA announcements, and numerous studies reporting evidence of abnormal changes in price and trading measures (which proxy for informed options trading) prior to major news announcements, we examine whether informed trading based on information leakage takes place in options markets prior to FDA announcements. We make a unique contribution; to the best of our knowledge, we conduct the first examination of informed options trading prior to FDA announcements during a 21-year sample period.

We examine 352 FDA new drug approvals and related announcements (which we term FDA announcements) between January 1, 1996, and December 31, 2016. As applied in prior studies as measures of informed trading, we use implied volatility spreads, options volume and order imbalance to capture the presence of informed options trading prior to FDA announcements (e.g., Bohmann & Patel, 2020; Cremers & Weinbaum, 2010; Govindaraj et al., 2020). For example, prior studies find that implied volatility spreads capture the direction of informed traders' private information.

Relative to a 50-day benchmark period, multivariate panel regressions show statistically significant increases in implied volatility spreads, call options volume and call order imbalance in the five-days preceding the FDA announcement date. Our findings are consistent with numerous studies that report abnormal changes in options trading

[1] The FDA has the aim of protecting the US public from the use of a wide range of products valued in excess of $2 trillion. These products include food, drugs, biologics, medical devices/products, electronic products, cosmetics, veterinary products and tobacco products. See https://www.fda.gov for further details.

[2] See Bosch & Lee (1994), Sharma & Lacey (2004), and Torabzadeh et al. (1998) for studies examining the stock market reaction to FDA announcements.

[3] For more details see https://www.sec.gov/litigation/complaints/2008/comp20485.pdf.

activity (which proxy for informed options trading) prior to major price-sensitive news announcements (e.g., mergers and acquisitions, earnings and repurchases).

Subsequently, we use cross-sectional regressions to examine whether abnormal pre-announcement options trading activity is informative about (or can predict) FDA abnormal announcement date stock returns. We report a positive and statistically significant relationship between FDA abnormal announcement date stock returns and abnormal pre-announcement implied volatility spreads, abnormal call options volume and abnormal call options order imbalance. Such findings indicate that some traders are informed about the finer details that affect the price impact of the announcement (e.g., drugs that have the potential to significantly improve the treatment of a life-threatening condition). Our main findings are robust to a number of alternate specifications (e.g., various measures of informed trading, sample construction, and econometric considerations).

Insider trading/information leakage (e.g., as evidenced by SEC prosecution cases) and the superior information processing skills of options investors provide two explanations for the positive association between abnormal pre-announcement options trading activity and FDA abnormal announcement date stock returns.[4] We show that the relationship between abnormal pre-announcement options trading activity and FDA abnormal announcement date stock returns is stronger for firms with higher levels of information asymmetry (i.e., private information will be more valuable for firms with inefficient prices; Huddart & Ke, 2010) and firms with weaker corporate governance quality (i.e., firms where information leakage is more likely to occur; Monks & Minow, 1995). Such findings suggest that at least some of the abnormal trading activity that we document in options markets is based on information leakage. Furthermore, we find that investors strategically trade prior to FDA announcements, using options that are more liquid, cheaper to trade and that expire soon after the horizon of their information.

We find that investors earn returns of approximately 15% by purchasing call options five-days prior to FDA announcements and closing out their positions on the day following the revelation of the news. Such returns are valuable for investors and provide an explanation for why we observe abnormal pre-announcement trading activity in options, and why such pre-announcement options trading activity is informative about the FDA abnormal announcement date stock returns.

This study will be of interest to regulators, investors and relevant pharmaceutical-related firms. To our knowledge, we are the first to examine and report informed trading in options markets prior to FDA announcements. This will be of concern to regulators and investors regarding whether financial markets work properly, the fairness of markets and the potential negative effects this could have upon investors' willingness to trade and flow-on effects to market liquidity. Pharmaceutical-related firms and related stakeholders should be concerned about the leakage of information and may want to revise which individuals are trusted with such material information. Our findings are also informative to regulators as they increase our knowledge of informed trading strategies, particularly where and when such investors choose to trade.

Our findings contribute to the growing body of literature that reports the abnormal behavior of returns, volume, open interest and implied volatility spreads/skew in stock and options markets around major corporate announcements. For example, around earnings releases (e.g., Bohmann et al., 2019a; Lu & Ray, 2016; Tsai, 2014; Udpa, 1996), mergers and acquisitions (e.g., Bugeja et al., 2015; Cao et al., 2005; Chan et al., 2015), repurchases (e.g., Hao, 2016), stock splits (e.g., Chern et al., 2008), management forecast disclosures (e.g., Cairney & Swisher, 2004), bankruptcies (e.g., Cheng et al., 2018) and large price changes (e.g., Patel & Michayluk, 2016b; Savor, 2012). Holistically, the literature suggests informed trading in options markets is a pervasive issue.

The remainder of the paper proceeds as follows. Section 2 provides a summary of the FDA approval process and details our sample data and methodology. We report and discuss our results in Section 3. Section 4 concludes.

[4] For example, Patel et al. (2020) show that an economically meaningful fraction of information is first impounded into options prices before being reflected in stock prices, these estimates indicate that options markets play an important role in reflecting private information and in increasing the informational efficiency of options and stock prices.

2 | FDA APPROVAL ANNOUNCEMENTS, DATA AND INFORMED TRADING MEASURES

2.1 | FDA approval announcements

A new drug (or device) goes through several stages before being considered by the FDA's Center for Drug Evaluation and Research for approval, marketing and sale.[5] Once a firm develops a new drug compound to prevent or treat a disease or injury, it will need to conduct pre-clinical tests of the drug on animals. Subsequently, a firm can submit an investigational new drug (IND) application to the FDA. The IND contains detailed information about the drug (e.g., regarding drug chemistry, manufacturing and pre-clinical results) and the proposed testing on human subjects.

The next stage of the drug development process consists of three clinical phases. In Phase 1, the drug is tested on up to 100 individuals to provide initial evidence regarding the drug's effectiveness, how it is metabolized, dosage, safety and side effects. Phase 2 is a larger-scale version of Phase 1, and testing is undertaken on several hundreds of individuals. In Phase 3, the drug is tested on several thousands of individuals, with the aim of identifying the wider success of the drug and its side effects. The drug development process is rigorous, as only 5% of drugs proceed past Phase 3.

Following Phase 3, firms can submit a new drug application (NDA) to the FDA. Through the NDA, the FDA reviews, assesses and validates the drug's effectiveness, safety, side effects, dosage, absorption, excretion, manufacturing process including facility inspection, pre-clinical and clinical study methodology/results and labeling. Successful FDA approval of the NDA allows the firm to market the new drug, such approvals are the focus of this study. The FDA notifies an applicant firm of their approval decision; subsequently, the FDA press office proceeds with announcing this information to the public. Following FDA approval (i.e., Phase 4, the post-marketing phase), a firm typically conducts further tests to learn more about the drug and provides updates to the FDA.

Information leakage of FDA news is possible as representatives of the firm and representatives of the FDA have advanced knowledge of this material information prior to the public. Therefore, it is possible for insider trading to take place prior to FDA announcements by company insiders, regulatory staff or by individuals connected to them. For example, a printing sub-contractor leaked inside information to a family member regarding the FDA's approval of MNT's breast implants and these individuals illegally traded on such information in stock and options markets. In another example, an Alimera Sciences (ALIM) officer was in possession of confidential information relating to the FDA's approval decision of a diabetes treatment drug. Prior to the FDA announcement date, this individual shared this information with his wife, who further shared this information with several members of her family, who illegally traded on this information. At the time, ALIM's market capitalization was less than $300 million. Insider trading in smaller firms suggests that the prevalence of insider trading could be related to the level of information asymmetry (e.g., private information can be more valuable for firms that have higher levels of information asymmetry and inefficient prices). In another example, the Chief Executive Officer, general counsel and a number of executives of ImClone Systems, and individuals connected to them, illegally traded prior to the FDA's announcement relating to a cancer treatment drug. Insider trading by various individuals at the same firm suggests that the prevalence of insider trading could be related to a firm's corporate governance quality (e.g., weaker corporate governance quality can be associated with a higher probability of information leakage). In another example relating to regulatory staff, a former FDA employee (who did not disclose their role as a hedge fund consultant) obtained non-public material information relating to FDA approvals from FDA staff and leaked this information to a hedge fund manager. The hedge fund manager made substantial profits from trading on such confidential information.[6]

[5] For further details, see Ciociola et al. (2014), FDA Manual of Policies and Procedures (MAPP) and https://www.fda.gov/patients/learn-about-drug-and-device-approvals.

[6] For further information regarding these SEC litigation cases, see:https://www.sec.gov/litigation/admin/2016/34-79581.pdf,https://www.sec.gov/news/press/2002-87.htm, andhttps://www.sec.gov/news/pressrelease/2016-119.html.

TABLE 1 Sample selection filters

	Total	Standard	Priority
(1) Total number of Food and Drug Administration (FDA) announcements between January 1, 1996, and December 31, 2016	2252	1834	418
(2) Keep announcements with corresponding data in the CRSP database	1385	1130	255
(3) Keep announcements with corresponding data in the OptionMetrics database	898	734	164
(4) Keep announcements with non-missing abnormal implied volatility spread values during the pre-announcement period [−5,−1]	352	257	95

Note: This table reports the sample selection filters applied to FDA announcements between January 1, 1996, and December 31, 2016. FDA announcements are obtained from the FDA drug database. Daily options data are obtained from OptionMetrics and corresponding stock data from CRSP and Compustat. *Priority* announcements are for drugs that demonstrate the potential to provide a significant improvement in the medical practice.

2.2 | Data

Daily US options data are obtained from OptionMetrics, and corresponding stock data are obtained from the Center for Research in Security Prices (CRSP) and Compustat between January 1, 1996, and December 31, 2016. For the same sample period, we obtain 2,252 new drug approval announcements from the FDA drug database accessible via https://www.accessdata.fda.gov.

Table 1 summarizes our sample selection filters. We merge FDA announcement data with OptionMetrics and CRSP data by ticker and company name which reduces our sample to 898 announcements. In addition, we exclude announcements with missing values of abnormal implied volatility spreads on any day in the five-day pre-announcement period [−5,−1] prior to the FDA announcement.[7] Our final sample consists of 352 announcements from 166 companies during a 21-year sample period.

We report the time series of FDA announcements during our sample in Table 2. After applying our selection filters, we have an average of 17 announcements per year. The number of announcements in our sample fluctuates between a maximum of 30 in 2014 and a minimum of six in 1999. A majority of announcements (257/352 or 73%) are given a *Standard* classification by the FDA, whereas 95 announcements are given a *Priority* classification. A *Priority* classification is determined for a "drug that demonstrates the potential to provide a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening condition from a drug that does not demonstrate such a potential" (FDA MAPP).

Table 3 shows a breakdown of 13 different FDA announcement classification types. For our sample of announcements, the most common type is *New molecular entity* news (105/352 or 30%) which relates to molecules that have never been previously approved by the FDA and are responsible for the beneficial effects of taking drugs. The second most common type is *New indication* news (91/352 or 26%) which relates to new applications of existing drugs in terms of their prevention or treatment of a disease. Unsurprisingly, a large majority of announcements are made by pharmaceutical companies with a Standard Industrial Classification code of 2834 (250/352 or 71%).

[7] If we omit this filter, we have a sample of 898 FDA announcements. Using this extended sample, we draw similar conclusions to our main results obtained using a sample of 352 FDA announcements (see Tables IA.1 and IA.2 in the Internet Appendix IA). In addition, our sample of FDA announcement dates does not correspond with the release of other corporate news (e.g., earnings, dividends, mergers and acquisitions and capital structure).

TABLE 2 FDA announcements over time

Year	Total	Standard	Priority
1996	17	10	7
1997	8	5	3
1998	13	9	4
1999	6	1	5
2000	10	8	2
2001	14	10	4
2002	16	15	1
2003	20	15	5
2004	22	11	11
2005	11	7	4
2006	29	21	8
2007	21	16	5
2008	17	15	2
2009	18	15	3
2010	21	19	2
2011	18	14	4
2012	14	11	3
2013	18	15	3
2014	30	19	11
2015	21	15	6
2016	8	6	2
Total	352	257	95

Note: This table reports the number of FDA announcements in our sample between January 1, 1996, and December 31, 2016. *Priority* announcements are for drugs that demonstrate the potential to provide a significant improvement in the medical practice.

2.3 | Informed trading measures

Similar to prior studies, we measure informed options trading using implied volatility spreads (*IVS*), as a widening of the implied volatility spread captures the direction of an informed trader's private information (e.g., Cremers & Weinbaum, 2010; Jin et al., 2012). For example, when investors possess positive news they can buy call options and/or sell put options. Given the positive relationship between options prices and implied volatility, this will increase the price spread and thus the implied volatility spread between call and put options. A similar argument applies when investors have negative information. For each stock-day (*it*), we calculate open interest-weighted implied volatility spreads:

$$IVS_{it} = \sum_{j=1}^{N_{it}} w_{jt}^{i} \left(IV_{jt}^{i,Call} - IV_{jt}^{i,Put} \right), \tag{1}$$

where $IV_{jt}^{i,Call}$ and $IV_{jt}^{i,Put}$ are the implied volatility for call and put option *j*, N_{it} is the total number of put–call pairs per stock day and w_{jt}^{i} is the average of the open interest between the call and put options for each put–call pair. Implied volatility spreads are calculated using implied volatility obtained from OptionMetrics where implied volatility is calculated using a binomial tree to account for discrete dividend payments and the early exercise premium. In the

TABLE 3 Classification of FDA announcements

Classification	Total	Standard	Priority
New molecular entity	105	50	55
New active ingredient	18	4	14
New dosage form	5	5	0
New combination	0	0	0
New formulation or new manufacturer	1	1	0
New indication	91	76	15
Drug already marketed without approved NDA	3	3	0
Partial Rx to OTC switch	29	24	5
New indication submitted as distinct NDA–consolidated with original NDA after approval	38	34	4
New indication submitted as distinct NDA–not consolidated	12	11	1
Efficacy	2	1	1
Medical gas	6	6	0
No classification	42	42	0
Total	352	257	95
Total (pharmaceutical companies only)	250	186	64

Note: This table reports the number and classification of 352 FDA announcements in our sample between January 1, 1996, and December 31, 2016. *Priority* announcements are for drugs that demonstrate the potential to provide a significant improvement in the medical practice. *New molecular entity* relates to molecules that have never been approved by the FDA previously and which are responsible for the beneficial effects of taking drugs. *New active ingredient* relates to any component that provides pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of man or animals. *New dosage form* relates to new ways of administering existing drugs. *New combination* relates to products that comprise any combination of drugs, devices and biological products. *New formulation or new manufacturer* relates to a change in the formulation of a drug or change in the manufacturing company. *New indication* relates to new applications of existing drugs in terms of their prevention or treatment of a disease. *Drug already marketed without approved new drug application (NDA)* relates to drugs that are already marketed without FDA approval. *Partial Doctor's Prescription (Rx) to over-the-counter (OTC) switch* describes the change in drug status from requiring a practitioner prescription due to its toxicity or potential harm to the permission of OTC sales. *New indication submitted as distinct NDA-consolidated with original NDA after approval* and *New indication submitted as distinct NDA-not consolidated* refer to consolidated and not consolidated usage indications to ensure that healthcare providers can identify appropriate use of drug therapy. *Efficacy* relates to performance-enhancing drug supplements. *Medical gas* relates to drugs in gas form that are manufactured, packaged and intended for administration to a patient in anesthesia, therapy or diagnosis. Extended classification definitions can be accessed in the FDA Manual of Policies and Procedures (MAPP). Pharmaceutical companies are classified by Standard Industrial Classification code 2834.

construction of implied volatility spreads, we exclude options with: daily average quoted spreads of greater than 50%, zero open interest, a delta of smaller than |0.02| or greater than |0.98|, and incomplete data for put–call pairs.[8] We obtain similar results using a volume, rather than an open interest, weighting to compute implied volatility spreads.

In addition, we use options trading activity to capture informed trading to ensure that our findings are not solely dependent on implied volatility-based measures. We measure options volume using the number of contracts traded. For each stock day, we calculate the daily traded options volume scaled by shares outstanding (*OV*). Similarly, we define call volume (*OV.Call*) and put volume (*OV.Put*).

[8] Following Bollen and Whaley (2004), we define options moneyness: in-the-money (ITM) options have a delta range between |0.625| and |0.98|, at-the-money (ATM) options have a delta range between |0.375| and |0.625| and out-of-the-money (OTM) options have a delta range between |0.02| and |0.375|.

TABLE 4 Descriptive statistics

Variable	Mean	Median	Standard deviation
AB.RET [0] (%)	0.973	0.187	3.921
IVS [−60, −11] (%)	−0.393	−0.300	3.760
AB.IVS [−5, −1] (%)	0.118	0.121	3.746
IV [−5, −1] (%)	41.309	32.686	28.702
OV [−60, −11] (%)	0.115	0.047	0.296
AB.OV [−5, −1] (%)	0.041	0.029	0.022
SV [−5, −1] (%)	2.343	0.202	1.351
PRC ($)	32.467	22.110	39.707
MktCap ($*m*)	18,028.34	1,189.09	47,966.32

Note: This table shows descriptive statistics of options and stock trading variables: *AB.RET* [0] is stock return minus the return on the value-weighted CRSP market index on the FDA announcement on day [0], *IVS* [−60, −11] is implied volatility spread averaged during the days [−60,−11], *AB.IVS* [−5, −1] is abnormal implied volatility spread averaged during the days [−5,−1], *IV* [−5, −1] is implied volatility averaged during the days [−5,−1], *OV* [−60, −11] is options volume scaled by shares outstanding averaged during the days [−60,−11], *AB.OV* [−5, −1] is abnormal options volume scaled by shares outstanding averaged during the days [−5,−1], *SV* [−5, −1] is stock volume scaled by shares outstanding averaged during the days [−5,−1], *PRC* is closing share price and *MktCap* is the market capitalization as of the end of the fiscal year prior to the announcement. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016.

We calculate the abnormal values of each informed trading measure ($AB.Metric_{ie}$) by taking the difference between the daily trading measure during the event period [−10,+10] around the FDA announcement and the average value of the trading measure during the benchmark period [−60,−11]:

$$AB.Metric_{ie} = Metric_{ie} - \frac{1}{50}\sum_{t=-60}^{t=-11} Metric_{it},\ e \in [-10, +10], \tag{2}$$

where $Metric_{ie}$ is *IVS*, *OV*, *OV.Call*, or *OV.Put*. The FDA announcement date is day 0. For our main analysis, the pre-announcement period is defined as the five-day period prior to the FDA announcement date [−5,−1].

3 | RESULTS

3.1 | Descriptive statistics

Table 4 reports descriptive statistics of options and stock variables used in our analysis. Our analysis focuses on larger stocks by construction (i.e., stocks that have listed options), and this is evident as the average market capitalization of sample stocks is approximately $18,000 million. Average FDA abnormal announcement date stock returns (*AB.RET* [0]) are approximately 1%, and average abnormal pre-announcement implied volatility spreads (*AB.IVS*[−5, −1]) are positive, indicating more options trading on positive rather than negative information. Consistent with prior studies, options trading volume is smaller than stock volume. For example, in the five-days prior to the announcement date, the mean stock volume (*SV*[−5, −1]) and options volume (*OV*[−5, −1]) scaled by shares outstanding are 2.34% and 0.15%, respectively. The average implied volatility (*IV*[−5, −1]) in the five days prior to an FDA announcement is approximately 41% indicating a significant amount of future volatility.

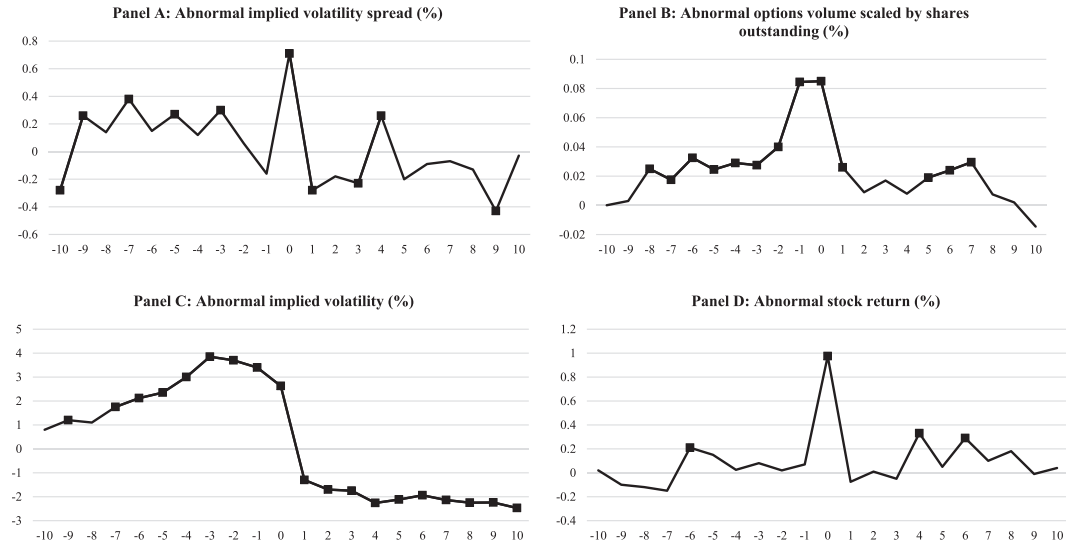

FIGURE 1 Abnormal behavior of implied volatility, options volume and stock returns around Food and Drug Administration (FDA) announcements

Note: This figure illustrates the average abnormal implied volatility spread (A), abnormal options volume scaled by shares outstanding (B), abnormal implied volatility (C) and abnormal stock returns (D) around FDA announcements. We calculate abnormal values of each trading/price measure as the difference between the daily trading/price measure during the event period [−10,+10] and the average of the trading/price measure during the benchmark period [−60, −11]. Solid squares indicate observations that are statistically significant at a 95% confidence level. The horizontal axis expresses days relative to the FDA announcement on day 0. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016

3.2 | Abnormal trading and price measures

We examine univariate plots of several variables of interest. Figure 1 plots the abnormal behavior of implied volatility spreads, options volume scaled by shares outstanding, implied volatility and stock returns during the period [−10,+10] around the FDA announcement date. Solid squares indicate observations that are statistically significant at a 95% confidence level.

Figure 1A shows that abnormal implied volatility spreads are positive during the [−9,−2] period, reaching a maximum of approximately 0.40% on day −7, before slightly declining, and again rising on day 0 to 0.70%. The mean abnormal implied volatility spreads during the period [−5,−1] prior to the announcement date is 0.118%.[9] Following the announcement, abnormal implied volatility spreads largely remain below 0%.

Figure 1B shows that abnormal scaled options volume increases from close to 0% on day −10 to a maximum of 0.08% on day 0. The abnormal options volume on day −1 is more than twice as large than during the period [−9,−2]. Post-announcement, abnormal scaled options volume fluctuates around 0.02% until day +8.

Abnormal levels of implied volatility reported in Figure 1C show a similar pattern to abnormal scaled options volume prior to the announcement date—increasing from approximately 1% on day −10 to 3% on day −1. Once the FDA announcement is revealed to the market, abnormal implied volatility quickly falls below 0% consistent with the announcement reducing the level of uncertainty between investors.

[9] We draw similar conclusions if we winsorize implied volatility spreads at the 5th and 95th percentiles and re-calculate abnormal implied volatility spreads, for example, the mean abnormal implied volatility spreads during the period [−5, −1] is 0.15%.

Figure 1D shows the behavior of abnormal stock returns. Largely speaking, abnormal returns fluctuate around 0% pre and post announcement. However, on the announcement date, abnormal returns peak at 1% consistent with the FDA announcement containing material information. The magnitude of the FDA abnormal announcement stock returns that we report in this study is economically meaningful and similar to the magnitude of abnormal stock returns observed on earnings, repurchases, stock splits and divestitures announcement dates (e.g., Chern et al., 2008; Hao, 2016; Patel & Michayluk, 2016a; Skinner, 1991).[10] Our results indicate that FDA announcements contain material information that causes a permanent increase in prices, as following the announcement date, cumulative abnormal returns reach 2% on day +10. If FDA announcements contain non-material information we would expect to see a reversal in prices after the announcement is revealed to the market.

Holistically, the abnormal behavior of implied volatility spreads, scaled options volume, implied volatility and stock returns provides univariate evidence that at least some traders are informed about the upcoming FDA announcement. A weakness of univariate tests is that it does not account for other important factors that can affect implied volatility spreads (e.g., changes in stock prices and volatility). As a result, in the following sections, we use multivariate analysis to more formally and more accurately investigate the prevalence of informed options trading prior to FDA announcements.

3.3 | Abnormal implied volatility spreads

Prior studies use implied volatility spreads to measure informed options trading. We use multivariate panel regressions to examine whether implied volatility spreads are significantly different in the days preceding FDA announcements while controlling for other factors. If some traders are informed we expect to observe abnormal increases in implied volatility spreads (*IVS*) prior to FDA announcements. Using stock-day observations during the window [−60,0], we estimate the following panel regressions:

$$IVS_{it} = \beta_0 + \beta_1 EventDV_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{it}, \quad (3)$$

where $EventDV_{it}$ is a dummy variable equal to one during the pre-announcement period [−5,−1] and equal to zero during the benchmark period [−60,−11]. We also include the following control variables: $Lag.AB.RET_{it}$ is stock return minus the value-weighted CRSP index return lagged by one-day, $|Lag.AB.RET|_{it}$ is the absolute value of $Lag.AB.RET_{it}$, $Lag.IVS_{it}$ is IVS_{it} lagged by one-day and $Lag.OV_{it}$ is options volume scaled by shares outstanding lagged by one-day. In addition, we include event fixed effects and cluster standard errors by month.

Across Models 1 to 3 in Table 5, we report a positive and significant relationship between IVS_{it} and $EventDV_{it}$. The $EventDV_{it}$ coefficient estimate indicates that average implied volatility spreads increase by approximately 0.22% in the five-days prior to FDA announcements, relative to its benchmark level. This increase in implied volatility spreads is statistically significant at a 95% level of confidence (i.e., *t*-statistics exceed 2.30 across the three models). Our findings are consistent with studies that report abnormal increases in implied volatility spreads prior to price-sensitive news (e.g., prior to repurchase announcements; Hao, 2016), where changes in implied volatility spreads proxy for informed options trading. In the next section, we examine whether the abnormal pre-announcement changes in implied volatility spreads are informative about (or can predict) FDA abnormal announcement date stock returns.

[10] Given that by definition our analysis focuses on larger stocks which have liquid listed options, the FDA abnormal announcement stock returns that we report are smaller than similar prior FDA studies which do not impose such filters on their sample. If we regress FDA abnormal announcement date stock returns on a dummy variable equal to one if the stock has listed options and equal to zero if the stock does not have listed options, we find that the abnormal announcement returns for stocks with listed options is approximately 0.50% smaller than for stocks without listed options (see Table IA.3, Model 3, $OptionDV_{it}$ *t*-statistic = −2.22). Given that we find larger announcement returns for smaller stocks when compared to larger stocks in our sample, this should bias against reporting evidence of informed trading for our sample of larger stocks as informed trading is more likely to occur for higher announcement returns (or where the value of information or trading profits is higher). In any case, for our sample of larger stocks we report evidence of informed trading prior to FDA announcements.

TABLE 5 Abnormal behavior of implied volatility spreads prior to FDA announcements

	Model 1	Model 2	Model 3
Intercept	−0.022 (−213.37)***	−0.021 (−66.92)***	−0.017 (−8.52)***
$EventDV_{it}$	0.226 (2.42)**	0.224 (2.30)**	0.216 (2.40)**
$Lag.AB.RET_{it}$		−0.046 (−2.25)**	0.008 (0.34)
$\lvert Lag.AB.RET\rvert_{it}$			−0.014 (−0.48)
$Lag.IVS_{it}$			0.165 (2.84)***
$Lag.OV_{it}$			−0.003 (−0.35)
Event FE	Yes	Yes	Yes
N	18,824	18,824	18,824
Adj. R^2	0.17	0.17	0.19

Note: This table reports coefficient estimates from the following panel regressions of daily implied volatility spread (IVS_{it}) on various independent variables using stock-day observations during the window [−60,0]:

$$IVS_{it} = \beta_0 + \beta_1 EventDV_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{it},$$

where $EventDV_{it}$ is a dummy variable equal to one during the pre-announcement period [−5,−1] and equal to zero during the benchmark period [−60,−11], $Lag.AB.RET_{it}$ is stock return minus the return on the value-weighted CRSP market index lagged by one-day, $|Lag.AB.RET|_{it}$ is the absolute value of $Lag.AB.RET_{it}$, $Lag.IVS_{it}$ is implied volatility spread lagged by one-day and $Lag.OV_{it}$ is options volume scaled by shares outstanding lagged by one-day. We include event fixed effects and cluster standard errors by month. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. *t*-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

In robustness tests, we report similar parameter estimates and statistical significance relating to the $EventDV_{it}$. First, we reach similar conclusions in Models 2 and 3 when we include an increasing number of control variables (adjusted R^2 ranging between 17% and 19%). Second, our findings are robust to clustering standard errors by month only, by firm only or by firm and month (i.e., $EventDV_{it}$ variable *t*-statistics exceed 2.10). Third, we report similar findings if we define $EventDV_{it}$ as a dummy variable equal to one during the pre-announcement period [−10,−1] or [−3,−1]. The motivation for these alternative definitions of the pre-announcement window is based on the behavior of implied volatility spreads prior to FDA announcements illustrated in Figure 1. Our conclusions remain unchanged, see Table IA.4, Model 3 (Model 6), average implied volatility spreads increase by 0.170% (0.238%) in the ten-days (three-days) prior to the FDA announcement from its benchmark level, and such increases in spreads are significant at a 95% confidence level. Fourth, our results are robust if we winsorize implied volatility spreads at the 5th and 95th percentiles. Finally, in the following sections, we draw similar conclusions using other proxies for informed trading (e.g., call options volume and order imbalance).

3.4 | Informed trading prior to FDA announcements

Using abnormal pre-announcement implied volatility spreads as a proxy for informed trading, we investigate whether some traders are informed about the details that affect the price impact of the announcement (e.g., the life-saving ability of a new drug). If some traders have such knowledge then we expect to observe a positive relationship between abnormal pre-announcement implied volatility spreads and FDA abnormal announcement date stock returns. We test this hypothesis using the following cross-sectional regressions:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 AB.IVS[-5,-1]_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t}, \quad (4)$$

TABLE 6 Abnormal implied volatility spreads and FDA announcement returns

	Model 1	Model 2	Model 3
Intercept	0.021 (2.59)***	0.023 (2.73)***	0.060 (1.52)
$AB.IVS[-5,-1]_{it}$	0.222 (2.47)**	0.214 (2.18)**	0.216 (2.06)**
$AB.RET[-5,-1]_{it}$		−0.118 (−0.44)	−0.142 (−0.53)
$SV[-5,-1]_{it}$		−0.045 (−0.21)	−0.316 (−1.10)
$Vola[-5,-1]_{it}$		−0.208 (−1.34)	−0.276 (−1.68)*
$Past.RET_{it}$			−0.111 (−0.06)
$Std.RET_{it}$			0.126 (0.49)
$MktCap_{it}$			−2.098 (−1.08)
$PriorityDV_{it}$	0.001 (0.26)	0.001 (0.23)	0.001 (0.22)
Type FE	Yes	Yes	Yes
Year FE	Yes	Yes	Yes
N	352	352	352
Adj. R^2	0.11	0.12	0.14

Note: This table reports coefficient estimates from the following cross-sectional regressions of abnormal announcement day [0] stock returns ($AB.RET[0]_{it}$) on various independent variables using stock-day observations:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 AB.IVS[-5,-1]_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t},$$

where $AB.IVS[-5,-1]_{it}$ is the abnormal implied volatility spread averaged during the days [−5,−1], $AB.RET[-5,-1]_{it}$ is stock return minus the return on the value-weighted CRSP market index averaged during the days [−5,−1], $SV[-5,-1]_{it}$ is stock volume scaled by shares outstanding averaged during the days [−5,−1], $Vola[-5,-1]_{it}$ is stock return volatility averaged during the days [−5,−1], $Past.RET_{it}$ is stock return minus the return on the value-weighted CRSP index calculated during the period [−40,−11], $Std.RET_{it}$ is the standard deviation of stock returns calculated during the period [−210,−11], $MktCap_{it}$ is the natural logarithm of market capitalization as of the end of the fiscal year prior to the announcement and $PriorityDV_{it}$ is a dummy variable equal to one if the announcement is classified by the FDA as *Priority* and equal to zero if the announcement is classified as *Standard*. We include FDA classification type fixed effects, year fixed effects and cluster standard errors by firm. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. *t*-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

where $AB.RET[0]_{it}$ is the abnormal return on the FDA announcement date which is calculated as the stock return minus the value-weighted CRSP index return, and $AB.IVS[-5,-1]_{it}$ is abnormal implied volatility spread averaged during the days [−5,−1]. Based on studies that find that relative to stock prices, options play a less important role in the price discovery process, we include the following stock market control variables: $AB.RET[-5,-1]_{it}$ is stock return minus the return on the value-weighted CRSP index averaged during the days [−5,−1], $SV[-5,-1]_{it}$ is stock volume scaled by shares outstanding averaged during the days [−5,−1] and $Vola[-5,-1]_{it}$ is stock return volatility averaged during the days [−5,−1]. In addition, we include the following variables that control for more general firm characteristics: $Past.RET_{it}$ is stock return minus the return on the value-weighted CRSP index calculated during the period [−40,−11], $Std.RET_{it}$ is the standard deviation of stock returns calculated during the period [−210,−11], $MktCap_{it}$ is the natural logarithm of market capitalization as of the end of the fiscal year prior to the announcement and $PriorityDV_{it}$ is a dummy variable equal to one if the announcement is classified as *Priority* and equal to zero if the announcement is classified as *Standard*. In addition, we include FDA classification type fixed effects, year fixed effects and cluster standard errors by firm.

Table 6 reports our cross-sectional regression findings. The key variable of interest is $AB.IVS[-5,-1]_{it}$. Consistent across Models 1 to 3, we find that abnormal implied volatility spreads are a positive determinant of FDA abnormal announcement date stock returns (i.e., regression coefficient of 0.22). This finding is statistically significant at a 95% level of confidence (i.e., *t*-statistics exceed 2.06) and economically significant (i.e., a one standard deviation

increase in $AB.IVS[-5,-1]_{it}$ (3.746) is associated with an estimated increase in $AB.RET[0]_{i,t}$ by 0.809%. An increase in $AB.RET[0]_{i,t}$ by 0.809% is economically meaningful as this captures 83% of the mean $AB.RET[0]_{i,t}$ or 21% of its standard deviation). Our results are economically meaningful and larger than reported in similar informed options trading studies. For example, Hao (2016) and Govindaraj et al. (2020) report that a one standard deviation increase in pre-announcement implied volatility spreads is associated with a 0.30% increase in abnormal announcement returns from repurchase and earnings news, respectively. A reasonable proportion of the variation in $AB.RET[0]_{it}$ is explained by our regression models with adjusted R^2 values between 11% and 14%. Using abnormal implied volatility spreads as a proxy for informed trading, we report evidence that suggests that at least some traders are informed about the finer details of the FDA news which affect its stock price impact.

Our cross-sectional findings are robust to several alternate specifications. First, we reach similar conclusions across Models 1 to 3 which includes an increasing set of control variables. Second, instead of clustering standard errors by firm only, we report similar results when applying standard errors clustered by month only or by firm and month (i.e., $AB.IVS[-5,-1]_{it}$ variable *t*-statistics exceed 2). Third, our findings are robust and statistically significant at a 95% level of confidence, if we instead calculate abnormal implied volatility spreads averaged during the days [−10,−1] and [−3,−1] (see Table IA.5). Fourth, we draw similar conclusions if we instead calculate abnormal implied volatility spreads using implied volatility spreads winsorized at the 5th and 95th percentiles. Last, our findings are not unique to measuring informed trading using implied volatility spreads; subsequently, we report that abnormal call options volume and order imbalance are also significant determinants of FDA abnormal announcement date stock returns.

3.5 | Leakage of inside information

There are two possible explanations for the positive association between abnormal pre-announcement implied volatility spreads and FDA abnormal announcement date stock returns. The first explanation is that investors illegally trade in the options market. SEC prosecution cases show that illegal insider trading in stock and options markets occurs prior to FDA announcements, where such information is leaked by company insiders, related stakeholders and individuals connected to them.

The second explanation is that options investors are advanced (or sophisticated) investors with a superior ability to process public information via directional trading strategies, whereby their trading increases the informational efficiency of options and stock prices. Consistent with this notion, Patel et al. (2020) find that options are the first to incorporate new information before being transmitted into stock prices, approximately one-fifth of the time. Such estimates indicate that options markets play an important role in increasing the informational efficiency of stock prices, and such estimates are larger during price-sensitive news releases.

We focus on firm-level information asymmetry and corporate governance characteristics to determine whether the positive association between abnormal pre-announcement implied volatility spreads and FDA abnormal announcement date stock returns can be attributed to insider trading or the information processing skills of options investors. In our analysis, we consider several proxies of information asymmetry and corporate governance, including dividends paid, analyst coverage and the value of institutional blockholdings. We note that information asymmetry and corporate governance are correlated, that is, firms that are associated with higher levels of information asymmetry are also associated with weaker corporate governance quality (e.g., Kanagaretnam et al., 2007).

In a traditional sense, firms that are smaller, pay low dividends and have low analyst coverage are associated with higher levels of information asymmetry (Chiang & Venkatesh, 1988). Therefore, if insider trading can explain the abnormal pre-announcement increases in implied volatility spreads (at least partly), we hypothesize that an insider's private information will be more valuable/profitable regarding firms with higher levels of information asymmetry that have inefficient prices (Huddart & Ke, 2010).

Furthermore, firms that have institutional owners are likely to have a larger oversight of managers and thus stronger corporate governance quality (Monks & Minow, 1995). We proxy for corporate governance using the total

value of institutional blockholding positions that exceed 5% (Dittmar & Mahrt-Smith, 2007). If insider trading can explain (at least in part) abnormal pre-announcement increases in implied volatility spreads, we expect firms with weaker corporate governance quality (proxied by institutional monitoring) to be associated with a higher probability of information leakage by corporate insiders.

To test our hypotheses, we define the following dummy variables: $DivDV_{it}$ is a dummy variable equal to one if the firm is in the top quartile of firms by annual dividends paid and equal to zero otherwise, $AnalystDV_{it}$ is a dummy variable equal to one if the firm is in the top quartile of firms by number of analysts covering the firm and equal to zero otherwise and $BHoldingsDV_{it}$ is a dummy variable equal to one if the firm is in the top quartile of firms by the value of institutional blockholding positions and equal to zero otherwise.[11] We find a positive correlation between the $DivDV_{it}$, $AnalystDV_{it}$ and $BHoldingsDV_{it}$ variables indicating that these variables capture similar information asymmetry and corporate governance phenomenon. The correlation between all variables of interest exceeds 0.10. We draw similar conclusions examining the correlation between size, dividends paid, number of analysts and value of blockholdings (i.e., the continuous versions of these variables).

We use cross-sectional regressions with interaction terms to investigate whether abnormal pre-announcement changes in implied volatility spreads prior to FDA announcements are related to firm-level information asymmetry and corporate governance characteristics. For example, when proxying for information asymmetry using dividends paid, we re-estimate equation (4) with the full set of independent variables and include $DivDV_{it}$, as well as interaction terms between the dummy variable and all of the independent variables. To be consistent with an information leakage/insider trading story, we would expect to observe a positive (negative) coefficient on the $AB.IVS[-5,-1]_{it}$ ($AB.IVS[-5,-1]_{it}$ x $DivDV_{it}$, $AB.IVS[-5,-1]_{it}$ x $AnalystDV_{it}$ and $AB.IVS[-5,-1]_{it}$ x $BHoldingsDV_{it}$) variable(s) indicating that informed options trading is more (less) likely to occur in firms with higher (lower) levels of information asymmetry and weaker (stronger) corporate governance quality.

Table 7 reports our cross-sectional regression findings. Across Models 1 to 3, we find that the $AB.IVS[-5,-1]_{it}$ coefficient estimate is positive and statistically significant, consistent with our predictions. The positive relationship between abnormal pre-announcement implied volatility spreads and FDA abnormal announcement date stock returns ($AB.RET[0]_{it}$) is more predominant for firms with higher levels of information asymmetry (e.g., smaller low dividend-paying firms (Model 1) or firms with low analyst coverage (Model 2)) and firms with weaker corporate governance quality (e.g., lower institutional monitoring (Model 3).

In our analysis, we also examine the following interaction terms in Models 1, 2 and 3: $AB.IVS[-5,-1]_{it}$ x $DivDV_{it}$, $AB.IVS[-5,-1]_{it}$ x $AnalystDV_{it}$ and $AB.IVS[-5,-1]_{it}$ x $BHoldingsDV_{it}$, respectively. Consistent with our hypotheses, and irrespective of how we proxy for information asymmetry/corporate governance, we report a negative and statistically significant interaction term; thereby indicating that abnormal pre-announcement changes in options trading activity are relatively weaker in firms where the value of information is lower (i.e., larger high dividend-paying firms (Model 1) or firms followed by a high number of analysts (Model 2)) or firms where information leakage is less likely (i.e., firms with higher levels of institutional monitoring (Model 3)).

In subsequent sections, we use options volume and options order imbalance as alternative proxies for informed trading in options markets. Using cross-sectional regressions with interaction terms, we draw similar conclusions to those reported in Table 7, if we proxy for informed options trading using abnormal pre-announcement call options volume during the period [−5,−1] ($AB.OV.Call[-5,-1]_{it}$) instead of $AB.IVS[-5,-1]_{it}$ or using abnormal pre-announcement call options order imbalance during the period [−5,−1] ($AB.OI.Call[-5,-1]_{it}$) instead of $AB.IVS[-5,-1]_{it}$. For example, using analyst coverage to proxy for information asymmetry, we find a positive relationship between $AB.RET[0]_{it}$ and $AB.OV.Call[-5,-1]_{it}$ (t-statistic = 2.17) and a negative relationship between $AB.RET[0]_{it}$ and $AB.OV.Call[-5,-1]_{it}$ x $AnalystDV_{it}$ (t-statistic = −2.77). For example, using the value of blockholding positions to proxy for corporate governance, we find a positive relationship between $AB.RET[0]_{it}$ and $AB.OI.Call[-5,-1]_{it}$

[11] We obtain the number of analysts covering the firm from Institutional Brokers Estimate System (*IBES*), and institutional holdings from *Thomson Reuters Institutional 13F Holdings*.

TABLE 7 Leakage of inside information

	Model 1	Model 2	Model 3
Intercept	−0.064 (−0.80)	−0.108 (−0.98)	0.041 (0.59)
$DivDV_{it}$	0.065 (0.83)		
$AnalystDV_{it}$		0.268 (1.84)*	
$BHoldingsDV_{it}$			0.117 (1.87)*
$AB.IVS[-5,-1]_{it}$	1.547 (2.14)**	1.233 (2.43)**	0.583 (1.94)*
$AB.IVS[-5,-1]_{it}$ x $DivDV_{it}$	−1.337 (−2.33)**		
$AB.IVS[-5,-1]_{it}$ x $AnalystDV_{it}$		−1.216 (−1.80)*	
$AB.IVS[-5,-1]_{it}$ x $BHoldingsDV_{it}$			−0.562 (−4.02)***
Controls	Yes	Yes	Yes
Controls x Interaction	Yes	Yes	Yes
Type FE	Yes	Yes	Yes
Year FE	Yes	Yes	Yes
N	352	352	352
Adj. R^2	0.78	0.51	0.68

Note: This table reports coefficient estimates from the following cross-sectional regressions of abnormal announcement day [0] returns ($AB.RET[0]_{it}$) on various independent variables using stock-day observations:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 X.DV_{it} + \beta_2 AB.IVS[-5,-1]_{it} + \beta_3 (X.DV_{it} \text{ x } AB.IVS[-5,-1]_{it}) + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t},$$

where $X.DV_{it}$ is $DivDV_{it}$, $AnalystDV_{it}$ and $BHoldingsDV_{it}$ in Models 1, 2 and 3, respectively. $DivDV_{it}$ is a dummy variable equal to one if the firm is in the top quartile of firms by annual dividends paid and equal to zero otherwise,$AnalystDV_{it}$ is a dummy variable equal to one if the firm is in the top quartile of firms by number of analysts covering the firm and equal to zero otherwise and $BHoldingsDV_{it}$ is a dummy variable equal to one if the firm is in the top quartile of firms by value of institutional blockholdings and equal to zero otherwise. $AB.IVS[-5,-1]_{it}$ is the abnormal implied volatility spread averaged during the days [−5,−1]. *Controls* include the following variables: $AB.RET[-5,-1]_{it}$ is stock return minus the return on the value-weighted *CRSP* market index averaged during the days [−5,−1], $SV[-5,-1]_{it}$ is stock volume scaled by shares outstanding averaged during the days [−5,−1], $Vola[-5,-1]_{it}$ is stock return volatility averaged during the days [−5,−1], $Past.RET_{it}$ is stock return minus the return on the value-weighted CRSP index calculated during the period [−40,−11], $Std.RET_{it}$ is the standard deviation of stock returns calculated during the period [−210,−11], $MktCap_{it}$ is the natural logarithm of market capitalization as of the end of the fiscal year prior to the announcement and $PriorityDV_{it}$ is a dummy variable equal to one if the announcement is classified by the FDA as *Priority* and equal to zero if the announcement is classified as *Standard*. We include FDA classification type fixed effects, year fixed effects and cluster standard errors by firm. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. t-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

(*t*-statistic = 2.30) and a negative relationship between $AB.RET[0]_{it}$ and $AB.OI.Call[-5,-1]_{it}$ x $BHoldingsDV_{it}$ (*t*-statistic = −2.04). Such findings indicate that the relationship between FDA abnormal announcement date stock returns and abnormal pre-announcement options trading activity is more pronounced for stocks with increased information asymmetry and weaker corporate governance characteristics, and such characteristics are consistent with informed options trading based on private information occurring prior to FDA announcements.

Holistically the findings in this section indicate that insider trading is a possible explanation for some of the pre-announcement options trading observed prior to FDA announcements. We report that the increases in abnormal pre-announcement options trading activity are larger in firms with inefficient prices where private information is more valuable (i.e., firms with higher levels of information asymmetry) and in firms where information leakage is more likely (i.e, firms with weaker corporate governance quality). Our findings are consistent with SEC prosecution cases that show instances of illegal insider trading occurring prior to FDA announcements.

3.6 | Informed trading characteristics

In this section, we investigate how different characteristics that affect the degree of informed trading affect our panel and cross-sectional specifications expressed in equations (3) and (4) and findings reported in Tables 5 and 6. The SEC notes that one feature of insider trading is trades made using shorter-term options, that is, insiders trade options that are cheaper and expire soon after the horizon of their information. To capture this first informed trading characteristic, we re-estimate implied volatility spreads using options with a shorter (5–50 days) and a longer (50–90 days) time-to-maturity.

Easley et al. (1998) suggest that the amount of informed trading in options is a function of the liquidity of options relative to the underlying stock. We measure relative options to stock liquidity (our second characteristic), using the ratio of the options bid–ask spread scaled by the options midpoint price scaled by Amihud's (2002) stock illiquidity.

A third characteristic that influences informed options trading is the degree of moneyness (Patel et al., 2020). For additional leverage, investors may prefer to trade away-from-the-money options, compared to ATM options. Alternatively, to hide the value of their information, investors may prefer to trade cheaper and more liquid ATM options.

Focusing on these three characteristics of informed trading, Table IA.6 reports our panel regression results, and Table IA.7 reports our cross-sectional regression results. The abnormal increases in pre-announcement implied volatility spreads (Table IA.6), and the predictability of FDA abnormal announcement date stock returns by abnormal pre-announcement implied volatility spreads (Table IA.7), are more pronounced for strategic informed options trading characteristics reported in prior studies, that is, using options with a shorter time-to-maturity (Model 1), using relatively more liquid options relative to the underlying stock (Model 2) and using ATM options (Model 3).

3.7 | Options trading volume

To examine whether our findings are unique to implied volatility-based measures, we use options trading volume as an alternate proxy for informed trading. Similar to equation (3), we estimate multivariate panel regressions, except we replace *IVS* with options volume scaled by shares outstanding (*OV*):

$$OV_{it} = \beta_0 + \beta_1 EventDV_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{it}. \quad (5)$$

Table IA.8, Model 1, shows that the $EventDV_{it}$ variable is positive and significant indicating that scaled options volume is 3.92% larger in the five-day period prior to FDA announcements relative to normal trading periods. If we include control variables, we obtain similar results in Models 2 and 3 where options volume is 3.95% and 3.57% larger in the days preceding the announcement, respectively.

We decompose OV_{it} into two components: call options volume scaled by shares outstanding ($OV.Call_{it}$) and put options volume scaled by shares outstanding ($OV.Put_{it}$). Using similar panel regression specifications detailed in equation (5), Table 8, Model 3, shows that scaled call options volume increases in level by approximately 2.14% from the benchmark to the pre-announcement period. Similarly, Model 6 shows that put options volume increases in level by approximately 1.43% from the benchmark to the pre-announcement period. Such increases in pre-announcement options volume could be due to informed trading. In the next section, we investigate whether such changes in call and put options volume are driven by buy or sell options volume (i.e., using order imbalance).

Following on, we use similar cross-sectional regressions as detailed in equation (4); however, we use abnormal pre-announcement options volume averaged during the days [−5,−1] ($AB.OV[-5,-1]_{it}$), rather than $AB.IVS[-5,-1]_{it}$, to

TABLE 8 Abnormal behavior of call/put options volume prior to FDA announcements

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Intercept	0.056 (110.37)***	0.053 (63.25)***	0.032 (8.80)***	0.048 (121.58)***	0.048 (67.96)***	0.030 (13.30)***
$EventDV_{it}$	2.286 (5.03)***	2.299 (4.98)***	2.135 (4.72)***	1.632 (4.58)***	1.646 (4.62)***	1.434 (4.57)***
$Lag.AB.RET_{it}$		0.154 (2.75)***	0.039 (0.54)		0.082 (1.68)*	−0.021 (−0.55)
$\lvert Lag.AB.RET\rvert_{it}$			0.352 (5.16)***			0.179 (3.29)***
$Lag.IVS_{it}$			0.009 (0.27)			−0.085 (−2.94)***
$Lag.OV_{it}$			0.152 (4.00)***			0.198 (8.93)***
Event FE	Yes	Yes	Yes	Yes	Yes	Yes
N	18,473	18,473	18,473	18,473	18,473	18,473
Adj. R^2	0.45	0.45	0.46	0.41	0.41	0.43

Note: This table reports coefficient estimates from the following panel regressions of daily call (put) options volume scaled by shares outstanding (where $OV.X_{it}$ is $OV.Call_{it}$ ($OV.Put_{it}$) in Models 1 to 3 (Models 4 to 6)) on various independent variables using stock-day observations during the window [−60,0]:

$$OV.X_{it} = \beta_0 + \beta_1 EventDV_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{it},$$

where $EventDV_{it}$ is a dummy variable equal to one during the pre-announcement period [−5,−1] and equal to zero during the benchmark period [−60,−11], $Lag.AB.RET_{it}$ is stock return minus the return on the value-weighted CRSP market index lagged by one-day, $\lvert Lag.AB.RET\rvert_{it}$ is the absolute value of $Lag.AB.RET_{it}$, $Lag.IVS_{it}$ is implied volatility spread lagged by one-day and $Lag.OV_{it}$ is options volume scaled by shares outstanding lagged by one-day. We include event fixed effects and cluster standard errors by month. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. *t*-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

investigate if some individuals are knowledgeable about the specific contents of FDA announcements:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 AB.OV[-5,-1]_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t}. \quad (6)$$

In Models 2 and 3 of Table IA.9, we find that abnormal pre-announcement options volume is a significant determinant of FDA abnormal announcement date stock returns controlling for a range of factors. Using similar cross-sectional specifications detailed in equation (6), in Models 1 to 3 (Models 4 to 6) of Table 9, we report the relationship between $AB.RET[0]_{it}$ and abnormal pre-announcement call (put) volume, $AM.OV.Call[-5,-1]_{it}$ ($AB.OV.Put[-5,-1]_{it}$). We find that abnormal levels of pre-announcement call options volume significantly explain FDA abnormal announcement date stock returns (i.e., regression coefficient (*t*-statistic) of 9.516 (1.80) in Model 2 and 9.468 (2.11) in Model 3). This relationship indicates that call options traders are informed about the stock price impact relating to the FDA news.[12] In contrast, we report an insignificant relationship between $AB.RET[0]_{i,t}$ and $AB.OV.Put[-5,-1]_{it}$ indicating that abnormal pre-announcement put options volume is not informative nor contains any predictability of FDA abnormal announcement date stock returns.[13]

3.8 | Options order imbalance

To shed further light on options trading activity prior to FDA announcements we examine call and put order imbalance. For each stock, we use bulk classification techniques developed by Easley et al. (2012) to decompose call and put options volume each day into buy and sell options volume. In essence, the bulk classification of volume uses standardized returns to decompose volume into buy and sell components during an interval.

Bulk classification provides a reliable and cost-effective approach to signing volume, has been applied in stock and derivatives markets (e.g., Easley et al., 2012a, 2012b, 2016, 2020) and has several advantages. First, many databases do not report buy and sell volume so bulk classification can be used to sign volume. Second, traditional methods of signing volume (e.g., Lee & Ready, 1991) require the examination of millions of trade and quote observations. In some cases, such large intraday data may not be available, may be costly to acquire/store and require additional computational power for analysis. Bulk classification can overcome such limitations. Third, due to the sheer amount of trading from high-frequency and algorithmic traders, exchanges cannot guarantee the exact sequence in which trades and quotes take place meaning that traditional methods to signing volume do so with error. When measurement error exists, determining signed volume can be more accurate using bulk classification/counting when compared to traditional signing methods using individual classification/counting (Mosteller, 1965). For example, Easley et al. (2012b) find that bulk classification is more accurate in signing futures volume when compared to the tick rule.

For each stock day (*it*), for each call option *j*, we classify the proportion of buys and sells using bulk classification:

$$V_{jt}^{i,Call,Buy} = V_{jt}^{i,Call}\, t'\left(\frac{r_{jt}^{i,Call}}{\sigma_{rj}^{i,Call}}, df\right), \quad (7)$$

[12] Instead of clustering standard errors by firm only, we report similar results when applying standard errors clustered by month only or by firm and month. For example, if we run the same cross-sectional regression specification as in Table 9, Model 3, except applying standard errors clustered by firm and month (rather than by firm only), we find that the *t*-statistic associated with the $AB.OV.Call[-5,-1]_{it}$ variable is 2.07.

[13] In Table 9, Models 3 and 6, firm size ($MktCap_{it}$) has a positive relationship with abnormal announcement date stock returns. All else equal, this indicates larger announcement returns for larger firms. Larger firms have an increased capacity to develop drugs which can have a larger benefit to society, thereby providing a possible driver for the magnitude of the announcement returns.

TABLE 9 Abnormal call/put options volume and FDA announcement returns

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Intercept	−0.005 (−0.26)	−0.000 (−0.02)	−0.128 (−2.08)**	−0.010 (−0.51)	−0.009 (−0.48)	−0.141 (−2.24)**
$AB.OV.X[-5,-1]_{it}$	6.314 (1.34)	9.516 (1.80)*	9.468 (2.11)**	0.747 (0.17)	2.381 (0.45)	3.695 (0.74)
$AB.RET[-5,-1]_{it}$		0.141 (0.48)	0.119 (0.39)		0.148 (0.50)	0.124 (0.42)
$SV[-5,-1]_{it}$		−0.348 (−1.09)	−0.203 (−0.53)		−0.129 (−0.37)	0.004 (0.01)
$Vola[-5,-1]_{it}$		−0.284 (−0.84)	−0.312 (−0.91)		−0.224 (−0.56)	−0.260 (−0.63)
$Past.RET_{it}$			−6.741 (−1.90)*			−6.910 (−1.94)*
$Std.RET_{it}$			0.972 (2.82)***			0.990 (2.48)**
$MktCap_{it}$			6.097 (2.17)**			6.264 (2.16)**
$PriorityDV_{it}$	−0.009 (−1.29)	−0.008 (−1.22)	−0.008 (−1.24)	−0.007 (−1.08)	−0.007 (−1.06)	−0.007 (−1.11)
Type FE	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
N	352	352	352	352	352	352
Adj. R^2	0.15	0.17	0.22	0.14	0.14	0.20

Note: This table reports coefficient estimates from the following cross-sectional regressions of abnormal announcement day [0] stock returns ($AB.RET[0]_{it}$) on various independent variables using stock-day observations:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 AB.OV.X[-5,-1]_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t},$$

where $AB.OV.X[-5,-1]_{it} = AB.OV.Call[-5,-1]_{it}$ ($AB.OV.X[-5,-1]_{it} = AB.OV.Put[-5,-1]_{it}$) is the abnormal call (put) options volume scaled by shares outstanding averaged during the days [−5,−1] in Models 1 to 3 (Models 4 to 6), $AB.RET[-5,-1]_{it}$ is stock return minus the return on the value-weighted CRSP market index averaged during the days [−5,−1], $SV[-5,-1]_{it}$ is stock volume scaled by shares outstanding averaged during the days [−5,−1], $Vola[-5,-1]_{it}$ is stock return volatility averaged during the days [−5,−1], $Past.RET_{it}$ is stock return minus the return on the value-weighted CRSP index calculated during the period [−40,−11], $Std.RET_{it}$ is the standard deviation of stock returns calculated during the period [−210,−11], $MktCap_{it}$ is the natural logarithm of market capitalization as of the end of the fiscal year prior to the announcement and $PriorityDV_{it}$ is a dummy variable equal to one if the announcement is classified by the FDA as *Priority* and equal to zero if the announcement is classified as *Standard*. We include FDA classification type fixed effects, year fixed effects and cluster standard errors by firm. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. *t*-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

$$V_{jt}^{i,Call,Sell} = V_{jt}^{i,Call}\left[1 - t'\left(\frac{r_{jt}^{i,Call}}{\sigma_{rj}^{i,Call}}, df\right)\right] = V_{jt}^{i,Call} - V_{jt}^{i,Call,Buy}, \quad (8)$$

where $V_{jt}^{i,Call,Buy}$ ($V_{jt}^{i,Call,Sell}$) is the buy (sell) call options volume, $V_{jt}^{i,Call}$ is the total call options volume, t' is the cumulative distribution function of the student t distribution with df degrees of freedom, $r_{jt}^{i,Call}$ is the daily call options return and $\sigma_{rj}^{i,Call}$ is the standard deviation of daily call options returns computed during the period [−60,−11] prior to the announcement date.[14] For each stock day, we calculate the total call order imbalance across all options:

$$OI.Call_{it} = \sum_{j=1}^{N_{it}} \left(V_{jt}^{i,Call,Buy} - V_{jt}^{i,Call,Sell}\right). \quad (9)$$

A similar process is used to estimate the total put options order imbalance:

$$OI.Put_{it} = \sum_{j=1}^{N_{it}} \left(V_{jt}^{i,Put,Buy} - V_{jt}^{i,Put,Sell}\right). \quad (10)$$

Similar to our earlier analysis of implied volatility spreads and options volume, we conduct multivariate panel regressions to examine the abnormal behavior of call ($OI.Call_{it}$) and put ($OI.Put_{it}$) order imbalance prior to FDA announcements:

$$OI.X_{it} = \beta_0 + \beta_1 EventDV_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{it}. \quad (11)$$

Table 10 reports our findings where $OI.X_{it}$ is $OI.Call_{it}$ in Models 1 to 3 and $OI.X_{it}$ is $OI.Put_{it}$ in Models 4 to 6. Models 1 to 3 show that call order imbalance is positive and abnormally elevated during the five-day pre-announcement window when compared to the benchmark period, controlling for other factors. Across the three models, the $EventDV_{it}$ coefficient is similar and statistically significant (i.e., t-statistics ranging between 4.29 and 6.90). Our findings indicate that the abnormal pre-announcement increases in call options volume are driven by long call options volume which is consistent with trading prior to positive news. In contrast, in Models 4 to 6, the $EventDV_{it}$ coefficient indicates that put options volume is not statistically different between the benchmark period and pre-announcement period.

Similar to previous cross-sectional regressions, we examine whether abnormal pre-announcement call ($AB.OI.Call[-5,-1]_{it}$) and put ($AB.OI.Put[-5,-1]_{it}$) order imbalance averaged during the days [−5,−1] is informative about FDA abnormal announcement date stock returns. Such tests will provide an indication as to whether some traders are informed about the finer details of the news which affect its stock price impact:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 AB.OI.X[-5,-1]_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t}. \quad (12)$$

We report our findings in Table 11 where $AB.OI.X[-5,-1]_{it}$ is $AB.OI.Call[-5,-1]_{it}$ ($AB.OI.Put[-5,-1]_{it}$) in Models 1 to 3 (4 to 6). We find that the relationship between FDA abnormal announcement date stock returns and abnormal pre-announcement call order imbalance is positive and significant (e.g., Model 3 t-statistic = 2.78). In contrast, Models 4 to 6 show that abnormal pre-announcement put order imbalance is not informative about FDA abnormal announcement date stock returns. Given this result, and given that put order imbalance does not significantly change prior to

[14] Following Easley et al. (2016), we set $df = 0.25$ to account for fat tails present in derivatives data. We obtain similar results if $\sigma_{rj}^{i,Call}$ is defined as the standard deviation of daily call options returns during the period [−60,+10] around the announcement date.

TABLE 10 Abnormal behavior of call/put order imbalance prior to FDA announcements

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Intercept	0.799 (9.63)***	0.699 (8.30)***	−3.916 (−2.51)**	1.124 (1.24)	1.216 (1.18)	−0.519 (−0.33)
$EventDV_{it}$	6.188 (6.90)***	6.252 (6.70)***	6.191 (4.29)***	−0.785 (−0.72)	−0.728 (−0.63)	−0.924 (−1.33)
$Lag.AB.RET_{it}$		1.957 (0.57)	−25.391 (−1.04)		38.552 (0.83)	34.590 (1.33)
$\lvert Lag.AB.RET\rvert_{it}$			36.935 (1.13)			−42.014 (−1.48)
$Lag.IVS_{it}$			15.932 (1.13)			−54.557 (−2.02)**
$Lag.OI_{it}$			0.023 (1.12)			0.001 (1.31)
Event FE	Yes	Yes	Yes	Yes	Yes	Yes
N	18,466	18,466	18,466	18,466	18,466	18,466
Adj. R^2	0.11	0.22	0.34	0.18	0.18	0.22

Note: This table reports coefficient estimates from the following panel regressions of daily call (put) order imbalance (where $OI.X_{it}$ is $OI.Call_{it}$ ($OI.Put_{it}$) in Models 1 to 3 (Models 4 to 6)) on various independent variables using stock-day observations during the window [−60,0]:

$$OI.X_{it} = \beta_0 + \beta_1 EventDV_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{it},$$

where $EventDV_{it}$ is a dummy variable equal to one during the pre-announcement period [−5,−1] and equal to zero during the benchmark period [−60,−11], $Lag.AB.RET_{it}$ is stock return minus the return on the value-weighted *CRSP* market index lagged by one-day, $\lvert Lag.AB.RET\rvert_{it}$ is the absolute value of $Lag.AB.RET_{it}$, $Lag.IVS_{it}$ is implied volatility spread lagged by one-day and $Lag.OI_{it}$ is options order imbalance lagged by one-day. We include event fixed effects and cluster standard errors by month. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. *t*-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

TABLE 11 Abnormal call/put order imbalance and FDA announcement returns

	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Intercept	0.976 (1.12)	0.238 (0.25)	0.282 (0.30)	0.432 (0.50)	0.477 (0.52)	0.829 (0.92)
$AB.OI.X[-5,-1]_{it}$	0.353 (1.81)*	0.414 (2.18)**	1.120 (2.78)***	−0.795 (−1.32)	−1.132 (−1.41)	−0.835 (−1.18)
$AB.RET[-5,-1]_{it}$		0.089 (0.21)	0.056 (0.14)		−0.181 (−0.40)	−0.289 (−0.69)
$SV[-5,-1]_{it}$		−0.001 (−0.32)	−0.001 (−1.07)		0.001 (1.32)	−0.001 (−0.61)
$Vola[-5,-1]_{it}$		0.811 (1.54)	0.729 (1.19)		0.032 (0.07)	−0.363 (−0.98)
$Past.RET_{it}$			−4.138 (−1.00)			10.347 (2.13)**
$Std.RET_{it}$			−0.001 (−0.01)			0.133 (0.39)
$MktCap_{it}$			−0.006 (−0.75)			−0.006 (−1.53)
$PriorityDV_{it}$	0.004 (0.46)	0.003 (0.43)	0.004 (0.50)	0.001 (0.13)	−0.001 (−0.17)	−0.001 (−0.19)
Type FE	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
N	352	352	352	352	352	352
Adj. R^2	0.09	0.12	0.14	0.09	0.11	0.11

Note: This table reports coefficient estimates from the following cross-sectional regressions of abnormal announcement day [0] stock returns ($AB.RET[0]_{it}$) on various independent variables using stock-day observations:

$$AB.RET[0]_{it} = \beta_0 + \beta_1 AB.OI.X[-5,-1]_{it} + \sum_j \gamma_j Controls_{it} + \varepsilon_{i,t},$$

where $AB.OI.X[-5,-1]_{it} = AB.OI.Call[-5,-1]_{it}$ ($AB.OI.X[-5,-1]_{it} = AB.OI.Put[-5,-1]_{it}$) is the abnormal call (put) order imbalance averaged during the days [−5,−1] in Models 1 to 3 (Models 4 to 6), $AB.RET[-5,-1]_{it}$ is stock return minus the return on the value-weighted CRSP market index averaged during the days [−5,−1], $SV[-5,-1]_{it}$ is stock volume scaled by shares outstanding averaged during the days [−5,−1], $Vola[-5,-1]_{it}$ is stock return volatility averaged during the days [−5,−1], $Past.RET_{it}$ is stock return minus the return on the value-weighted CRSP index calculated during the period [−40,−11], $Std.RET_{it}$ is the standard deviation of stock returns calculated during the period [−210,−11], $MktCap_{it}$ is the natural logarithm of market capitalization as of the end of the fiscal year prior to the announcement and $PriorityDV_{it}$ is a dummy variable equal to one if the announcement is classified by the FDA as Priority and equal to zero if the announcement is classified as Standard. We include FDA classification type fixed effects, year fixed effects and cluster standard errors by firm. The sample comprises 352 FDA announcements from 166 firms between January 1, 1996, and December 31, 2016. t-statistics are reported in parentheses. ***, ** and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

the announcement date, suggests that puts play a lesser role with regard to informed options trading prior to FDA announcements.

Holistically, we find abnormal increases in implied volatility spreads, call options volume and call order imbalance in the days leading up to FDA announcements. Such findings are robust to using three different measures of informed trading and consistent with prior studies that report informed options trading prior to mergers and acquisitions, earnings and other price-sensitive news announcements. In addition, we find that such abnormal pre-announcement changes in informed options trading proxies (measured using implied volatility spreads, call options volume and call order imbalance) can predict FDA abnormal announcement date stock returns indicating that some traders are informed about the details of FDA announcements which affect its stock price impact.

3.9 | Returns from trading options

We report evidence that indicates that informed options trading takes place prior to FDA announcements. In this section, we provide an indication as to whether trading in options markets prior to FDA announcements is profitable. Our earlier findings show that call options trading activity is significantly elevated in the five-days prior to the announcement date and that such pre-announcement trading activity is informative about FDA abnormal announcement date stock returns. As a result, we examine the returns from trading call options. Following Augustin et al. (2016), we calculate call options returns in the following manner:

$$\frac{Bid^{i}_{j,t+1}}{Ask^{i}_{j,t-5}} - 1, \tag{13}$$

where $Bid^{i}_{j,t+1}$ is the best closing bid price for stock i call option j (with unique strike price and time-to-maturity) on the day following the announcement $t + 1$ (i.e., selling date), and $Ask^{i}_{j,t-5}$ is the best closing ask price for stock i call option j five-days before the announcement $t - 5$ (i.e., purchase date). By calculating the percentage change in ask to bid prices we account for the options bid–ask spread.

The mean call options return across all options in our sample from trades made five-days before the announcement and closed out on the day after the announcement is 17.25%. The mean call option return across all sample OTM options is 68.71%, approximately four times larger than the full sample results. The magnitude of our call options returns findings is in the same ballpark as Augustin et al. (2016), who find that illegal insiders' call options returns from trading prior to earnings announcements is 109.89%.[15] Our findings indicate that investors make money by trading options prior to FDA announcements. This provides an explanation for why we observe abnormal options trading activity prior to FDA announcements, and why such trading activity is informative about abnormal announcement date stock returns.

4 | CONCLUSION

Our paper is the first to report evidence of informed trading in options markets prior to FDA announcements during a 21-year sample period. Our main results are as follows. First, we report abnormal pre-announcement increases in implied volatility spreads, call options volume and call order imbalance. Our findings are consistent with studies that report abnormal changes in options trading activity (evidence of informed options trading) prior to major price-

[15] The call option returns that we report from trading on FDA news is smaller than reported by Augustin et al. (2016), as they report call option returns for a small subset of options traded by illegal insiders (not using a large cross-section of options) and a subset of earnings announcements (likely to be earnings that have larger abnormal stock returns, where such returns incentivize traders to illegally trade as they can earn larger trading profits).

sensitive announcements (e.g., mergers and acquisitions, earnings, divestitures, repurchases and stock splits). Second, we find that such abnormal pre-announcement implied volatility spreads, call options volume and order imbalance are informative about FDA abnormal announcement date stock returns, thereby indicating that some investors are informed about the finer details that dictate the price impact of the news. Third, we find a stronger association between abnormal pre-announcement options trading activity and FDA abnormal announcement date stock returns for firms with higher levels of information asymmetry and weaker corporate governance quality, suggesting that at least some options trading is based on information leakage. Fourth, we report evidence consistent with strategic informed options trading prior to FDA announcements, using options that are cheaper, liquid and have short-term maturities. Finally, we find that investors make reasonable returns from trading call options prior to FDA announcements.

This study will be of interest to a number of parties, including regulators, investors and relevant drug-related firms. Our findings add to the growing number of studies that document informed trading prior to major corporate announcements in stock and options markets, regulators should be concerned with the pervasive leakage of information. If some investors are privy to confidential information this can result in inequity in trading which can have negative effects on investors' willingness to trade and the liquidity of markets. Firms that make FDA announcements should be concerned with the leakage of information and may want to re-examine the individuals who are trusted with such material information.

ACKNOWLEDGMENTS

We thank Henk Berkman, David Easley, Sean Foley, Seungoh Han, Allan Hodgson, Petko Kalev, Alexander Kurov, Craig Lewis, Peter MacKay, David Michayluk, Phuc Nguyen, Maureen O'Hara, Richard Payne, Talis Putnins, Robert Van Ness, Terry Walter, Ralf Zurbrugg and participants at the Financial Management Association Conference (San Diego), Financial Management Asia Conference (Vietnam), International Accounting and Finance Symposium (Milan), Capital Markets Cooperative Research Centre (Sydney) and University of Technology Sydney for helpful comments. This paper was previously titled "Informed options trading around US FDA announcements."

Open access publishing facilitated by University of Technology Sydney, as part of the Wiley - University of Technology Sydney agreement via the Council of Australian University Librarians.

ORCID

Marc J. M. Bohmann https://orcid.org/0000-0001-8504-9580
Vinay Patel https://orcid.org/0000-0002-1696-3325

REFERENCES

Ahern, K. R. (2020). Do proxies for informed trading measure informed trading? Evidence from illegal insider trades. *Review of Asset Pricing Studies*, *10*, 397–440. https://doi.org/10.1093/rapstu/raaa004

Amihud, Y. (2002). Illiquidity and stock returns: Cross-section and time-series effects. *Journal of Financial Markets*, *5*, 31–56. https://doi.org/10.1016/s1386-4181(01)00024-6

Augustin, P., Brenner, M., Grass, G., & Subrahmanyam, M. G. (2016). *How do insiders trade?* (Working Paper No. 541), CFS, Goethe University, Frankfurt. https://doi.org/10.2139/ssrn.2848989

Bohmann, M. J. M., Michayluk, D., & Patel, V. (2019). Price discovery in commodity derivatives: Speculation or hedging? *Journal of Futures Markets*, *39*, 1107–1121. https://doi.org/10.1002/fut.22021

Bohmann, M. J. M., Michayluk, D., Patel, V., & Walsh, K. (2019). Liquidity and earnings in event studies: Does data granularity matter? *Pacific-Basin Finance Journal*, *54*, 118–131. https://doi.org/10.1016/j.pacfin.2018.12.007

Bohmann, M. J. M., & Patel, V. (2020). Information leakage in energy derivatives around news announcements. *Journal of Derivatives*, *27*, 13–29. https://doi.org/10.3905/jod.2020.1.095

Bollen, N. P. B., & Whaley, R. E. (2004). Does net buying pressure affect the shape of implied volatility functions? *The Journal of Finance*, *59*, 711–753. https://doi.org/10.1111/j.1540-6261.2004.00647.x

Bosch, J. C., & Lee, I. (1994). Wealth effects of Food and Drug Administration (FDA) decisions. *Managerial and Decision Economics*, *15*, 589–599. https://doi.org/10.1002/mde.4090150606

Bugeja, M., Patel, V., & Walter, T. (2015). The microstructure of Australian takeover announcements. *Australian Journal of Management*, *40*, 161–188. https://doi.org/10.1177/0312896213517247

Cairney, T., & Swisher, J. (2004). The role of options markets in the dissemination of private information. *Journal of Business Finance and Accounting*, *31*, 1015–1042. https://doi.org/10.1111/j.0306-686X.2004.00565.x

Cao, C., Chen, Z., & Griffin, J. M. (2005). Informational content of option volume prior to takeovers. *Journal of Business*, *78*, 1073–1109. https://doi.org/10.1086/429654

Chan, K., Ge, L., & Lin, T. C. (2015). Informational content of options trading on acquirer announcement return. *Journal of Financial and Quantitative Analysis*, *50*, 1057–1082. https://doi.org/10.1017/s0022109015000484

Cheng, C., Jones, S., & Moser, W. J. (2018). Abnormal trading behavior of specific types of shareholders before US firm bankruptcy and its implications for firm bankruptcy prediction. *Journal of Business Finance and Accounting*, *45*, 1100–1138. https://doi.org/10.1111/jbfa.12338

Chern, K. Y., Tandon, K., Yu, S., & Webb, G. (2008). The information content of stock split announcements. *Journal of Banking and Finance*, *32*, 930–946. https://doi.org/10.1016/j.jbankfin.2007.07.008

Chiang, R., & Venkatesh, P. C. (1988). Insider holdings and perceptions of information asymmetry: A note. *The Journal of Finance*, *43*, 1041–1048. https://doi.org/10.2307/2328153

Ciociola, A. A., Cohen, L. B., & Kulkarni, P. (2014). How drugs are developed and approved by the FDA: Current process and future directions. *American Journal of Gastroenterology*, *109*, 620–623. https://doi.org/10.1038/ajg.2013.407

Cremers, M., & Weinbaum, D. (2010). Deviations from put-call parity and stock return predictability. *Journal of Financial and Quantitative Analysis*, *45*, 335–367. https://doi.org/10.1017/s002210901000013x

Dittmar, A., & Mahrt-Smith, J. (2007). Corporate governance and the value of cash holdings. *Journal of Financial Economics*, *83*, 599–634. https://doi.org/10.1016/j.jfineco.2005.12.006

Easley, D., O'Hara, M., & Srinivas, P. S. (1998). Option volume and stock prices: Evidence on where informed traders trade. *The Journal of Finance*, *53*, 431–465. https://doi.org/10.1111/0022-1082.194060

Easley, D., Lopez de Prado, M. M., & O'Hara, M. (2012b). *Bulk classification of trading activity.* (Working paper), Cornell University.

Easley, D., Lopez de Prado, M. M., & O'Hara, M. (2012a). Flow toxicity and liquidity in a high-frequency world. *Review of Financial Studies*, *25*, 1457–1493. https://doi.org/10.1093/rfs/hhs053

Easley, D., Lopez de Prado, M. M., & O'Hara, M. (2016). Discerning information from trade data. *Journal of Financial Economics*, *120*, 269–285. https://doi.org/10.1016/j.jfineco.2016.01.018

Easley, D., Michayluk, D., O'Hara, M., Patel, V., & Putnins, T. P. (2020). Information flows and systematic risk. (Working paper), Society for Financial Studies Cavalcade.

Ge, L., Lin, T. C., & Pearson, N. D. (2016). Why does the option to stock volume ratio predict stock returns? *Journal of Financial Economics*, *120*, 601–622. https://doi.org/10.1016/j.jfineco.2015.08.019

Govindaraj, S., Li, Y., & Zhao, C. (2020). The effect of option transaction costs on informed trading in the option market around earnings announcements. *Journal of Business Finance and Accounting*, *47*, 615–644. https://doi.org/10.1111/jbfa.12443

Hao, Q. (2016). Is there information leakage prior to share repurchase announcements? Evidence from daily options trading. *Journal of Financial Markets*, *27*, 79–101. https://doi.org/10.1016/j.finmar.2015.11.003

Huddart, S. J., & Ke, B. (2010). Information asymmetry and cross-sectional variation in insider trading. *Contemporary Accounting Research*, *24*, 195–232. https://doi.org/10.1506/0277-1110-4434-M627

Jin, W., Livnat, J., & Zhang, Y. (2012). Option prices leading equity prices: Do option traders have an information advantage? *Journal of Accounting Research*, *50*, 401–432. https://doi.org/10.1111/j.1475-679X.2012.00439.x

Johnson, T. L., & So, E. C. (2012). The option to stock volume ratio and future returns. *Journal of Financial Economics*, *106*, 262–286. https://doi.org/10.1016/j.jfineco.2012.05.008

Kanagaretnam, K., Lobo, G. J., & Whalen, D. J. (2007). Does good corporate governance reduce information asymmetry around quarterly earnings announcements. *Journal of Accounting and Public Policy*, *26*, 497–522. https://doi.org/10.1016/j.jaccpubpol.2007.05.003

Lee, C. M. C., & Ready, M. J. (1991). Inferring trade direction from intraday data. *The Journal of Finance*, *46*, 733–746. https://doi.org/10.1111/j.1540-6261.1991.tb02683.x

Lu, Y., & Ray, S. (2016). Too good to be true? An analysis of the options market's reactions to earnings releases. *Journal of Business Finance and Accounting*, *43*, 830–848. https://doi.org/10.1111/jbfa.12214

Monks, R., & Minow, N. (1995). *Corporate governance.* Blackwell.

Mosteller, F. (1965). *Fifty challenging problems in probability with solutions.* Dover Publications.

Pan, J., & Poteshman, A. M. (2006). The information in options volume for future stock prices. *Review of Financial Studies*, *19*, 871–908. https://doi.org/10.1093/rfs/hhj024

Patel, V., & Michayluk, D. (2016b). Return predictability following different drivers of large price changes. *International Review of Financial Analysis*, *45*, 202–214. https://doi.org/10.1016/j.irfa.2016.03.004

Patel, V., & Michayluk, D. (2016a). *Do divestitures create value? Evidence from options markets.* (Working paper), University of Technology Sydney.

Patel, V., Putnins, T. P., Michayluk, D., & Foley, S. (2020). Price discovery in stock and options markets. *Journal of Financial Markets*, *47*, 1–28. https://doi.org/10.1016/j.finmar.2019.100524

Patel, V., & Putnins, T. P. (2020). *How much insider trading occurs in stock markets?* (Working paper), University of Technology Sydney.

Savor, P. (2012). Stock returns after major price shocks: The impact of information. *Journal of Financial Economics*, *106*, 635–659. https://doi.org/10.1016/j.jfineco.2012.06.011

Sharma, A., & Lacey, N. (2004). Linking product development outcomes to market valuation of the firm: The case of the US pharmaceutical industry. *Journal of Product Innovation Management*, *21*, 297–308. https://doi.org/10.1111/j.0737-6782.2004.00084.x

Skinner, D. J. (1991). *Stock returns, trading volume, and bid-ask spreads around earnings announcements: Evidence from the NASDAQ national market system.* (Working paper), University of Michigan. https://doi.org/10.2139/ssrn.2143649

Torabzadeh, K. M., Woodruff, C. G., & Sen, N. (1998). FDA decisions on new drug applications and the market value of pharmaceutical firms. *American Business Review*, *16*, 42–50.

Tsai, S. (2014). Individuals' trading prior to earnings announcements. *Journal of Business Finance and Accounting*, *41*, 1124–1156. https://doi.org/10.1111/jbfa.12093

Udpa, S. C. (1996). Insider trading and the information content of earnings. *Journal of Business Finance and Accounting*, *23*, 1069–1095. https://doi.org/10.1111/j.1468-5957.1996.tb01159.x

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Bohmann, M. J. M., & Patel, V. (2022). Informed options trading prior to FDA announcements. *J Bus Fin Acc*, *49*, 1211–1236. https://doi.org/10.1111/jbfa.12600