

Seeking Out Non-Public Information: Sell-Side Analysts and the Freedom of Information Act

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ABSTRACT: A number of sell-side healthcare analysts gain access to information outside the purview of management through Freedom of Information Act requests to the Food and Drug Administration for records on factory inspections, complaints, and drug and medical device applications. Using a difference-in-differences methodology, we find that buy (sell) recommendations and upgrades (downgrades) earn higher (lower) stock returns over the year following the receipt of FDA records. We also examine the type of information revealed in FDA factory inspection reports, and find that analysts are less likely to downgrade and are less pessimistic in their recommendations than the consensus recommendation when the information contained in the FDA report is not particularly severe. Our findings are consistent with a subset of analysts utilizing non-public information channels independent of management to gain value-relevant information about their covered firms.

Keywords: sell-side analysts; Freedom of Information Act; stock recommendations; equity analysts; analysts' recommendations; non-public information.

I. INTRODUCTION

Sell-side analysts are important to capital markets. They produce research reports and generate earnings forecasts and stock recommendations on covered firms, which move stock prices (Bradshaw 2011) and create liquidity within the U.S. stock market (Kelly and Ljungqvist 2012). Bradshaw (2011) and Brown, Call, Clement, and Sharp (2015) refer to the process by which analysts use both public and private sources of information to generate their outputs as a “black box,” and call for more research on understanding how analysts acquire and use various sources of information. Whereas most early studies concentrate on analysts' use of public quantitative information (e.g., financial statements), a burgeoning area of research has emerged examining their acquisition of private and qualitative sources of information. These sources include management conference calls (Frankel, Johnson, and Skinner 1999),¹ broker-sponsored conferences (Francis, Hanna, and Philbrick 1997; Bushee, Jung, and Miller 2011; Green, Jame, Markov, and Subasi 2014), analyst/investor days (Kirk and Markov 2016), site visits (Cheng, Du, X. Wang, and Y. Wang 2016), and private meetings with management (Soltes 2014).

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¹ Beginning on March 28, 2003, Regulation G requires public companies to furnish a Form 8-K to the U.S. Securities and Exchange Commission (SEC) within five business days after issuing an earnings release. These releases are usually part of a conference call, suggesting that after this date, conference calls may be considered public, rather than private, information.

A common thread running through these studies is that the channel of private information acquisition goes primarily from firm management to analyst. However, many sell-side analysts profess to engage in the acquisition of information outside the purview of management (Brown et al. 2015). Yet little has been written on understanding how analysts gather and utilize data not generated by the firm, primarily because it is difficult for researchers to identify specific outside sources analysts use and the dates on which they receive these data.

In this study, we identify a source of external information used by some healthcare analysts: Freedom of Information Act (FOIA) requests to the Food and Drug Administration (FDA) for FDA-generated records pertaining to healthcare firms. The FDA maintains records on its factory inspections, drug and medical device applications, and complaints by consumers and healthcare professionals. These records generally are non-public in that firms are not required to share them with outsiders. Thus, analysts can access the non-public records only through FOIA requests to the FDA.

Using our own FOIA requests to the FDA, we received a PDF file delineating all FOIA requests and outcomes made to the FDA between 1999 and 2014. The file contains over 180,000 requests; we are able to identify 873 of these requests as originating from sell-side analysts, with the remaining requests coming from other interested parties, including investors, insurance companies, hospitals, and law firms.²

We use the full I/B/E/S database to identify all healthcare analysts and classify them as FOIA analysts (treatment) and non-FOIA analysts (control) based on whether they made a FOIA request to the FDA. Consistent with Brown et al. (2015), that only a subset of analysts engage in the acquisition of outside private information, and with Grossman and Stiglitz's (1980) contention that the acquisition of private information is inversely related to the costs associated with acquisition (e.g., processing costs), we find that only 21 percent of our sample of healthcare analysts made at least one FOIA request for FDA records. A probit model explores cross-sectional differences in analyst traits associated with the likelihood to make these requests.

Our first analysis examines the association between the receipt of FDA records and the propensity of the analyst to provide a subsequent recommendation on the requested firm. We find the receipt of FDA records to be related to a subsequent recommendation change 46.3 percent of the time. Although this finding suggests that the receipt of FDA records may include useful information to the FOIA analyst less than half of the time, we find that this percentage is significantly greater than subsequent recommendation changes by analysts without access to these records. This latter group includes FOIA analysts who were denied the records by the FDA and non-FOIA analysts covering the same stocks.

Next, we examine stock returns following the subsequent recommendations. Groysberg, Healy, and Maber (2011) show that analyst compensation is influenced heavily by whether an analyst is a "top stock picker" in his or her industry, and Brown et al.'s (2015) survey of what factors are important to analysts' compensation ranks the profitability of stock recommendations above accuracy and timeliness of earnings forecasts. Thus, stock returns align analysts' benefits with their incentives to acquire non-public information.

We estimate difference-in-differences (DiD) regressions of long-term stock returns for portfolios of buy (sell) recommendations for all analysts on I/B/E/S covering the same company. In these regressions, the FOIA analysts and all non-FOIA analysts must have a buy (sell) recommendation both in the year before and after the FDA record receipt date. Thus, we keep analyst ability constant in both time periods, only varying the model by whether the treatment analyst has or does not have his or her requested FDA records. We control for analyst ability and effort, the information environment surrounding the firm, public information about the firm or the FDA record itself, and stock risk factors. Our regression findings are consistent with buy portfolios following the receipt of FDA records outperforming buy portfolios of analysts without these records. We find similar results for sell portfolios—sell/hold recommendations perform worse after receipt of FDA records when compared to sell/hold recommendations without these records. In economic terms, the extra monthly return on the buy portfolio is 1.69 percent per month, and the extra return on the sell/hold portfolio is -1.38 percent per month. In annualized terms, these amount to 20.3 percent and -16.6 percent.

One of the central tenets of Grossman and Stiglitz (1980) is that investors search for non-public information only if the benefits exceed the costs of finding the information. Our findings are consistent with their theory. Specifically, despite the fact that any analyst can make a FOIA request, only a minority of healthcare analysts avail themselves of this information channel, suggesting a cost to processing the information.³ On the other hand, when the information is associated with a subsequent recommendation, the benefits, i.e., the stock returns, are economically significant.

² To understand the extent to which healthcare analysts use FOIA, we sent out similar FOIA requests to the Federal Aviation Administration (FAA; airlines) and the Department of Energy (DOE; utilities and oil). From the PDF files they sent us, we found no analyst requests to the FAA and only 13 analyst requests to the DOE. We interpret this finding as indicative of analysts using different sources of information for different industries (see, for example, Cheng et al. 2016).

³ The direct dollar costs of filing a FOIA request to the FDA are trivial. According to the FDA website, the current charges for filing a FOIA request are: search and review charges: \$23.00, \$46.00, and \$83.00, depending on the grade level of the FDA employee filling the request; duplication: \$0.10 per page for standard-size paper or actual cost per page for odd-size paper, with no charge for the first 100 pages of duplication; certification: \$10 each; computer charges: actual cost for time involved; electronic forms/formats: actual cost for form/format requested.

Although our results are consistent with analysts using FDA records when issuing new recommendations, the evidence can be considered circumstantial. To somewhat remedy this criticism, we examine some FDA records themselves to try to determine what information in these records is related to the likelihood that an analyst would downgrade the covered stock. We choose two types of *ex ante* “bad news” records to examine—Warning Letters and Forms 483—both containing violations resulting from an FDA inspection of a firm’s factory. Using two FOIA requests, we obtain copies of 39 usable FDA records that also were requested and received by our sample of analysts. We manually read each record and determine that the violations in these records can be classified into four general categories—product, manufacturing, testing, and documentation. Consistent with expectations that the first two categories might be more damaging to the firm than the latter two categories, we find evidence that downgrades are less likely following the receipt of information about a documentation violation.

Our study extends the current literature on analysts’ acquisition of private information along several new dimensions. First, our setting differs from most previous studies in that FDA records are a source of information independent of management. Thus, this is the first study to do an extensive examination into a process by which analysts gather private information from a source not emanating from the firm itself. In fact, a discussion with a FOIA analyst reveals that her main purpose for asking for FDA records is to evaluate the veracity of management’s claims during conference calls and other face-to-face meetings.

To illustrate, on January 10, 2012, Hospira participated in a brokerage conference sponsored by J.P. Morgan by giving a corporate presentation (see [Bushee et al. 2011](#); [Green et al. 2014](#)). The presentation was upbeat, but it also included a slide on a Form 483 issued by the FDA on January 4, 2012 on a factory located in Kansas.⁴ Notably, the slide stated that the Kansas factory accounted for approximately 12 percent of net sales, that the FDA raised six “observations,” but that these observations “can be addressed with minimal or no disruption.” One week after the conference, a Citigroup analyst filed a FOIA request to the FDA asking for that particular Form 483. Our reading of the Form 483 revealed three manufacturing violations, including the “propagation of microbial contamination” within the factory’s drug products. Prior to the request, the analyst’s recommendation was a hold (I/B/E/S = 3). On February 16, 2012, shortly after receiving the Form 483, the analyst lowered his recommendation to a strong sell (I/B/E/S = 5).

Second, our setting is novel in that FOIA requests are private to the extent that each request is made by one analyst only, and unless another analyst sends in a FOIA request for the identities of previous requesters (we found none in the FDA PDF file), other analysts are not aware that the FOIA request was made. These joint properties of privacy and being the sole recipient of the private information are similar to [Soltes \(2014\)](#), who examines private meetings between analysts, but differ from studies with settings involving groups of analysts or preannounced meeting dates ([Bushee et al. 2011](#); [Green et al. 2014](#); [Kirk and Markov 2016](#); [Cheng et al. 2016](#)).

Third, our study extends the literature that uses content analysis to discern the types of private information analysts use in their outputs. [Huang, Lehavy, Zang, and Zheng \(2018\)](#) analyze analyst reports using this approach. We use a subset of actual FDA records received by analysts to examine the types of information they use when making their first post-receipt stock recommendations.

Fourth, our study generally speaks to the costs and benefits of acquiring non-public information. Therefore, even though our setting is analysts covering healthcare firms only, it is applicable to other industries or settings. For example, analysts can make FOIA requests to other public agencies, including the Securities and Exchange Commission (SEC) or state-level agencies ([Bolton, Li, Ravina, and Rosenthal 2019](#)).

Like all research studies, this study has its limitations. Its main limitation is that, although we can observe the timing and the source of non-public information, we cannot unambiguously map the direct link from FDA records to the analysts’ stock recommendations. Unlike financial data or management forecasts, FDA records contain qualitative information about the firm and give no indication of the future economic effects that the FDA’s decision or regulatory action will have on the firm. Further, we do not know the full extent of each analyst’s information set about his or her covered firm prior to the receipt of the requested records. Thus, we are unable to place the contents of the FDA records within the mosaic of the analyst’s information. Despite these caveats, our study opens a new window into the realm of non-public information that analysts access to better value their covered firms.

II. FDA AND FOIA REQUESTS

The FDA is an agency within the U.S. Department of Health and Human Services. Since its creation in 1906, the U.S. Courts and Congress have expanded and contracted the scope of its oversight. Today, the FDA has three main roles: (1) oversight of the process leading up to the marketing of new products, particularly drugs and medical devices, (2) post-marketing monitoring of products, and (3) factory inspections.

⁴ Hospira placed the 34 slides of its presentation on an 8-K filing prior to the presentation. This discussion is based on those slides, as well as the records sent to us by the FDA in a FOIA request.

Under the FOIA, analysts may ask the FDA for a copy of any records the agency holds pertaining to the requested firm. These reports are non-public in that firms are not required to share them with investors, analysts, or other individuals. The FDA, with discretion, places some of these records on its website. However, the timing and choice of which records to post are completely within the FDA's discretion, and are sporadic at best (Mullins and Weaver 2013; Bruser and McLean 2014).

Figure 1 describes the FDA drug approval process. The process begins with preclinical animal testing and winds its way through three separate human testing phases. If Phases I through III are each successful, the firm most likely will file an application with the FDA seeking approval to begin marketing the new drug. On average, the FDA takes approximately six months to a year to make its decision on the application.⁵ The FDA decision issued to the company is called an "approval recommendation" (REC); it can be either (1) a rejection, (2) a conditional approval or a non-approval (subject to further modifications, sometimes referred to as a Phase IV), or (3) an approval for the firm to begin marketing its new drug. Only the REC is subject to a FOIA request; that is, all documentation and records between a firm and the FDA, up to and including the application, are deemed by the FDA to be proprietary and, therefore, are exempt from all FOIA requests.^{6,7}

As Figure 1 shows, the FDA has an elaborate post-marketing surveillance system. It maintains four databases of "adverse events," based on either mandatory or voluntary reports by the firm, consumers, doctors, hospitals, or other individuals. These databases include records on drugs (FDA Adverse Event Reporting System [FAERS]); medical devices (Medical Device Reporting [MDR]); food, dietary supplements, and cosmetics (Center for Food Safety and Applied Nutrition [CFSAN] Adverse Event Reporting System [CAERS]); and vaccines (Vaccine Adverse Event Reporting System [VAERS]). Each record type is subject to FOIA requests.

In 1938, the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 gave the FDA the authority to conduct factory inspections on food and drug companies. The 1953 Factory Inspection Amendment required the FDA to give manufacturers written reports of conditions observed during inspections and analyses of factory samples.

Figure 2 describes the factory inspection process (McDuffee 2011). Under the FD&C Act, registered domestic drug factories are to be inspected by the FDA at least once every two years. Notice is not required. Instead, an FDA inspector arrives at the factory with his or her credentials and a Form 482, the latter being a general form of what the inspector can and cannot examine. After the inspection, which can take several days or weeks, the FDA issues an Establishment Inspection Report (EIR) if the inspection produces no violations, or a Form 483, which is a list of violations. The firm has a right to remediate the violations or appeal to the FDA; often, there will be correspondences between the firm and the FDA about either process. After the FDA determines that all violations are corrected, it issues an EIR. Tangentially, the FDA issues Warning Letters (WL) to manufacturers about "significant" violations of FDA regulations; for example, a mislabeling of an ingredient in a drug or food supplement, or its inability to correct factory inspection violations. EIRs, Forms 483, warning letters, and related correspondences between the company and the FDA are subject to FOIA requests.

III. SAMPLE SELECTION AND SUMMARY STATISTICS

Analysts' Identities and FOIA Requests

On January 29, 2014, February 11, 2014, March 21, 2014, and June 10, 2015, respectively, we filed FOIA requests to the FDA. The information we requested was a list of all FOIA requests by outsiders to the FDA between January 1, 1999 and December 31, 2014. The FDA responded to our inquiries by giving us PDF files containing 182,149 individual requests. The information provided to us is (1) requester's identity (both person ["Signature"] and company ["Requester"], if applicable); (2) date of request; (3) outcome date; (4) target firm or individual; (5) outcome of the request (e.g., sent, withdrawn, denied); and (6) a short description of which agency records were requested.⁸

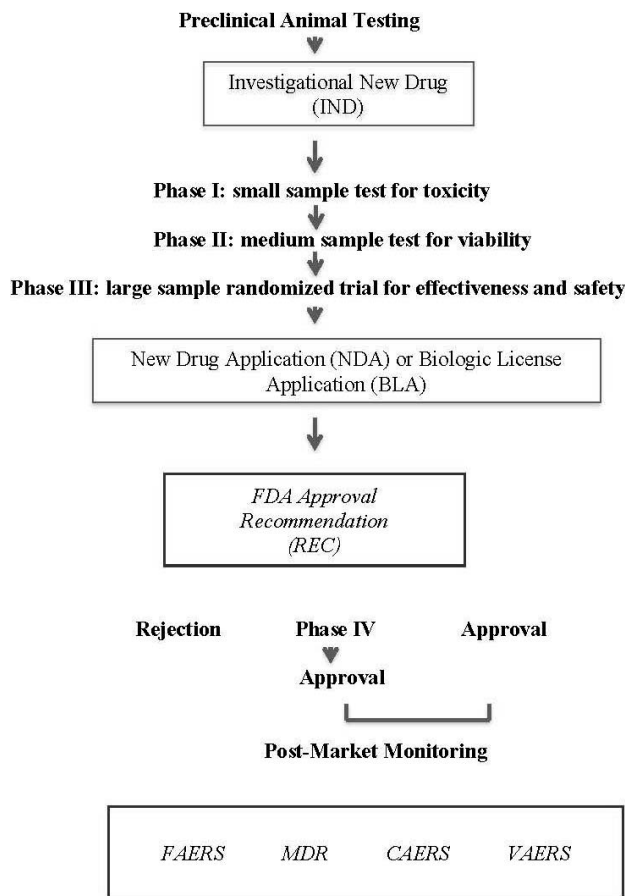
⁵ The FDA's vetting process is threefold. It first evaluates the results of the Phase I–III trials. Next, it examines drug labeling on dosage, usage, and side effects. Last, it inspects the facilities where the drug will be produced.

⁶ In the FOIA, there are nine stated exemptions to the presumption of mandatory disclosure. These exemptions include breaches of national security, individual privacy, trade secrets, financial confidentiality, internal memoranda or letters that are privileged in civil litigation, confidential sources to law enforcement agencies, documents that are related to financial institution regulation, and geological information. These exemptions with respect to FDA requests have been upheld by various court decisions (Lurie and Zieve 2006).

⁷ Companies are not precluded from voluntarily providing information to the public. Examination of select pharmaceutical and biotech companies' Forms 8-K reveals that some companies include selective information on the three clinical phases and/or their FDA applications in their earnings releases or, more rarely, in a standalone 8-K filing. We also find some, but many fewer, cases in which the Form 8-K includes selective information about factory inspections and post-market surveillance records. Further, the FDA maintains a website, <https://clinicaltrials.gov/>, in which pharmaceutical companies sometimes place their trial results (Capkun, Lou, and Wang 2017).

⁸ We submitted the second and third requests to the FDA to better understand the dates provided by the FDA. What we call the request date, the FDA calls the "record date"; what we call the outcome date, the FDA calls the "close date." In both requests, the FDA's record and close dates align with our request and outcome dates, which was included in the FDA's file to us. We use our terminology for the sake of clarity.

FIGURE 1
FDA Drug Approval Process and Post-Market Monitoring^a



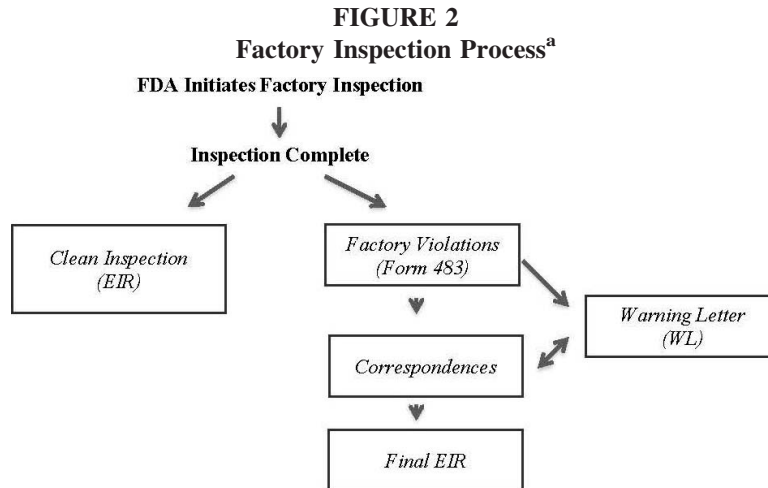
^a The rectangles contain all FDA records subject to FOIA requests (REC, FAERS, MDR, CAERS, VAERS). Everything above REC is not subject to FOIA requests.

See Appendix B for a description of the FOIA-eligible FDA records.

We identify FOIA analysts through the following process. First, we manually examine all “Requesters” to identify which ones are brokerage firms. Next, we manually use several internet sites to determine if the “Signature’s” position at the time of the request was an analyst. Most “Signatures” have both first and last names, although we have a few cases with a last name, but only an initial for the first name. Our first search engine is LinkedIn. If LinkedIn does not have the needed information, then we turn to BrokerCheck, a website maintained by the Financial Industry Regulatory Authority (FINRA) containing background information on current and former FINRA-registered security industry professionals. If BrokerCheck does not have the needed information, then we search Bloomberg, company websites, and Zoominfo.com, the latter being a search engine that collects biographical data using publicly available information. These steps result in a file of 76 brokerage firms and 221 equity analysts.⁹

Table 1, Panel A shows the 182,149 FOIA requests from 1999 through 2014 by year (column (4)). We have 873 individual requests from the 221 sell-side analysts we identify from the FDA PDF file (column (2)), with the 181,276 remaining requests coming from non-analysts, including hedge funds, insurance companies, public and private companies, hospitals, doctors, law firms, consulting firms, and individuals (column (1)).

⁹ Sometimes, an analyst makes a request in his or her own name. In this case, the “Requester” would be the name of the analyst, not the name of the brokerage house. To obtain a complete set of analysts’ requests, we search again using analyst names as “Requesters”; we include these requests in our sample. Despite these efforts, we acknowledge that our sample may not contain the full set of analyst requests from the FDA file.



^a The rectangles contain all records subject to FOIA requests. See Appendix B for a description of the FOIA FDA records.

To derive our final sample, we manually match the 221 equity analysts from the PDF file to the I/B/E/S translation file.¹⁰ If the requesting person (“Signature”) is on I/B/E/S, then we keep that analyst. However, sometimes the “Signature” is not an analyst, but instead is an equity analyst associate, assistant, or administrative assistant. In this case, we assume the “Signature” works for the chief analyst from the brokerage firm who covers the stock at the time of the FOIA request, and we include that chief analyst in our sample. Our final sample contains 62 brokerage houses, comprising 199 equity analysts making 528 individual requests (Table 1, Panel A, column (3)). Panel B presents the identity and frequency of requests for all brokerage firms with 20 or more requests over our time period. As the panel shows, Favus Institutional Research (a private firm providing healthcare consulting services to institutional investors), Cowen and Company, and Collins, Stewart LLC (a mid-cap stockbroker before being acquired by Canaccord in 2012; Mundy 2011) are not in the I/B/E/S database. These three firms account for a reduction of 144 requests from the original FDA PDF file. Despite these three companies not being on I/B/E/S, they illustrate the use of FOIA requests to the FDA as a source of information to individuals providing information to investors.

Analysts’ Characteristics: FOIA Requesters and Non-FOIA Requesters

Using the I/B/E/S database, we identify 924 unique healthcare analysts covering each FOIA-requested stock in our sample over 1999–2014. Of these analysts, 199 are FOIA requesters and 725 never used FOIA to request an FDA record. Thus, FOIA requesters represent 21.5 percent of our full sample of I/B/E/S analysts covering these specific healthcare stocks.

Table 2, Panel A contains descriptive statistics for FOIA and non-FOIA (control) analysts. All variable definitions are in Appendix A. FOIA analysts, on average, have 5.8 years of direct analyst experience, cover 8.6 stocks, work in brokerage firms with 82.7 analysts, and are designated Star Analysts 15.3 percent of the time. Table 2, Panel B reports summary statistics for a probit model on whether the analyst is a FOIA requester (*FOIA Requester* = 1) or a non-FOIA requester (*FOIA Requester* = 0) for any individual FOIA-requested stock in the year of the FOIA request.

Our probit findings are similar to previous studies in that an analyst’s propensity to seek FDA records is positively related to analyst effort (#*Forecasts*; Barth, Kasznik, and McNichols 2001; Kirk, Reppenhagen, and Tucker 2014); to the resources available to the analyst (#*Analysts at Brokerage Firm*; Clement 1999); and to previous forecasts errors (*Past Forecast Error*). It is also negatively related to *Analyst Experience*, suggesting that newer analysts are more likely to request FDA records. New to this study, we consider both advanced degrees in business (*MBA*) and advanced degrees in biology, chemistry, other sciences, and medicine (*PhD/MD*) as being useful to healthcare analysts. We find no difference between groups. Finally, based on a

¹⁰ The I/B/E/S translation file is for the year 2008. Thus, our matching criteria will not capture sell-side analysts working in the years 2009 through 2014 who are not already working as an analyst in 2008. Nor will it capture analysts working in earlier years who have left the field by 2008. On average, the I/B/E/S match retains 60 percent of the FDA PDF file sell-side analysts. Interestingly, we do not see patterns of attrition from 2008 outward—instead, we see random deviations from the mean over time. However, one should not draw conclusions from these patterns since our sample selection does not allow us to examine the counterfactual.

TABLE 1
FOIA Requests to the FDA

Panel A: FOIA Requests by Year

Year	Requests from Non-Analysts (1)	Requests from Analysts (2)	Requests from Analysts on I/B/E/S (3)	Total Requests (4)
1999	3,637	3	0	3,640
2000	3,963	6	4	3,969
2001	4,540	7	3	4,547
2002	19,629	45	24	19,674
2003	16,586	17	9	16,603
2004	19,959	19	12	19,978
2005	17,458	32	24	17,490
2006	18,394	37	23	18,431
2007	10,946	31	15	10,977
2008	8,942	31	18	8,973
2009	9,980	70	47	10,050
2010	9,330	73	57	9,403
2011	9,341	102	77	9,443
2012	8,783	133	68	8,916
2013	9,830	155	77	9,985
2014	9,958	112	70	10,070
Total	181,276	873	528	182,149

Panel B: Most Frequent Analyst Requests (Over 20 Requests)

Brokerage Firm	No. of Requests	Rank	No. of Requests in Final Sample
Favus Institutional Research	87	1	0
RBC Capital Markets	61	2	54
Jefferies & Co.	57	3	45
Wells Fargo Securities	57	3	49
Merrill Lynch	34	5	32
Leerink Swan & Co.	32	6	21
Cowen and Company	32	6	0
Morgan Stanley	29	8	21
Northcoast Research	29	8	19
Robert W. Baird & Co.	28	10	18
Collins Stewart LLC	25	11	0
Sanford Bernstein & Co.	23	12	17
Citigroup	23	12	15
Deutsche Bank	22	14	18
J.P. Morgan	21	15	16
UBS	20	16	11
Stifel Nicolaus & Co.	20	16	12

Panel A presents the number of requests by year. Requests from Non-Analysts include public and private companies, hospitals, doctors, law firms, consulting firms, and individuals. Requests from Analysts are requests from sell-side analysts identified in the FDA PDF file. Requests from Analysts on I/B/E/S are requests from sell-side analysts in the FDA PDF file matched with the I/B/E/S database. Year is the year the request was made. Panel B ranks the brokerage or research firm by the number of FOIA requests.

TABLE 2
Analysts' Characteristics

Panel A: Analysts' Characteristics

	<i>FOIA Analysts</i>			<i>Control Analysts</i>			<i>Difference with Control Analysts</i>	
	<u>Average</u>	<u>Std. Dev.</u>	<u>Obs.</u>	<u>Average</u>	<u>Std. Dev.</u>	<u>Obs.</u>	<u>Diff. in Avg.</u>	<u>t-stat. of Diff.</u>
<i>Analyst Experience</i>	5.798	4.055	245	7.580	4.492	7,008	-1.782***	-6.74
<i>#Stocks Covered</i>	8.606	4.279	245	8.365	5.358	7,008	0.241	0.86
<i>Star Analyst</i>	0.153	0.360	245	0.104	0.305	7,008	0.049**	2.10
<i>MBA</i>	0.526	0.499	245	0.483	0.500	7,008	0.043	1.32
<i>PhD/MD</i>	0.262	0.440	245	0.314	0.464	7,008	-0.052*	-1.82
<i>#Forecasts</i>	6.208	2.811	245	5.002	2.924	7,008	1.206***	6.59
<i>Past Recommendation</i>	2.437	1.037	245	2.216	0.937	7,008	0.221***	3.29
<i>Past Forecast Error</i>	0.006	0.017	245	0.004	0.012	7,008	0.002**	2.33
<i>#Analysts at Brokerage Firm</i>	82.669	70.077	245	70.988	62.192	7,008	11.681**	2.57

Panel B: Probit Model for the Prediction of FOIA Requests

<u>Dependent Variable: FOIA Requester</u>	<u>Coefficient</u>	<u>t-statistic</u>	<u>Marginal Probability</u>
<i>Analyst Experience</i>	-0.049***	-5.61	-0.3%
<i>Ln (#Stocks Covered)</i>	0.021	0.52	0.1%
<i>Star Analyst</i>	0.099	1.03	0.6%
<i>MBA</i>	0.095	1.58	0.6%
<i>PhD/MD</i>	-0.111	-1.60	-0.7%
<i>Ln (#Forecasts)</i>	0.343***	6.03	2.0%
<i>Past Recommendation</i>	0.099***	3.25	0.6%
<i>Past Forecast Error</i>	4.374**	2.35	25.5%
<i>Ln (#Analysts at Brokerage Firm)</i>	0.082**	2.54	0.5%
Observations	7,253		
Pseudo R ²	0.06		

*, **, *** Indicate statistical significance at the 10 percent, 5 percent, and 1 percent levels, respectively (two tailed).

Panel A presents characteristics of FOIA analysts and control analysts, respectively. Panel B presents a probit model for predicting FOIA requests. We require that each observation must have non-missing information for all covariates. We report coefficients, their heteroscedasticity-robust t-statistics, and the marginal probability change induced by a one-unit change in the value of specific covariate from its sample average. See Appendix A for variable definitions.

private conversation with a biotech sell-side analyst, we predict and find that analysts are more likely to use FOIA requests to monitor firms after the issuance of more negative stock recommendations (*Past Recommendation*).¹¹

FDA Records Requested under FOIA

Table 3 contains summary statistics on FOIA analysts' FDA requests. Panel A presents a breakdown of record requests by type (see Appendix B for definitions). Since many analysts request more than one FDA record type, for example, an analyst may request an EIR and a Form 483 on the same date, the number of records exceeds the number of requests from Table 1. For our final sample of analysts, 226 out of 655 total requests are for a Form 483, a list of factory inspection violations. Other possibly adverse information documents requested are post-market surveillance complaints (127), EIRs (54), and warning letters (57). As for potentially positive news, there are 65 requests for approval recommendation documents (RECs).

¹¹ Stock recommendations are taken from the I/B/E/S numeric recommendation code, which assigns recommendations on a scale of 1 through 5, representing strong buy, buy, hold, underperform, and sell, respectively.

TABLE 3
FOIA Requests to FDA

Panel A: Types of FDA Records Requested by Analysts under the FOIA

<u>Year</u>	<u>Establishment Inspection Report (EIR)</u>	<u>Form 483</u>	<u>Post-Market Surveillance Database</u>	<u>Warning Letter (WL)</u>	<u>Approval Recommendation (REC)</u>	<u>Other</u>	<u>Total</u>
Total	54	226	127	57	65	126	655

Panel B: Outcomes of Requests by Analysts for Unique FDA Records

	<u>Sent</u>	<u>Partial Sent</u>	<u>Denial</u>	<u>No Record</u>	<u>Withdrawn</u>	<u>Other Reason</u>	<u>Pending</u>	<u>Total</u>
Total	385	8	18	52	37	25	3	528

Panel C: Percent of Unique Firms in the FOIA Analyst's Portfolio with FOIA Requests

<u>Average</u>	<u>25 Percentile</u>	<u>Median</u>	<u>75 Percentile</u>	<u>Std. Dev.</u>
31.7%	9.1%	16.7%	41.7%	31.8%

Panel D: Variations in FOIA Requests with Receipts

	<u>Number of Analysts</u>	<u>Percent of All FOIA Analysts</u>	<u>Number of Requests</u>
FOIA Requests on Multiple Stocks in at Least One Month	65	32.7%	218
Analyst's Requests ≥ 3	63	31.7%	234
Requests on Non-Covered Stocks	46	23.1%	66
Of Which Covered Later	17	8.5%	20

This table presents descriptive data on the type of FDA records analysts request under the FOIA (Panel A) and the outcomes of these requests (Panel B). For Panel A, see Appendix B for a description of each FDA report type. Post-Market Surveillance Database is a combination of FAERS, MDR, CAERS, and VAERS. In Panel B, Sent is when the FDA grants FOIA information to the investment company requester; Partial Sent is when at least one, but not all, of the requested records are sent; Denial is when no record is sent; No Record is when the FDA's response is that the requested record does not exist; Withdrawn involves cases in which the requester voluntarily withdraws its FOIA request; and Other Reason refers to cases when the request is closed due to other reasons and no information is released to the requester. A single FOIA request may cover multiple categories. Panel C reports the percent of unique firms in the FOIA analyst's portfolio with FOIA requests. Panel D reports variations in how FOIA analysts use FOIA to make their requests.

Table 3, Panel B has the outcomes of these requests. The FDA can send all or some of the requested documents ("Sent" or "Partial Sent") or can deny the release of the documents to the requester ("Denial" or "Other Reason"). As the panel shows, 393 requests (385 + 8) were either fully or partially granted, which accounts for 74.4 percent of the total individual requests. The other 25.6 percent consists of requests in which the analyst received no information. To compare this with the full FDA population, we gather the percentage of requests granted (partial or full) from the FDA website for all processed requests over our time period. Full or partial grants, as a percentage of all processed requests, are 74 percent, a number highly consistent with our sample.

Panels C and D of Table 3 present some cross-sectional data on how healthcare analysts use FOIA to obtain information. As Panel C shows, FOIA analysts, on average, made at least one request for 31.7 percent of their covered companies, which translates to approximately three out of 8.7 covered companies. However, there is variation in the percentage of requested firms across analysts, with the bottom quartile requesting FDA records on less than 9.1 percent of their covered firms, and the top quartile making FOIA requests on 41.7 percent of their covered firm portfolio.

As Table 3, Panel D illustrates, analysts use FOIA requests in different ways. Some analysts target multiple stocks with simultaneous FOIA requests—65 of the 199 FOIA analysts (32.7 percent) sent out multiple FOIA requests in any one month at least once. For example, in March 2002, a Goldman Sachs analyst sent out FOIA requests for AERs for Amgen and Johnson &

Johnson, respectively. Some analysts are frequent FOIA users—63 FOIA analysts (31.7 percent) made at least three FOIA requests to the FDA over our sample period. Some analysts use FOIA to make requests on healthcare stocks not covered by the analyst—46 FOIA analysts (23.1 percent) made requests on non-covered stocks in the same industry. Of these 46 analysts, 17 requested FDA records on a company that the analyst covered at a later time. Thus, even among our FOIA analysts, we observe variability in how and when analysts request FDA records.

IV. SUBSEQUENT RECOMMENDATION CHANGES

Table 4, Panel A presents a breakdown of new stock recommendations by FOIA analysts occurring within one year after receipt of the requested records. The receipt of FDA records is associated with a subsequent upgrade, downgrade, or a new affirmation 46.3 percent of the time, with the percentages being 11.0 percent for upgrades, 15.3 percent for downgrades, and 20.0 percent for affirmations. This finding suggests that the receipt of FDA records may include useful information less than half of the time.

Looking across record types, most new recommendations fall within a 50 percent range, with the exception of REC, which elicits new recommendations only 33 percent of the time. RECs are the FDA's final decision as to whether the new drug or medical device has been approved for subsequent sale and marketing. Since 2007, the FDA requires pharmaceutical firms to register their clinical trials and to publish the results of these trials on the <https://clinicaltrials.gov/> website within 12 months of completion.¹² Thus, for many trials, analysts have access to prior information leading up to FDA approval, which may explain the relatively small number of recommendation changes following the receipt of these RECs.

To better understand the frequencies in which FDA records are followed by new stock recommendations, in Table 4, Panel B, we compare recommendation changes by whether the FOIA analyst has or does not have the requested FDA record. Column (1) shows the same percentages as the last column of Panel A—this is the treatment group where the analyst receives at least one FOIA-requested record from the FDA.

As shown in Table 3, FOIA analysts do not always receive the requested FDA records. In Table 4, Panel B, column (2), we present the percentage of new recommendations for these stocks. As the column illustrates, the overall percent of new recommendations made when the analyst is denied the records is 33.0 percent, compared to 46.3 percent when he or she receives the records; testing for differences in percentages yields a z-statistic of 4.09, significant at the 0.01 level. When examining upgrades/downgrades/affirmations, we see evidence that the percentage differences are significantly lower for upgrades and affirmations only.

As Table 3 also shows, analysts do not make FOIA requests on all of their covered stocks. In Table 4, Panel B, column (4), we present recommendation changes for covered stocks without FOIA requests. For these stocks, the analyst issued new recommendations 29.3 percent over the same year, a percentage significantly lower than the 46.3 percent for the FOIA stocks. When comparing the breakdown of upgrades/downgrades/affirmations, we see that this difference hails from downgrades and affirmations, but not from upgrades.

In Table 4, Panel B, column (6), we keep the analyst and the stock the same, but we examine changes in recommendations made two years prior to the receipt of the FOIA records.¹³ The overall percent of new recommendations made in year -2 is 31.9 percent, compared to 46.3 percent in the year when the analyst receives the records; testing for differences in percentages yields a z-statistic of 4.44, significant at the 0.01 level. When examining upgrades/downgrades/affirmations, we see evidence that all three types of recommendation changes are significantly lower in the year in which the FOIA analyst did not have FDA records.

In Table 4, Panel C, we compare percent changes in recommendations in the same covered stocks between FOIA and non-FOIA analysts. We see a markedly lower percentage of new recommendations by non-FOIA analysts—11.8 percent compared to the 46.3 percent for the FOIA-requesting analysts. The differences in new recommendations are significantly different for all three classifications of upgrades/downgrades/affirmations.

The findings in Table 4, Panels B and C are consistent with an association between the receipt of FDA records and the frequency in which the analyst provides a new stock recommendation. However, as Panel A shows, the receipt of FDA records is associated with a subsequent recommendation change only 46.3 percent of the time. In total, Table 4 supports the view that some requested FDA records contain new information to the FOIA requester.

¹² Enforcement of these rules, however, is weak, with only 41 percent of trial results actually appearing on the website (Zarin, Tse, and Sheehan 2015; Capkun et al. 2017), and an even smaller percentage appearing within the 12-month window.

¹³ Using a two-year look-back period instead of the year immediately prior to the request year allows us to better isolate the recommendation period from containing information that may have led the analyst to issue the FOIA request.

TABLE 4
Analysts' Stock Recommendations Following Receipt of FDA Records

Panel A: Number of New Recommendations After Receipt of FDA Records

<u>Direction of First New Recommendation</u>	<u>EIR</u>	<u>Form 483</u>	<u>Complaints</u>	<u>WL</u>	<u>Other</u>	<u>REC</u>	<u>Total Recommendations</u>	<u>Percent of Receipts</u>
Upgrade	6	25	4	4	8	2	49	11.0%
Downgrade	3	27	12	6	15	5	68	15.3%
Affirmation	6	40	14	6	17	6	89	20.0%
Total	15	92	30	16	40	13	206	46.3%
Number of Receipts	27	190	61	32	96	39	445	100.0%

Panel B: Comparisons of Percent of New Recommendations by Whether FOIA Analysts Receive or Do Not Receive FOIA Requested Records

<u>Direction of First New Recommendation</u>	<u>FOIA Request with Receipt (1)</u>	<u>FOIA Request without Receipt (2)</u>	<u>z-stat (1) – (2) (3)</u>	<u>Non-FOIA Requested Stock (4)</u>	<u>z-stat (1) – (4) (5)</u>	<u>FOIA Request with Receipt (Year –2) (6)</u>	<u>z-stat (1) – (6) (7)</u>
Upgrade	11.0%	6.3%	2.09**	10.4%	0.39	6.3%	2.51**
Downgrade	15.3%	13.6%	0.58	8.8%	3.68***	11.2%	1.78*
Affirmation	20.0%	13.1%	2.28**	10.1%	5.05***	14.4%	2.23**
Total Percent	46.3%	33.0%	4.09***	29.3%	6.85***	31.9%	4.44***
Observations	445	206		3,414		445	

Panel C: Comparisons of Percent of New Recommendations on Same Stocks between FOIA and Non-FOIA Requesting Analysts

<u>Direction of First New Recommendation</u>	<u>FOIA Analyst with Receipt (1)</u>	<u>Non-FOIA Analyst (2)</u>	<u>z-stat (1) – (2) (3)</u>
Upgrade	11.0%	3.9%	4.76***
Downgrade	15.3%	4.7%	6.19***
Affirmation	20.0%	3.2%	8.82***
Total Percent	46.3%	11.8%	14.49***
Observations	445	13,182	

*, **, *** Indicate statistical significance at the 10 percent, 5 percent, and 1 percent levels, respectively (two tailed).

Panel A describes the direction of the first new stock recommendation by FOIA analysts after receiving FDA records. See Appendix B for a description of the record types. Panels B and C present the percentages of new recommendations by FOIA analysts with FDA records and compare them to percentages of new recommendations by analysts without these records. Pending requests are excluded from the sample.

V. STOCK RETURNS FROM SELL-SIDE ANALYST STOCK RECOMMENDATIONS

Methodology and Descriptive Statistics

Calendar Time Portfolio Approach

In this section, we test whether healthcare analysts' stock recommendations are more profitable after receiving requested FDA records. [Brown et al. \(2015\)](#) find that analysts consider the profitability of stock recommendations to be more important than the accuracy and timeliness of earnings forecasts, a finding consistent with [Groysberg et al. \(2011\)](#).

We employ a standard calendar time portfolio approach to measure stock returns ([Fama 1998](#); [Lyon, Barber, and Tsai 1999](#); [Cohen, Frazzini, and Malloy 2010](#)). We construct two treatment portfolios: (1) a BUY portfolio of stocks consisting of FOIA analyst upgrades to buy or strong buy from the previous recommendation, or initial coverage with a buy or strong buy rating, or reiterations of buy or strong buy recommendations; and (2) a SELL portfolio of stocks consisting of FOIA analyst downgrades to

hold, underperform, or sell from the prior recommendation, or initial coverage with a hold, underperform, or sell recommendation, or reiterations of hold, underperform, or sell recommendations. A stock is included in each portfolio only if a new recommendation appears within 12 months after receipt of FDA records. We also create two BUY and SELL control sample portfolios for healthcare analysts covering the same stocks as the FOIA analysts, but who do not request FOIA FDA records.

We next accrue daily stock returns on each of the four portfolios. Figure 3 demonstrates the time line following the FOIA analyst's receipt of FDA records on day t_0 . As an example, we designate day t_1 as the day in which a FOIA analyst upgrades, initiates, or reiterates a buy or strong buy recommendation after receiving FDA records. Consistent with Cohen et al. (2010), we skip day t_1 and begin accruing returns on day t_1+1 . We accrue stock returns until the analyst downgrades the stock (day t_2) or until the end of one year after the receipt of FDA records (day t_0+1 year), whichever is shorter. If no new recommendation is issued over the year following day t_0 , then we do not include that stock in the portfolio. If more than one FOIA analyst covers the stock, then we keep the duplicate stock in the portfolio and treat them as distinct stocks (Cohen et al. 2010). Raw returns are calculated on a daily basis and averaged across all FOIA analysts and calendar days.

We adopt the same procedure for non-FOIA (control) analysts, except that we begin accruing stock returns on the day in which the control analyst issues his or her upgrade/buy recommendation. Because the stock recommendation date (t_1) and the end date (t_2) differ between FOIA and non-FOIA analysts, our approach assesses the stock-picking ability of the FOIA analyst *vis-à-vis* the non-FOIA analyst covering the same stock after the FOIA analyst's receipt of FDA records. We repeat the same procedure for sell recommendations, accruing stock returns for treatment and control analysts.

For a stock to be included in a specific portfolio, for example, the FOIA BUY portfolio, the same FOIA analyst must give a buy or strong buy recommendation on the same stock within one year prior to day t_0 . As shown in Figure 3, we designate this pre-period recommendation as day t_{-2} . We accrue stock returns for this pre-period FOIA BUY portfolio from day t_{-2} until the FOIA analyst either issues an opposite recommendation on day t_{-1} , or until day t_0 . Our approach creates a balanced sample in terms of having the same analyst and similar recommendation in both the pre- and post-receipt return portfolios.

Timing Differences

We calculate the average timing difference in days between FOIA and control analysts' first post-receipt date recommendations. For the BUY portfolio, the mean (median) difference is 104 (92) days, consistent with FOIA analysts providing more timely recommendations than non-FOIA analysts following the receipt of an FDA record. For the SELL portfolio, the mean (median) is 95 (69) days, a finding also consistent with FOIA analysts issuing more timely recommendations following the receipt of an FDA record.

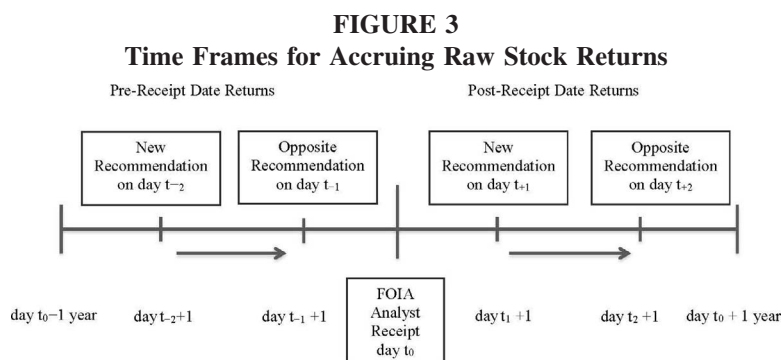
Univariate Comparisons of Stock Returns

Table 5, Panel A presents monthly calendar time portfolio stock returns and their differences across analyst type or time period. These statistics are descriptive because we do not control for differences in risk, analyst characteristics, firm characteristics, or other available information. For the BUY portfolios, post-receipt date returns across analysts with and without FOIA records produces an average difference in monthly returns of 1.21 percent (t-statistic = 2.22), which translates into a yearly return of 14.52 percent. Since each portfolio is predicated on the analyst providing a buy/strong buy recommendation and/or an upgrade, the primary difference between the two portfolios is the receipt of information. In contrast, we cannot reject the hypothesis of no difference in post-receipt date returns for SELL portfolios between requesting FOIA analysts and our sample of control analysts. The difference in post-receipt date returns between FOIA and non-FOIA analysts is -0.45 percent (t-statistic = -0.96).

Multivariate Analyses

To examine whether our univariate results are driven or affected by other factors, we employ a difference-in-differences regression methodology. The regressions are run on daily stock returns (*Return*), but consistent with Cohen et al. (2010), the coefficients on all independent variables are adjusted to represent monthly returns. Variable definitions are in Appendix A. For the portfolio of BUY or SELL, respectively, we estimate the following regression:

$$\begin{aligned}
 \text{Return} = & \alpha + \beta_1 \text{FOIA Analysts} + \beta_2 \text{Post} + \beta_3 (\text{FOIA Analysts} \times \text{Post}) + \beta_4 \text{Firm Size} + \beta_5 \text{B/M} + \beta_6 \text{Momentum} \\
 & + \beta_7 \text{Analyst Experience} + \beta_8 \text{Ln}(\# \text{Stocks Covered}) + \beta_9 \text{Ln}(\# \text{Analysts at Brokerage Firm}) + \beta_{10} \text{PhD/MD} \\
 & + \beta_{11} \text{MBA} + \beta_{12} \text{Star Analyst} + \beta_{13} \text{Frequent FOIA Requester} + \beta_{14} \text{FOIA Industry Expertise} \\
 & + \beta_{15} \text{Forecast Dispersion} + \beta_{16} \text{Institutional Ownership} + \beta_{17} \text{Ln}(1 + \text{News Articles}) + \beta_{18} \text{Prior 8K Filing} \\
 & + \beta_{19} \text{Multiple FOIA Requests on Stock} + \text{FE} + \varepsilon.
 \end{aligned}
 \tag{1}$$



FOIA Analysts is 1 if the analysts receive FDA records, and 0 otherwise. *Post* is 1 if the stock recommendation is made after the FDA receipt date, and 0 otherwise. The interaction between *FOIA Analysts* and *Post* tests whether stock returns after the receipt of the FDA records are different for analysts with and without these records.

We create two new analyst ability measures based on how FOIA analysts use FOIA to request FDA records. Presumably, frequent FOIA requesters find FDA records to be useful. *Frequent FOIA Requester* is an indicator if the analyst filed at least three FOIA requests over our time period.¹⁴ According to [Brown et al. \(2015\)](#), 83.42 percent of surveyed sell-side analysts consider “industry knowledge” to be an important input when making stock recommendations; *FOIA Industry Expertise* is an indicator if the analyst made at least one FOIA request to the FDA for an uncovered healthcare stock. We interpret this practice as the FOIA analyst seeking out information on competing firms or, more broadly, on his or her covered industry.

PhD/MD and *MBA* measure whether an analyst has these post-graduate degrees. To control for the timeliness of the information contained in the FDA record, we include *Prior 8K Filing* as an independent variable. For our sample of FOIA receipts, 208 (39 percent) Forms 8-K were filed with the SEC prior to the request with some information about the requested FDA record. On average, these Forms 8-K preceded the formal FOIA request by 10.3 days, with a median lead time of 7.0 days. To understand the contents of these filings, we manually downloaded and read through each 8-K filing. Notably, the filings do not contain the FDA record itself, but only reveal the existence of the record. Thus, the FDA record itself contains more information than what is on the 8-K filing. *Multiple FOIA Requests on Stock* is an indicator if at least two separate analysts placed FOIA requests with the FDA on the same stock within a month of each other.

Our multivariate regression includes many controls based on the prior literature on stock returns (*Firm Size*, *B/M*, *Momentum*) and analysts’ recommendations or forecast errors. We control for analysts’ ability and available resources (*Analyst Experience*, *#Stocks Covered*, *#Analysts at Brokerage Firm*, and *Star Analyst*), and for the firm’s information environment (*Forecast Dispersion*, *Institutional Ownership*, and *#New Articles*). We include fixed effects (*FE*) for month and for firm.¹⁵ Table 5, Panel B presents covered firms’ characteristics. Other variables are in Tables 2 and 3.

Column (1) of Table 6 presents the regression results for BUY. The coefficient on (*FOIA Analysts* × *Post*) is significantly positive at the 0.05 level. Thus, after controlling for equity risk, analyst characteristics, and the firm’s information environment, we find evidence consistent with FDA records providing value-relevant information to FOIA-requesting analysts. In economic terms, the 0.0169 coefficient is the extra monthly return a BUY portfolio earns *after* a FOIA analyst receives the requested FDA records. This translates to a 20.3 percent annualized return. The magnitude of the return is consistent with [Grossman and Stiglitz’s \(1980\)](#) information search model, which suggests that an analyst would search for non-public information when the benefits of the search are economically significant.

We find a significantly positive coefficient on *PhD/MD* in Table 6, consistent with analysts with terminal science or medical degrees leveraging their specialized knowledge to better assess future stock values for healthcare companies. This finding is consistent with [Bradley, Gokkaya, and Liu \(2017\)](#), who find that analysts with prior work experience in their covered industries are better predictors of future earnings. In contrast, having an *MBA* degree provides no significant additional

¹⁴ Conversely, we create an indicator if the FOIA analyst request is the first FOIA request to the FDA. Because this indicator and *Frequent FOIA Requester* are highly negatively correlated, we redo our analyses with this indicator instead of *Frequent FOIA Requester*. The empirical results are qualitatively the same with either variable and, therefore, we only show the empirical results with *Frequent FOIA Requester*.

¹⁵ Alternatively, we include a fixed effect for the analyst. With this fixed effect, we cannot include time-invariant analyst characteristics such as *MBA* or *PhD/MD* into the regression equation. The empirical results with this fixed effect are qualitatively the same as those without the analyst fixed effect. Specifically, the coefficients on *FOIA Analysts* × *Post* are qualitatively the same and remain significant at the same levels.

TABLE 5
Descriptive Statistics

Panel A: Monthly Stock Returns Before and After the Receipt Date

	BUY Portfolios			SELL Portfolios		
	Pre-Receipt Date (1)	Post-Receipt Date (2)	Diff. (3)	Pre-Receipt Date (4)	Post-Receipt Date (5)	Diff. (6)
<i>FOIA Analysts</i>	0.61% [1.10]	2.71%*** [5.12]	2.10%*** [2.73]	1.14%** [2.13]	1.86%*** [4.13]	0.72% [1.03]
<i>Control Analysts</i>	1.04%*** [9.06]	1.50%*** [11.41]	0.46%*** [2.64]	1.54%*** [11.87]	2.31%*** [17.90]	0.77%*** [4.21]
Difference	-0.43% [-0.76]	1.21%** [2.22]		-0.40% [-0.73]	-0.45% [-0.96]	

Panel B: Firm Characteristics

	Average	Median	Std. Dev.	No. of Firms
<i>Market Capitalization</i> (\$Billion)	23.76	6.43	44.43	130
<i>B/M</i>	0.61	0.34	1.89	130
<i>Momentum</i> (BUY, Past 12 Months)	28.99%	12.71%	64.73%	129
<i>Momentum</i> (SELL, Past 12 Months)	16.35%	7.79%	50.50%	126
<i>Forecast Dispersion</i>	0.29	0.17	0.34	130
<i>Institutional Ownership</i>	68.45%	78.30%	29.20%	130
<i>#News Articles</i>	0.67	0.00	1.38	130

, * Indicate statistical significance at the 5 percent and 1 percent levels, respectively (two tailed).

Panel A shows the average calendar time monthly returns of stocks based on buy or sell recommendations. BUY encompasses both buys and upgrades in columns (1) through (3); SELL has holds/sells and downgrades in columns (4) through (6). Panel B presents summary statistics for firm characteristics. See Appendix A for variable definitions.

expertise, a finding somewhat consistent with [De Franco and Zhou \(2009\)](#), who find weak evidence that having a CFA improves analyst's ability to forecast earnings.

The significantly positive coefficient on *Multiple FOIA Requests on Stock* in Table 6 supports the view that FOIA analysts interpret the requested FDA records in similar ways. The statistically negative coefficient on *Prior 8K Filing* is consistent with an 8-K filing muting an analyst's advantage in using the information contained in the requested FOIA record. *Frequent FOIA Requester* has a significantly positive coefficient, consistent with the view that analysts who use FOIA requests more frequently are the ones who benefit most from these records. The coefficient on *FOIA Industry Expertise*, however, is insignificantly different from zero. The other variables support those found in prior literature (*Firm Size*, *B/M*, *Momentum*, *Analyst Experience*, *#Stocks Covered*, *Forecast Dispersion*, *Institutional Ownership*, *#News Article*).

Table 6, column (2) contains the regression results on stock returns on SELL portfolios. Stock returns are negatively related to the receipt of FDA records by requesting analysts, as seen by the significantly negative coefficient on (*FOIA Analysts* × *Post*) (p-value < 0.10). In economic terms, FOIA analysts issuing sell recommendations after the receipt of a requested FDA record, on average, avoid a monthly loss of 1.38 percent when compared to analysts without these records. This translates to an annualized loss of 16.6 percent, which is consistent with [Grossman and Stiglitz's \(1980\)](#) information search model.

Similar to BUY portfolios, stock returns on SELL portfolios are significantly related to the risk factors *Firm Size*, *B/M*, and *Momentum*. SELL portfolios earn more negative stock returns for analysts with science or medical knowledge (*PhD/MD*) or have an expertise with respect to the FOIA process (*Frequent FOIA Requester*). We also find that returns on sell recommendations are associated with a better information environment in general (*Forecast Dispersion*, *Institutional Ownership*), with *#News Articles*, and with other analysts requesting the same FDA record (*Multiple FOIA Requests on Stock*). Similar to the results on BUY portfolios, the filing of a Form 8-K prior to the receipt of the FDA record mutes the negative return on the SELL portfolios. The other independent variables are insignificantly different from zero. In summary, Table 6 presents evidence consistent with analysts finding FOIA-requested FDA records to be informative in making their future stock recommendations.

TABLE 6
Regressions on BUY and SELL Portfolios

Dependent Variable	Returns on BUY Portfolios (1)	Returns on SELL Portfolios (2)
<i>FOIA Analysts</i>	-0.0026 [-0.33]	-0.0077 [-1.10]
<i>Post</i>	0.0099 [1.11]	0.0184* [1.95]
<i>FOIA Analysts × Post</i>	0.0169** [2.38]	-0.0138* [-1.89]
<i>Firm Size</i>	-0.0085*** [-4.12]	-0.0041*** [-4.42]
<i>B/M</i>	0.0053** [2.05]	0.0151** [2.41]
<i>Momentum</i>	-0.0904*** [-3.11]	-0.5827*** [-6.35]
<i>Analyst Experience</i>	0.0005 [1.64]	0.0005 [1.02]
<i>Ln (#Stocks Covered)</i>	-0.0090** [-2.44]	0.0031 [1.21]
<i>Ln (#Analysts at Brokerage Firm)</i>	0.0010 [0.57]	-0.0002 [-0.15]
<i>PhD/MD</i>	0.0101** [2.56]	-0.0189*** [-2.69]
<i>MBA</i>	-0.0009 [-0.35]	-0.0012 [-0.36]
<i>Star Analyst</i>	-0.0015 [-0.31]	-0.0089 [-0.60]
<i>Frequent FOIA Requester</i>	0.0229** [2.10]	-0.0472*** [-2.70]
<i>FOIA Industry Expertise</i>	0.0034 [0.26]	-0.0064 [-0.22]
<i>Forecast Dispersion</i>	-0.0292*** [-3.16]	0.0548*** [3.69]
<i>Institutional Ownership</i>	0.0190** [2.48]	-0.0465*** [-3.00]
<i>Ln (1 + News Articles)</i>	0.0145* [1.69]	-0.0577*** [-3.94]
<i>Prior 8K Filing</i>	-0.0104*** [-3.55]	0.0130* [1.66]
<i>Multiple FOIA Requests on Stock</i>	0.0117** [2.40]	-0.0078*** [-2.60]
Constant	0.0556*** [6.63]	0.0470 [0.55]
Month and Firm FE	Yes	Yes
Observations	363,234	352,931
R ² (%)	0.88	0.93

*, **, *** Indicate statistical significance at the 10 percent, 5 percent, and 1 percent levels, respectively (two tailed).

This table presents regression results on daily stock returns for BUY and SELL portfolios. t-statistics are in brackets. Returns are winsorized at 0.01 percent, and standard errors are clustered at the month level.

See Appendix A for variable definitions.

Information or Better Skill: Alternative Control Sample

An alternative explanation is that FOIA analysts are better stock pickers than non-FOIA analysts. That is, even though we control for many analyst characteristics, we cannot rule out the possibility that omitted analyst characteristics might be driving our results. For example, FOIA analysts may pay more attention to their covered stocks than non-FOIA analysts.

To examine this alternative explanation, we gather all FOIA requests that were rejected by the FDA (see Table 3) and examine differences in subsequent stock returns between FOIA analysts receiving their requested FDA records (treatment group) and FOIA analysts not receiving their requested FDA records (new control group). Since the treatment and control samples encompass the same group of analysts, the primary difference between the two groups is the receipt/non-receipt of requested FDA records. We already found evidence (see Table 4, Panel B) that FOIA analysts are more likely to provide a new recommendation after they receive their requested records.

We create a new indicator variable, *Receipt of FOIA Request*, equal to 1 if the FOIA analyst received his or her requested records, and 0 otherwise. We interact this variable with *Post*, thus testing for differences in stock returns on BUY (SELL) portfolios before and after receipt of FDA records. The regressions control for equity risk, the overall information environment of the firm, the number of news stories, and the information environment surrounding the FDA record itself. Since our sample includes only those analysts making FOIA requests, we omit the analyst experience and ability variables in our regression specifications.¹⁶

Table 7 contains the regression results. The empirical findings are consistent with the information hypothesis associated with the receipt of the FDA records. Specifically, the coefficient on (*Receipt of FOIA Request* × *Post*) is significantly positive at the 0.05 level for the regressions on BUY portfolios and is significantly negative at the 0.10 level for the regressions on SELL portfolios. In economic terms, FOIA analysts earn, on average, 2.32 percent higher monthly returns on their BUY portfolios, and avoid 1.70 percent lower monthly returns on their SELL portfolios when in possession of the FDA records. The equity risk variables and some of the information environment variables remain significantly different from zero. In sum, Table 7 provides evidence consistent with FDA records providing valuable information to requesting analysts.

VI. INSIDE THE FDA RECORDS

Our large-sample stock return results are consistent with FOIA records providing value-relevant information to FOIA analysts. However, they do not lend much insight into the type of information FOIA analysts use in revising their recommendations. In this section, we go inside a subset of FDA records and examine (1) the content of these records, and (2) the types of information within these records most associated with analysts' revised stock recommendations.

To gain access to FDA records, we filed two separate FOIA requests to the FDA in July 2017 asking for a subset of Forms 483 and warning letters sent to our FOIA analysts. Forms 483 and most warning letters contain a list of factory violations only. We select these two record types because they are relatively easy (for us) to read and understand when compared to EIRs or RECs, and the information contained in these records is similar across records, allowing us to classify the information into various "buckets."

To keep our sample manageable, we randomly selected 46 of the 92 Forms 483 and all 16 warning letters from our initial sample that resulted in a post-receipt recommendation by the FOIA analyst. The FDA sent us files on all our requests. However, only 41 of the requested files contained all of the needed information for this analysis—a record of the analyst's request letter, a record of the FDA's reply to the analyst, and the FDA Form 483 or warning letter itself. Two of the warning letters were not related to factory inspections and, therefore, were not used. Most of the missing records are from requests by the analyst prior to 2011, leading us to infer that the FDA only sent us records from their computer bank. Our final sample has 27 Forms 483 and 12 warning letters.

We printed and manually read each of the 39 FDA records. After a joint consultation, we classified the factory violations into four distinct types: product, manufacturing, testing, and documentation. A product violation is a mention of a substandard drug or medical device. A manufacturing violation refers to a defect in a factory's manufacturing process. A test violation is when the firm fails to establish a mandated test to monitor its processes or products, or receives a criticism as to how a test was conducted. A documentation violation occurs when the firm fails to adequately document its procedures or test results.

Appendix C contains snapshots from the records the FDA sent us. The blackened parts are redactions by the FDA. We classify the excerpt from the Thoratec Corporation Warning Letter as a product violation because it refers to a medical device that "may have caused or contributed to a [patient's] death." The excerpt from the Hospira Form 483 is a manufacturing violation because it discusses how a factory "promotes the propagation of microbial contamination." The Alphaform Form 483 includes a "failure to perform the preparatory test for the validation of the membrane filtration method" and, therefore, is

¹⁶ We also estimate the DiD equation with analyst experience and ability variables. The results are qualitatively similar to those reported in Table 7.

TABLE 7
Regressions on Alternative Control Sample

Dependent Variable	Stock Returns on BUY Portfolios (1)	Stock Returns on SELL Portfolios (2)
<i>Receipt of FOIA Request</i>	−0.0040 [−0.38]	−0.0032 [−0.33]
<i>Post</i>	0.0131 [1.01]	0.0157** [2.34]
<i>Receipt of FOIA Request</i> × <i>Post</i>	0.0232** [2.12]	−0.0170* [−1.71]
<i>Firm Size</i>	−0.0091*** [−2.71]	−0.0164*** [−4.19]
<i>B/M</i>	0.0322*** [3.96]	0.0072* [1.73]
<i>Momentum</i>	−0.1399*** [−3.29]	−0.7285*** [−8.46]
<i>Forecast Dispersion</i>	−0.0146 [−1.38]	0.0550*** [2.98]
<i>Institutional Ownership</i>	0.0070 [0.50]	−0.0546*** [−3.69]
<i>Ln (1 + News Articles)</i>	0.0528*** [3.51]	−0.0926*** [−4.46]
<i>Multiple FOIA Requests on Stock</i>	0.0034 [0.25]	−0.0244** [−2.05]
Constant	0.1675*** [4.11]	0.2972*** [5.29]
Month and Firm FE	Yes	Yes
Observations	24,987	33,497
R ² (%)	0.58	0.84

*, **, *** Indicate statistical significance at the 10 percent, 5 percent, and 1 percent levels, respectively (two tailed).

This table presents regression analyses of daily stock returns on BUY and SELL portfolios. The control sample consists of FOIA analysts who did not receive a requested FDA record. t-statistics are in brackets. Stock returns are winsorized at 0.01 percent, and standard errors are clustered at the month level.

See Appendix A for variable definitions.

classified as a testing violation. The Genzyme Form 483 disclosure is an example of a documentation violation in that it states that “activities performed during drug substance manufacture are not adequately documented.”

Table 8, Panel A contains a numeration of our violation categories. On average, each record contains 9.82 violations, with a range of one to 25 violations (untabulated). The two most prevalent violations relate to testing and documentation, with 82 percent and 74 percent of the records having at least one testing or documentation violation, respectively. Manufacturing (44 percent) and product (33 percent) violations are also commonly found. We further note that 21 percent of the records use the existence of a current or previous complaint as an example of a product violation and, therefore, we include it as a separate category.

Ex ante, we expect product, manufacturing, and complaints to be associated with more negative news, as these violations may be indicative of more severe, and possibly more expensive, problems within the firm. Conversely, we expect testing and documentation violations to be less costly to the firm, thus being indicative of less negative or problematic news.¹⁷

¹⁷ Anecdotally, in 2014, an analyst at Leerink Partners wrote in a “research note” that she is not changing her “outperform” rating on HeartWare after the company released a statement announcing the receipt of a warning letter related to its Florida manufacturing facility (Seiffert 2014). Notably, the warning letter found issues with the plant’s “procedures for validating device design, procedures for implementing corrective and preventive action, maintaining records related to investigations and validation of computer software” (Seiffert 2014). We would classify these issues as testing and documentation violations.

TABLE 8
Information Contained in Warning Letters and Forms 483

Panel A: Types of Violations

	<u>Mean Total Violations</u>	<u>Product Violation</u>	<u>Manufacturing Violation</u>	<u>Testing Violation</u>	<u>Documentation Violation</u>	<u>Complaint</u>
Full Sample						
Number	9.82	13	17	32	29	8
%		33%	44%	82%	74%	21%
Warning Letters		7	5	12	6	5
Forms 483		6	12	20	23	3

Panel B: FOIA Analyst's First Post-Receipt Recommendation is More Negative than Consensus Recommendation

	<u>Dependent Variable = <i>NegConsensus</i></u>		
	<u>(1)</u>	<u>(2)</u>	<u>(3)</u>
<i>Ln (Number of Violations)</i>	0.0376 [0.46]		
<i>Product</i>		0.0588 [0.29]	
<i>Manufacturing</i>		0.0310 [0.12]	
<i>Testing</i>		0.0234 [0.07]	
<i>Documentation</i>		-0.4754** [-2.45]	
<i>Complaint</i>		0.3133* [1.66]	
<i>Lawsuit</i>			0.6240** [2.09]
Constant	0.5678*** [2.82]	0.9530*** [2.87]	0.3610*** [3.68]
Observations	39	39	39
R ²	0.01	0.19	0.05

(continued on next page)

Regression Results

We regress two measures of FOIA analysts' post-receipt stock recommendations on the number and type of each violation. *NegConsensus* is an indicator if the FOIA analyst's first post-receipt recommendation is more negative than the consensus recommendation on that date for all non-FOIA analysts. *Downgrade* is an indicator if the FOIA analyst's first post-receipt recommendation is a downgrade from his or her previous stock recommendation. If our *ex ante* expectations are correct about the relative costs of correcting these violations, and if the analyst is using this information, then we would expect to see positive associations between *NegConsensus* (*Downgrade*) and product, manufacturing, or complaint violations, and negative associations with testing or documentation violations.

Table 8, Panel B contains the regression results on *NegConsensus*. In column (1), we find no association between *NegConsensus* and the number of violations contained in the FDA record, suggesting that the number of violations itself does not influence the FOIA analyst's post-receipt recommendation. However, in column (2), we find evidence that the severity of the information contained in the FDA records is associated with the FOIA analyst's first post-receipt recommendation, as evidenced by the significantly negative coefficient on *Documentation* and the significantly positive coefficient on *Complaint*. Further, we note that the R² value for the regression in column (2) is 0.19, explaining about 19 percent of variation in *NegConsensus*. In Panel C, we present the regression results on *Downgrade*. The results are consistent with FOIA analysts

TABLE 8 (continued)

Panel C: FOIA Analyst's First Post-Receipt Recommendation is a Downgrade

	Dependent Variable = <i>Downgrade</i>		
	(1)	(2)	(3)
<i>Ln (Number of Violations)</i>	0.0872 [0.90]		
<i>Product</i>		-0.3187 [-1.60]	
<i>Manufacturing</i>		-0.0060 [-0.02]	
<i>Testing</i>		0.1129 [0.34]	
<i>Documentation</i>		-0.5730*** [-2.69]	
<i>Complaint</i>		0.1109 [0.33]	
<i>Lawsuit</i>			0.4583*** [3.32]
Constant	0.5422** [2.39]	1.0146*** [2.73]	0.5417*** [5.11]
Observations	39	39	39
R ²	0.01	0.29	0.04

*, **, *** Indicate statistical significance at the 10 percent, 5 percent, and 1 percent levels, respectively (two tailed). t-statistics are in brackets. Panel A has a numeration of the types of violations (see Appendix A for definitions). Panel B presents summary statistics for regressions on whether the FOIA analyst's post-receipt first stock recommendation is more negative than the consensus stock recommendation. Panel C presents summary statistics for regressions on whether the FOIA analyst downgraded the stock recommendation after receipt of FOIA-requested FDA records.

being less likely to downgrade stocks with *Documentation* violations, as evidenced by its significantly negative coefficient in column (2).¹⁸ Both panels support our expectations about associations between recommendation revisions and the severity of the listed violations.

Finally, we discover that seven of the 39 records resulted in subsequent class action lawsuits in which plaintiffs specifically accuse the firm of hiding adverse information from investors by not revealing the existence or contents of the Form 483 or warning letter. To see if FOIA analysts anticipate the ramifications surrounding this negative event, we create an indicator (*Lawsuit*) for these seven firms. As column (3) of Table 8, Panels B and C show, FOIA analysts are more likely to have a negative post-receipt stock recommendation *vis-à-vis* the consensus recommendation (Panel B), and are more likely to downgrade the firm's stock (Panel C) for firms that ultimately are sued for not disclosing the contents of these specific records. In summary, this section presents evidence consistent with analysts differentiating among violation types when making their subsequent recommendations.

VII. CONCLUDING REMARKS

This study adds to the literature on sell-side analysts' search for private information by examining a source of not readily accessible information—FOIA-requested FDA records. We obtain our data through our own FOIA requests, asking the FDA to send us information on past FOIA requests, as well as copies of some specific records sent to analysts.

Our findings are consistent with healthcare analysts using FOIA-requested FDA records to make more profitable stock recommendations. We also present evidence that these FOIA analysts revise their stock recommendations more frequently and sooner than healthcare analysts not receiving FDA records. Further, a content analysis of specific FDA records on factory

¹⁸ We also regress individual one-year stock returns following the first post-receipt recommendation on the number of violations and the type of violations, respectively, for each record. F. Wong, T. Wong, and Zhang (2017) do a similar type of analysis for earnings forecast accuracy in China based on the content of home based/international based analyst reports. Our results are consistent with our analyst recommendation results in that we find significantly negative coefficients on *Ln (Number of Violations)* and on *Manufacturing*, respectively. That is, we find valuation effects associated with the severity of the violations stated in the Form 483/Warning Letter.

inspections provides evidence consistent with less serious violations (e.g., testing or documentation) being less aligned with downward recommendation revisions than more serious violations (e.g., product or manufacturing).

Our study is the first to do an extensive analysis into the process by which analysts gather qualitative non-public information from a source outside of firm management. As such, it complements prior studies on analysts' search for private information by providing a new peek into a different "black box" of inputs used by sell-side equity analysts when formulating their stock recommendations.

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APPENDIX A
Variable Definitions

Variable	Definition
Dependent Variables	
<i>FOIA Requester</i>	Indicator equal to 1 for an analyst who filed FOIA requests to the FDA, and 0 otherwise.
<i>Returns</i>	Daily stock returns as reported by CRSP.
<i>NegConsensus</i>	Indicator equal to 1 if a FOIA analyst's first post-receipt recommendation is more negative than the consensus recommendation on that date for all non-FOIA analysts.
<i>Downgrade</i>	Indicator equal to 1 if a FOIA analyst's first post-receipt recommendation is a downgrade.
FOIA Variables	
<i>FOIA Analysts</i>	Indicator equal to 1 for analysts who receive requested FOIA records, and 0 otherwise.
<i>Post</i>	Indicator equal to 1 for periods after the FOIA receipt date, and 0 otherwise.
<i>Receipt of FOIA Request</i>	Indicator equal to 1 if the FDA sends the FOIA requested record to the requesting analyst, 0 if the analyst does not receive the requested record.
Analyst Characteristics	
<i>Analyst Experience</i>	Number of years the analyst has made recommendations from I/B/E/S.
<i>#Forecasts</i>	Number of the analyst's forecasts on the FOIA stock within one year before the FOIA request from I/B/E/S.
<i>#Stocks Covered</i>	Number of stocks covered by the analyst from I/B/E/S.
<i>Past Forecast Error</i>	The analyst's last one-year earnings forecast error for the previous fiscal year from I/B/E/S.
<i>Past Recommendation</i>	The last stock recommendation prior to the FOIA analyst's request. It is equal to 1 for Strong Buy, 2 for Buy, 3 for Hold, 4 for Underperform, and 5 for Sell from I/B/E/S.
<i>PhD/MD (MBA)</i>	Indicator equal to 1 if the analyst has a Ph.D./M.D. (M.B.A.) degree, and 0 otherwise, from LinkedIn and other websites.
<i>Star Analyst</i>	Indicator equal to 1 if the analyst is voted an all-American star analyst in the October issue of <i>Institutional Investor</i> magazine for the given year, and 0 otherwise.
<i>#Analysts at Brokerage Firm</i>	Number of analysts at the analyst's brokerage firm from I/B/E/S.
FOIA Characteristics	
<i>FOIA Industry Expertise</i>	Indicator equal to 1 if the analyst filed at least one FOIA request on uncovered stocks in the same industry, and 0 otherwise.
<i>Frequent FOIA Requester</i>	Indicator equal to 1 if the analyst filed at least three FOIA requests to the FDA, and 0 otherwise.
<i>Multiple FOIA Requests on Stock</i>	Indicator equal to 1 if there were more than one FOIA request on the same stock within a month of each other, and 0 otherwise.
<i>Prior 8K Filing</i>	Indicator equal to 1 if the FOIA request is preceded by a Form 8-K filing with some information about the FDA record, and 0 otherwise.
FDA Record Violations	
<i>Number of Violations</i>	Number of violations identified in the FDA record.
<i>Product</i>	Indicator equal to 1 if an FDA record mentions a substandard drug or medical device.
<i>Manufacturing</i>	Indicator equal to 1 if the FDA record refers to a defect in a factory's manufacturing process.
<i>Testing</i>	Indicator equal to 1 if the FDA record refers to the firm's failure to establish a mandated test to monitor its processes or products, or receives a criticism as to how a test is conducted.
<i>Documentation</i>	Indicator equal to 1 if the FDA record mentions a failure to adequately document its procedures or test results.
<i>Complaint</i>	Indicator equal to 1 if the FDA record refers to the existence of a current or previous consumer complaint as an example of a product violation.
<i>Lawsuit</i>	Indicator equal to 1 for a subsequent class action lawsuit in which the plaintiffs specifically accuse the firm of hiding adverse information from investors by not revealing the existence or contents of the Form 483 or warning letter.
Other Independent Variables	
<i>B/M</i>	Ratio of the book value of equity to the market value of equity from Compustat.
<i>Firm Size</i>	Natural logarithm of lagged market capitalization in \$millions from CRSP.
<i>Forecast Dispersion</i>	Standard deviation of the current two-year-ahead EPS forecasts from I/B/E/S.
<i>Institutional Ownership</i>	Proportion of shares held by institutional investors as reported by the Thomson Reuters Ownership Database.
<i>Momentum</i>	Firm's monthly equivalent buy-and-hold return in the past 12 months as reported from CRSP.
<i>#News Articles</i>	Number of daily newspaper articles on a given firm by Dow Jones Newswires as reported by RavenPack.

APPENDIX B
FDA Record Types

Factory Inspections

Establishment Inspection Report (EIR)	Upon completion of an inspection, an EIR is written that details inspection findings.
Form 483	A Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that may constitute violations of the Food, Drug, and Cosmetic (FD&C) Act and related Acts.

Post-Market Surveillance Databases

FDA Adverse Event Reporting System (FAERS)	FAERS is a database that contains information on adverse drug reactions (ADR) and medication error reports submitted to the FDA. It supports the FDA’s post-market safety surveillance program for all approved drugs and therapeutic biologics.
Medical Device Reporting (MDR)	MDR is the FDA’s post-market surveillance tool to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. Both mandatory and voluntary reports are included.
Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS)	CAERS are reports about adverse health events and product complaints related to CFSAN-regulated products, including conventional foods, dietary supplements, and cosmetics. Reports are mandatory and voluntary for dietary supplements, and are voluntary for all other products.
Vaccine Adverse Event Reporting System (VAERS)	The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. Reports are voluntary only.
Warning Letter (WL)	When the FDA finds that a manufacturer has significantly violated FDA regulations, it notifies the manufacturer in the form of a warning letter.
Approval Recommendation (REC)	Approval recommendations (REC) contain the FDA’s decisions on New Drug Applications (NDA) and Biologic License Applications (BLA). The NDA application is the vehicle through which drug sponsors formally propose to the FDA approval of the sale and marketing in the U.S. of a new drug. The BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce.
Other	Includes company responses to FDA reports, correspondence, meeting minutes, alert, safety review, and Notices of Inspection (Form 482).

APPENDIX C

Examples of Types of Disclosures in Warning Letters and Forms 483 (Factory Inspections)

1. Product Violation: Thoratec Corporation Warning Letter (January 3, 2012)

1. Failure to report to the FDA no later than 90 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1). Under the authority of 21 CFR Part 803.19(e), your firm was granted an exemption from the 30 calendar day reporting timeframe required by 21 CFR 803.50(a)(1) for events that your firm receives from the INTERMACS Registry. However, your firm did not submit an MDR to FDA within the 90 calendar day timeframe for the following:

Complaint 201 008-0145 indicates that your firm's device may have caused or contributed to the patient's death. Your firm became aware of this event on April 30, 2010, and the MDR was received by FDA on August 17, 2010, which is beyond the 90 calendar day timeframe.

2. Manufacturing Violation: Hospira Form 483 (January 4, 2012)

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

The design of the personnel entryway, personnel and material traffic flow, and gowning practices promotes the propagation of microbial contamination. The following was observed during the entirety of the inspection 11/28/11-1/4/12. This is applicable to all drug products, (b) (4) different pharmaceutical configurations.

Procedure MF0101.01 General Rules and Regulations: Aseptic Areas (effective Dec 16 2011) states "****The McPherson Aseptic Manufacturing areas are the most critical manufacturing locations in our site operations.****" Training Course Plan PRT0106 attachment 2 under Importance of Correct Gowning (bullet 2) states "****Protecting the product from particulate and microbial contamination.****" Dedicated plant clothing is intended to mitigate the ingress of dirt, debris and microorganisms into the cleaner areas of the plant. However, it was observed aseptic filling room personnel are allowed to frequent common public areas such as administrative offices, restrooms, and the cafeteria without being required to change out of dedicated plant scrubs and shoes which are then worn back into aseptic fill rooms under aseptic gowning. There is common interaction and comingling of personnel in street clothing and those performing manufacturing in the aseptic core.

Failure to mitigate the ingress of dirt, debris and microorganisms is exemplified by:

- men and women's locker rooms and personal area required to don factory attire and factory dedicated shoes prior to entering into the manufacturing areas is not delineated to avoid cross contamination of street clothing to factory clothing. Lockers where street clothing/shoes and plant shoes are kept are shared.
- There is no record or document which dictates factory shoes are cleaned/sanitized on a routine basis.
- Aseptic personnel are required to don factory attire and dedicated shoes used to reduce the ingress and presence of objectionable microorganisms yet employees can and do access the production staging warehouse, cafeteria, restrooms and office corridors which are uncontrolled environments.
- Aseptic personnel are required to don a disposable lab coat prior to entering the cafeteria in order to protect their plant uniform. However, they disposable coats can be reused up to 30 days.

3. Testing Violation: Form 483: Alparma Form 483 (September 27, 2001)

5. Failure to perform the preparatory test for the validation of the membrane filtration method used in microbial limits testing of the following products:

Epinephrine Mist;
Oxymetazoline HCl (12 hr Nasal spray);
Lindane 1% Shampoo; and,
Povidine Surgical Scrub.

4. Documentation Violation: Genzyme Form 483 (October 10, 2008)

4. A. Activities performed during drug substance manufacture are not adequately documented. For example:

- When performance of an activity is optional at a given time point (b) (4) there is frequently no place in the batch record to record whether the activity was performed.
- Dated and signed crossing-out of optional activities that are not performed is not used consistently in the batch record.
- Additional activities may be performed during manufacture of some commercial batches as part of a study. These activities are not always reflected in the batch record.
- Data are recorded in incorrect units.

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