Bad News Bear(er)s: FDA Inspection Outcomes and Managers' Voluntary Disclosure Choices

by

Andrea Kristine Down

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
(Business Administration)
in the University of Michigan
2020

Doctoral Committee:

Professor Gregory Miller, Chair
Associate Professor Jeffrey McCullough
Professor Amiyatosh Purnanandam
Associate Professor Christopher Williams
Associate Professor Gwen Yu

Andrea Kristine Down
akdown@umich.edu
ORCID iD: 0000-0003-3485-2239

Dedication

For Mom and Dad – thanks for always believing in me.

Acknowledgments

I am very grateful to the members of my dissertation committee for all of their time, feedback, and support. In particular, I thank my dissertation chair, Greg Miller, for his continuous guidance throughout this process and for teaching me how to be a better researcher. I thank Chris Williams for his unwavering mentorship and support since the beginning of my doctoral studies. I thank Gwen Yu for always challenging me to think deeply and write clearly. I also thank the other members of my dissertation committee, Amiyatosh Purnanandam and Jeff McCullough, for their constructive and thoughtful comments.

I thank the Accounting Ph.D. students and faculty who have helped me along this journey and have contributed to my development as a scholar. I thank Ruby Lee for her friendship, moral support, and advice. I thank FDAzilla for generously sharing their inspection data with me. I gratefully acknowledge financial support from the Stephen M. Ross School of Business, the Paton Fellowship, and the Deloitte Foundation Doctoral Fellowship.

Finally, I am forever grateful to my Mom, Dad, and brother, Kyle, for their endless support and encouragement.

All errors are my own.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

ABSTRACT

This study examines the association between bad news and managers' disclosure choices. It is empirically challenging to investigate this relationship because bad news resides in managers' private information sets, which are often unobservable and difficult to measure. To overcome this obstacle, I use a proprietary dataset that documents the dates and outcomes of FDA inspections. With the ability to detect the existence and content of news, I find that bad inspection outcomes are associated with a higher probability of disclosure and higher quantities of disclosure in the following three months. These results are stronger when inspection outcomes are more material or more severe. Further, the relation between bad news and disclosure disappears when the FDA begins publicly disclosing outcomes on a monthly basis. My timeliness tests suggest that managers accelerate, as opposed to delay, the disclosure of bad news. I also explore incentives that may influence managers' choices and provide direct evidence supporting the importance of litigation risk in managers' disclosure decisions; however, I do not find any evidence of managerial self-dealing. Collectively, these results document a significant link between private information and voluntary disclosure: managers disclose – rather than withhold – bad news, and litigation risk functions as a key motivating mechanism.

CHAPTER 1

Introduction

In this paper, I examine the relation between bad news and managers' voluntary disclosure choices. Theoretically, a manager's private information set is a key determinant of disclosure choice (Verrecchia [1983]). When investors are able to perfectly ascertain whether managers are endowed with value-relevant information, the negative inference that investors draw from silence forces rational managers to reveal their news and the market unravels into a full disclosure equilibrium (Grossman and Hart [1980]; Grossman [1981]). However, if there is uncertainty regarding managers' possession of private information, investors cannot disentangle whether non-disclosure is due to the lack of news or due to its adverse content (Dye [1985]; Jung and Kwon [1988]). In this case, investors' uncertainty weakens the adverse selection effect and a partial disclosure equilibrium emerges. When the unravelling result no longer occurs, managers can exercise discretion in deciding to disclose or withhold their private information. My study investigates this choice by examining *if* and *when* managers share their bad news with the capital markets.

Managers' private information set is often unobservable to the researcher and difficult to measure. Without the ability to directly identify the existence and content of managers' private information, it is empirically challenging to assess whether they are incentivized to disclose or withhold bad news. I overcome this obstacle by using a rich proprietary dataset that details the dates and outcomes of Food and Drug Administration ("FDA") inspections. Responsible for regulating a broad scope of firms, the FDA performs inspections to ensure that the manufacturing and processing firms under its authority comply with the relevant legislation. I define bad news as

inspectors' discovery and documentation of practices that deviate from the law. Such a result constitutes bad news because managers must address any noted violations, and it is often costly to remediate them. If satisfactory actions are not implemented in a timely manner, the FDA can impose significant penalties that could threaten the viability of the firm's operations. This regulatory environment represents a powerful setting in which to test the impact of private information on disclosure choice for three reasons. First, managers enjoy exclusive access to timely inspection results for the duration of my main sample period. A primary benefit of my data is that I can observe this piece of managers' private information sets, regardless of their ultimate disclosure choices. Second, managers have little control over the timing, staffing, length, or scope of inspections; therefore, they are generally less able in this setting than in other circumstances to influence the arrival of bad news or any other aspects of inspections that may be associated with disclosure choice. Third, the potential economic significance of these regulatory events suggests that managers factor inspection outcomes into their disclosure decisions.

When considering their disclosure choices, managers face various incentives that affect whether they disclose or withhold their bad news.[1] On one hand, managers may elect to disclose bad news to protect their reputation and credibility (Yang [2012]), avoid limitations on their future employment triggered by a misrepresentation of their firm's performance (Desai, Hogan, and Wilkins [2006]; Karpoff, Lee, and Martin [2008]; Hazarika, Karpoff, and Nahata [2012]), lower the exercise price on their stock options (Yermack [1997]; Aboody and Kasznik [2000]), demonstrate their skill in identifying and resolving economically important issues (Trueman [1986]), or mitigate legal exposure. Notably, prior literature suggests that litigation risk may motivate managers to promptly reveal adverse inspection outcomes to avoid shareholder lawsuits and minimize expected legal costs (Skinner [1994]; Kasznik and Lev [1995]; Skinner [1997]; Johnson, Kasznik, and Nelson [2001]; Baginski et al. [2002]; Cao and Narayanamoorthy [2011]).

[1]Prior literature connects a plethora of factors to disclosure choices. Examples of these determinants include: litigation risk (Skinner [1994]; Kasznik and Lev [1995]; Baginski, Hassell, and Kimbrough [2002]), firm performance (Miller [2002]), career concerns (Graham, Harvey, and Rajgopal [2005]; Kothari, Shu, and Wysocki [2009]; Baginski, Campbell, Hinson, and Koo [2018]), option strike prices (Yermack [1997]; Aboody and Kasznik [2000]), compensation (Nagar, Nanda, and Wysocki [2003]), and performance evaluation (Nagar [1999]). This is, of course, only a partial list.

On the other hand, career concerns and opportunities to self-deal may promote attempts to permanently bury bad news by delaying disclosure until events or circumstances force managers to publicly share their information (Kothari et al. [2009]; Baginski et al. [2018]; Bao, Kim, Mian, and Su [2019]). I conjecture that managers in the FDA inspection environment will disclose bad news.

Prior research broadly supports my hypothesis that managers will voluntarily reveal bad inspection outcomes. Using an analytical model, Kaplow and Shavell [1994] show that individuals self-report their own misconduct when they fear that more severe consequences could arise from silence and subsequent detection. Relatedly, Dye [2017] shows that sellers will disclose private information when the product of the probability that a fact finder will subsequently uncover any withheld information and the damages multiplier is sufficiently high. In an empirical setting, Solomon and Soltes [2019] examine managers' disclosure choices when they are under investigation for financial fraud. They find that even though managers face significant negative stock market reactions and possible turnover, managers still opt to disclose their bad news. Taken together, these findings suggest that – on average – managers may prefer to accept the costs associated with the voluntary revelation of bad inspection outcomes, rather than risk bearing the costs associated with non-disclosure.

If managers choose to withhold bad inspection outcomes, they could face significant legal and settlement costs. My prediction that managers will disclose bad news stems primarily from the presence of litigation risk in the FDA setting. Although inspection outcomes reside in managers' private information sets, there are channels through which this bad news can eventually leak. Prior research demonstrates that capital market participants incorporate this information – when it is available – into their investment decisions (Gargano, Rossi, and Wermers [2016]; Klein, Li, and Zhang [2017]). If managers try to hide decision-useful bad news and it is later released to the public, this series of events could trigger a lawsuit. There is anecdotal evidence that shareholders have sued managers for withholding inspection outcomes; therefore, the threat of litigation is not an idle one. I also predict that the clear presence of litigation risk will increase managers' propensity

to issue voluntary disclosure and will increase the magnitude of the relation between bad news and voluntary disclosure.

While the literature suggests that managers suppress bad news to attenuate career concerns and serve their own interests (Kothari et al. [2009]; Baginski et al. [2018]; Bao et al. [2019]), any gains accrued may be temporary and may not offset the severe penalties associated with concealing bad inspection outcomes in the long-term. By hiding bad inspection outcomes, managers risk damaging their reputation and credibility (Yang [2012]). Further, any obfuscation of their firm's performance could be perceived as a form of misconduct, and managers could bear substantial financial losses through forced turnover with restrictions on their future job prospects and a significant decline in the value of their holdings of the firm's stock, as well as other fines and penalties (Desai et al. [2006]; Karpoff et al. [2008]; Hazarika et al. [2012]). As a result, managers' personal interests could also align with forthcoming disclosure choices. Given that self-dealing managers may disclose or withhold bad inspection outcomes, I hypothesize – in null form – that this incentive will not affect managers' propensity to issue voluntary disclosure and will not affect the magnitude of the relation between bad news and voluntary disclosure.

To construct my sample, I obtain inspection data from the third-party FDAzilla platform. Since its inception in 2010, FDAzilla has built a comprehensive repository of inspection data by routinely submitting Freedom of Information Act ("FOIA") requests to the FDA. Once these requests are fulfilled, the company parses information from the requested records to offer customers access to data analytics, benchmarking tools, monitoring services, and inspection documents. This resource contains specific data on an array of inspection parameters such as the outcome, the names of the inspector(s), and the duration. FDAzilla serves a diverse range of users, such as FDA-regulated companies, law firms, consultants, and banks. In order to operationalize this data for my study, I use the FDA's Significantly Regulated Organizations ("SRO") list to identify publicly traded firms subject to FDA supervision. For each firm, I manually query and retrieve its inspection history from the FDAzilla database.

I begin my analysis by examining the link between inspection outcomes and managers' disclosure choices. My research design primarily relies on two dependent variables: am indicator variable that captures the disclosure decision, and a continuous measure that captures disclosure intensity. Controlling for a vector of time-varying firm characteristics that are known determinants of disclosure, as well as for firm, industry-year, and quarter fixed effects, I document the following main results from my multivariate tests. I find that bad inspection outcomes are associated with a higher probability of voluntary disclosure in the subsequent three months. I also show that bad inspection outcomes are correlated with higher levels of disclosure in the following three months. These results are economically significant: the incidence of a bad inspection increases the probability of disclosure by 18 to 20 percent of the sample mean and increases the quantity of disclosure by 34 to 36 percent of the sample mean. Together, my findings support my prediction that on average, managers disseminate their bad news.

Next, I posit that litigation risk is a key incentive that motivates managers to disclose bad inspection outcomes; therefore, I use cross-sectional analysis to directly test this conjecture. I hypothesize that if legal exposure induces managers to reveal their private information, then high litigation risk will increase managers' propensity to issue disclosure, and it will increase the magnitude of the association between bad news and voluntary disclosure. In line with this expectation, I find stronger results when litigation risk is high than when it is low. This suggests that litigation risk is an important consideration in managers' disclosure decisions.

I substantiate the internal validity of my main results by performing cross-sectional tests along dimensions of inspections that proxy for materiality and severity. I construct my materiality measure based on the FDA Center[2] in which the inspection occurs. I capture severity by counting the number of staff assigned to each inspection and calculating the duration of the inspection. I contend that the worst news will arise from highly material or highly severe inspections with bad outcomes. If managers are legitimately using these disclosures to convey their negative private information, then I expect to document stronger results in these cross-sections. Consistent with

[2]FDA Centers are product-level industry assignments. For example, a given firm may have two products, each belonging to a different FDA Center. Therefore, this is not a firm-level measure, but rather an inspection-level measure.

this prediction, I find that both materiality and severity increase the probability and quantity of disclosure following a bad inspection outcome.

In addition to considering *if* managers disclose their bad news, I also investigate *when* managers disseminate their private information about adverse inspection outcomes. Delaying disclosure may diminish its informational content and value for investors if the same information ends up aggregated with other firm performance news (e.g., forecasts, earnings announcements) or becomes stale. Furthermore, deferring disclosure increases the likelihood that capital market participants will make investment decisions that they otherwise would not make if they were aware of the inspection outcomes. As a result, incidence and timing are both central elements of managers' disclosure choice. Univariate tests reveal that on average, managers disclose bad inspection outcomes within 36 days, and clean inspection outcomes within 39 days. This three day difference is statistically significant. Although this may seem like a long disclosure delay, managers likely prioritize developing a plan to address the noted deficiencies and writing an adequate response letter to the FDA – which takes about three weeks – prior to disseminating this news to the capital markets. Results from my multivariate analysis also indicate that managers issue disclosure on a timelier basis when they experience a bad inspection outcome than when they experience a clean inspection outcome. Extending my litigation risk analysis, I also find managers issue more timely disclosure when they face high litigation risk, as compared to when they face low litigation risk. Combined, this evidence suggests that managers not only disclose bad inspection outcomes but do so in a timely manner.

To attribute managers' disclosure choices to the privacy of the bad news, I exploit the implementation of the Open Government Initiative ("OGI") as a regime shift. Prior to this initiative, inspection outcomes effectively resided in managers' private information sets. However, under the mandate of this program, the FDA began publicly disclosing outcomes on a monthly basis. Once inspection outcomes entered the public domain, investors could no longer file a lawsuit based on the claim that managers withheld this information; and as a result, they suffered financial losses. Analytically, Frenkel, Guttman, and Kremer [2018] predict that

managers decrease their provision of voluntary disclosure as external sources increase the supply of public information. Consistent with this prediction, I document a significant decline in disclosure following the execution of the OGI directives. Estimating litigation risk cross-sectional specifications with this post-period sample reveals that public disclosure reduces managers' legal exposure, which explains the decrease in disclosure.

Although managers on average disclose bad inspection outcomes, I explore whether there are any settings in which they may diverge from this practice and engage in self-dealing. Existing research suggests that managers' disclosure choices may be impacted by career concerns, weak governance structures, financing incentives, and opportunities to execute insider trades. Under all of these conditions, managers may be tempted to choose disclosure strategies that facilitate rent extraction. However, none of my tests provide evidence to suggest that managers are self-dealing. While I cannot completely rule out the possibility that misspecification or mismeasurement explains my inability to document systematic cross-sectional variation, my consistent lack of findings minimally suggests that self-dealing incentives are not strong in the FDA inspection environment.

I also perform a number of robustness tests to address potential endogeneity issues. First, I use an entropy-balanced sample to address the concern that an omitted correlated variable may drive both the inspection outcome and the manager's disclosure choice. With this quasi-matching approach, I continue to document qualitatively and quantitatively similar findings. Second, I estimate changes specifications and find that my results survive this more rigorous specification. Finally, given that I cannot rule out all plausible alternative explanations, I use Oster [2019]'s partial identification technique to formally assess the impact of unobservable factors on my main inferences. I show that a correlated omitted variable would need to have a greater impact on my coefficient of interest than that of my control variables and fixed effects combined to threaten the internal validity of my results. Collectively, these robustness tests provide additional support for my inferences and reinforce that the existence of such a significant correlated omitted variable is unlikely.

With this study, I make two primary contributions to the accounting literature. The main innovation in this paper is my ability to observe managers' private information. Prior studies either rely on implicit proxies to measure managers' private information or capture only the news that is eventually released to the public.[3] With my FDA inspection data, I observe the existence of bad news regardless of managers' disclosure choices. To further differentiate my study, I exploit variation in the inspection characteristics, as well as the privacy of the outcomes, to understand when these bad news disclosures occur. As a result, I directly examine the association between bad news and voluntary disclosure, and I explore the strength of this relationship in a variety of settings.

Second, I contribute to the literature examining the link between managerial incentives and disclosure choice. Existing research suggests that litigation risk encourages managers to disclose bad news (Skinner [1994]), whereas career concerns tempt managers to withhold adverse information (Kothari et al. [2009]). Equipped with a more precise measure of bad news, I contribute to this debate by explicitly testing the influence of these incentives. Without observing both disclosed and undisclosed private information, it is difficult to truly understand the incentives that affect managers' decisions. I provide direct evidence that litigation risk increases managers' propensity to issue disclosure and increases the magnitude of the relationship between bad news and voluntary disclosure. Conversely, I fail to document evidence of managerial self-dealing. These findings validate the importance of litigation risk in managers' disclosure choices.

The remainder of the paper is organized as follows: Chapter 2 describes the institutional context and develops my hypotheses, Chapter 3 describes my sample selection procedure and highlights key descriptive statistics, Chapter 4 outlines my research design and reports on the results of my empirical analyses, and Chapter 5 concludes.

[3]Two exceptions include Solomon and Soltes [2019] and Blackburne, Kepler, Quinn, and Taylor [Forthcoming]. In their concurrent working paper, Solomon and Soltes [2019] use a dataset that includes all SEC financial fraud investigations, regardless of managers' disclosure choice and regardless of whether they led to subsequent public enforcement actions. They are interested in the consequences of bad news disclosure, whereas my study focuses on managers' choice to disclose bad news and whether that choice differs in a variety of cross-sections. Blackburne et al. [Forthcoming] obtain data on all SEC investigations and examine whether managers trade on their inside information for personal gain.

CHAPTER 2

Conceptual Framework and Related Literature

2.1 Institutional Background

The FDA's regulatory authority spans numerous different types of organizations, as it is responsible for enforcing the Food and Drugs Act of 1906, as well as subsequent laws and amendments. Accordingly, its jurisdiction is extensive: this government agency regulates food, drugs, biologics, medical devices, electronic devices that emit radiation, cosmetics, veterinary products, and tobacco products. Estimates suggest that it oversees $1 trillion of product each year (Food and Drug Administration [2018a]).

One branch of this Agency – the Office of Regulatory Affairs ("ORA") – is responsible for inspecting manufacturers and processors of FDA-regulated products to verify that these organizations are in compliance with the applicable regulations. Within the FDA's organizational structure,[4] this unit operates independently; therefore, the inspections are less affected by firm-level factors (e.g., pending approvals) that may also be associated with disclosure incentives. For example, an ORA office may inspect a drug company, but the Center for Drug Evaluation and Research assesses the safety and effectiveness of its new products and ultimately decides whether the drug will receive approval for sale.

There are four primary types of inspections: (1) pre-approval, (2) routine, (3) compliance follow-up, and (4) for-cause (Akin Gump Strauss Hauer & Feld LLP [2017]; Food and Administration [2018]). Pre-approval inspections verify the data provided in the firms' application to market a new product and confirm that the firm is adequately equipped to

[4] Appendix B presents the FDA's organizational structure.

manufacture the product. Occurring at varying frequencies, routine inspections could examine any aspect of the firm under the purview of the FDA's regulatory mandate.[5] Compliance follow-up inspections allow FDA personnel to review remedial actions taken by the firm to address severe problems previously noted by the FDA. Finally, a for-cause inspection investigates a report submitted to the FDA and focuses on a specific issue; however, the scope of the investigation can expand if other problems are detected.

An FDA inspection differs from a financial statement audit in that firms cannot influence who performs the inspection, what is within its scope, when it occurs, or how long it lasts. In addition, the FDA is not directly engaged by firms, so its personnel function under different incentives when conducting and reporting on the inspections (Duflo, Greenstone, Pande, and Ryan [2013a,b]). Firms may or may not receive advance notice of an imminent inspection. The Agency allocates resources according to its own risk-assessment methodology[6] and the inspections are conducted in accordance with the relevant procedural manual. During the inspection, the FDA personnel note any observations (i.e., violations of legislation) on a Form 483. Issues are listed in order of significance. Once the inspection is complete, the FDA representative(s) meet with management to discuss the findings. Appendix C provides an example of an actual Form 483, and Appendix D lists a sample of observations documented by FDA personnel during these inspections.

If a firm receives a Form 483, managers have 15 days to write a response to the FDA (Chen [2018a]). In this letter, managers are expected to outline corrective measures and the implementation timeline. These issues can be costly to rectify. Often, internal teams are

[5]During the time period covered by this paper, legislation mandated the frequency of inspections for certain types of high-risk establishments, such as those in the fields of drugs and biologics. These firms were subject to most stringent incidence of inspection, as they were required to be inspected once every two years. In the past, budgetary and resource constraints prevented the FDA from meeting this legal obligation (Government Accountability Office [2009]). FDA representatives indicate that the estimated inspection frequency is much lower for establishment types that do not have stipulated time frames for inspection frequency. For fiscal year 2016, the FDA reported that approximately 278,000 establishments were covered under its regulations (Food and Drug Administration [2017a]), but only approximately 40,000 inspections were performed. Considering that some firms must be audited more regularly, this statistic implies that some firms may experience a low inspection rate.

[6]There is an element of judgment involved in assessing which firms should be inspected. Not all firms are subject to mandatory inspection frequencies. Further, even when inspection rates are required by law, the FDA faces capacity constraints, which force it to select strategically as a means to maximize its regulatory impact (Macher, Mayo, and Nickerson [2011], Duflo, Greenstone, Pande, and Ryan [2018]).

assembled to address the deficiencies. This carries a significant opportunity cost, as the team members' attention is diverted away from routine activities to the actions necessary to resolve the documented problems. The firm may also hire expensive external consultants if it requires specific expertise. Furthermore, numerous hours may be devoted to remediation, training, process redesign, process implementation, and meetings (Chen [2018b]). All of these costs are incremental to any form of capital expenditures required to successfully execute the managers' action plan. Accordingly, receipt of a Form 483 constitutes bad news for a firm.

On January 21, 2009, the federal government announced the Open Government Initiative, which required "direct executive departments and agencies to take specific actions to implement the principles of transparency, participation, and collaboration" (Orszag [2009]). Under this directive, the FDA launched its Transparency Initiative in June 2009 and formed a Task Force with an objective "to improve the public's understanding of how the FDA works to protect the public health, provide the public with a rationale for the Agency's enforcement actions, and to help inform public and industry decision-making allowing them to make more informed marketplace choices and help to encourage compliance" (Food and Drug Administration [2018c]). The Task Force solicited public feedback, developed plans, and implemented the final recommendations in phases Food and Drug Administration [2017b]. In Phase I, an online resource was created to offer the public basic information about the FDA. Phase II focused on disclosing information about FDA-regulated firms and products, while still protecting confidentiality. The third and final phase aimed to improve the efficiency and cost-effectiveness of the FDA's regulatory process.

As a key component of Phase II, on May 26, 2011, the FDA began publicly disclosing inspection outcomes on a monthly basis Food and Drug Administration [2011]. This information is electronically available on the Agency's website in a machine-readable format. Among other outcomes, it significantly increased outside stakeholders' ability to easily access detailed information on firms subject to FDA regulation (Food and Drug Administration [2018c]). As a result, on average, managers can keep inspection outcomes private for no longer than one month

(i.e., they can suppress this information only from the inspection date to the monthly publication date). I include truncated examples of the FDA disclosures in Appendix E[7]

Before this program, outside stakeholders could obtain inspection information by submitting requests to the FDA under FOIA; however, this process did not facilitate a timely flow of information from the FDA to the capital markets. Requestors often faced significant delays: reported wait times for these documents have been up to two years (Chen [2018c]). For example, the December 2018 Closed FOIA Log, which lists all of the requests fulfilled in that month, indicates that personnel only recently completed requests from 2012, 2013, and 2014, along with other more recent ones. Other Closed FOIA Logs from this time period reveal that such time lags are not unusual. Records that have been previously released under FOIA may have quicker processing times. Under the Electronic Freedom of Information Act Amendments of 1996, once a document has been requested multiple times (i.e., approximately three times), it should be posted online via the e-Reading Room. Still, there is no specific time frame within which this public disclosure must occur, so the timeliness of publication could vary with Agency capacity. To further complicate the acquisition of this information, requestors could not determine if or when a given firm was inspected. In response, these external stakeholders could submit large, blanket requests; however, these are more time consuming for the FOIA personnel to fulfill. Alternatively, requestors could be more specific and ask for a narrower range of documents, but if inspections had not occurred, this approach would not yield any new information.

[7]This document illustrates the FDA's disclosure of inspection outcomes, which are listed in the last column of the table. No Action Indicated (NAI) inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further actions (Food and Drug Administration [2020a]). Voluntary Action Indicated (VAI) means that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend further regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that the firm address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" (Food and Drug Administration [2020b]). Official Action Indicated (OAI) inspection classification occurs when significant objectionable conditions or practices were found and regulatory action is warranted to address the establishment's lack of compliance with statute(s) or regulation(s) (Food and Drug Administration [2020a]). Each month, the FDA posts an updated version of this document on its website for public consumption.

Event study analysis suggests that on average, investors are unable to promptly procure and impound the information into stock prices. From January 2000 to January 2009, cumulative abnormal returns in the 3 or 5 day window surrounding the inspection date are positive for both clean and bad outcomes, with the difference being statistically insignificant. Conversely, in the public disclosure regime from May 2011 to December 2016, the market exhibits a negative (positive) reaction in the last five days of the month in which a bad (clean) inspection occurs.[8] The difference between the cumulative abnormal returns for clean and bad inspections is statistically significant. This post-period result validates the economic significance of these inspections and demonstrates the reaction that occurs when the capital market participants are able to acquire and use this information in their investment decisions. The lack of a statistically different response to clean and bad inspection outcomes in the pre-period, along with all of the other evidence, suggests that inspection outcomes effectively resided in managers' private information sets prior to the implementation of the OGI.

Regardless of the time period, if firms do not adequately address these issues, or the problems pose a significant risk to the public – such that immediate attention and escalation are warranted – the FDA may issue a warning letter. A warning letter is issued publicly on the FDA's website and indicates that a higher-level official believes that the deviations from law are significant (Lehmann [2013]). This letter is used as an instrument to more strongly urge firms to address deficiencies in their operations. In recent years, this correspondence has been released within 10 to 11 months of the problematic inspection (Unger [2018]). Firms that are subject to this public reprimand will suffer significant costs, such as damage to their reputations, delays in drug approvals, increased marketing efforts by competitors to exploit this opportunity to steal customers, and an overall loss of business (Chen [2018b]). Receipt of this letter can be interpreted as a final warning before enforcement actions are imposed (e.g., fines, injunctions, recalls, seizures, criminal prosecution).

[8]The FDA does not post inspection outcomes on the same day every month. As a result, I use the last five days of the month to approximate the period in which the market would learn of that month's outcomes and capture its reaction.

2.2 Development of Hypotheses

Analytical models predict that the market will deviate from a full disclosure equilibrium (Grossman and Hart [1980]; Grossman [1981]) when there is uncertainty surrounding the existence of managers' private information (Dye [1985]; Jung and Kwon [1988]). If rational investors recognize that managers possess value-relevant information, they equate silence with the worst possible news. To avoid this discount, managers fully disclose their information. However, if investors are uncertain as to whether managers are endowed with private information, the unravelling result ceases to exist. The market reaches a partial disclosure equilibrium because investors cannot determine whether non-disclosures are due to bad news or the absence of news. Consequently, adverse selection subsides along with the non-disclosure penalty. This provides managers with the choice to disclose or withhold their private information.

The intuition from these models directly applies to the FDA environment: investors are generally unable to determine whether a firm has recently undergone an inspection, so managers have the option to reveal or conceal bad outcomes. In making this decision, managers become susceptible to incentives that could support either disclosure choice. Prior research provides mixed evidence. One collection of studies finds that managers disclose their bad news in a timely manner, while another series of papers shows that managers delay disclosure of bad news, and attempt to permanently hide it. This ongoing debate suggests that managers' decisions may be contextual. Because of the institutional attributes of the FDA setting, I predict that managers will disclose rather than withhold bad inspection outcomes.

Within this environment, a number of incentives could motivate managers to disclose their adverse private information. In the voluntary disclosure literature, litigation risk is a prominent explanation (Skinner [1994]): managers reveal bad inspection outcomes to eliminate shareholders' ability to initiate a lawsuit on the grounds that this information was withheld. However, this is not the only reason managers may voluntarily communicate bad inspection outcomes. Trueman [1986] suggests that managers may issue voluntary disclosure to exhibit their ability. Through

these communications, managers can demonstrate competence by recognizing the importance of inspection outcomes and adjusting the firm's plans to swiftly remedy the violations. In addition, the markets may perceive managers who voluntarily disclose bad news as honest and credible individuals. To avoid tarnishing their reputation and maintain investor trust, managers may pursue more transparent disclosure choices (Yang [2012]). The literature suggests that the costs associated with the revelation of misconduct are significant. If managers attempt to suppress bad inspection outcomes and are subsequently exposed, they could face forced turnover (Desai et al. [2006]; Hazarika et al. [2012]) and substantial financial losses through limitations on their future job prospects, their shareholdings in the firm, and other fines and penalties (Karpoff et al. [2008]).

All of these potential costs fit into Kaplow and Shavell [1994]'s model of voluntary disclosure. They use a probabilistic model to examine self-reporting behavior. Without altering incentives to commit wrongful acts, they theoretically show that individuals can be induced to report their misbehavior if they are sufficiently concerned about more severe consequences that could emerge if they do not confess and are subsequently exposed. Similarly, Dye [2017] builds a model in which a seller of an asset is liable for damage payments if a fact finder subsequently discovers that information was withheld prior to the sale. He shows when the product of the probability that the fact finder successfully uncovers withheld information and the damages multiplier is sufficiently high, the seller is deterred from ever not disclosing his information. From an empirical perspective, Solomon and Soltes [2019] find that managers disclose the launch of SEC financial fraud investigations, despite the resulting negative stock market returns and weakened career prospects. Enache, Li, and Riedl [2018] also provide preliminary evidence that incentives to disclose bad news exist within the biotech industry. Using observable 10-K filings (i.e., publicly available information) to construct their dependent and independent variables of interest, they find that product disclosures are increasing in bad news. Thus, given that any of the above costs could be imposed on managers who operate in FDA-regulated industries if they withhold bad inspection outcomes, I offer the following hypotheses:

Hypothesis 1A: *Bad news is positively associated with the probability of voluntary disclosure.*

Hypothesis 1B: *Bad news is positively related to the quantity of voluntary disclosure.*

More specifically, litigation risk is noticeably present in the FDA environment. At the conclusion of inspections, FDA personnel communicate outcomes only to the managers; therefore, knowledge of a Form 483 issuance sits in managers' private information sets. However, there are a number of outlets through which this information could leak: (1) an investor could successfully submit a FOIA request and receive a firm's inspection history; (2) if the firm does not adequately rectify deficiencies noted during the inspection, the FDA could issue a public warning letter; (3) business deals may disintegrate because counterparties do not want to assume the operational risk and then firms may have to explain why the transaction collapsed; (4) the Agency can ultimately deny future approvals and cite inspection concerns as the basis for rejection; and (5) the problem could be so severe and pervasive that someone from within the firm communicates the news to the public. Existing research finds that when capital market participants have access to inspection information, they factor it into their decisions.[9] Furthermore, the press has also highlighted instances of trading following the discovery of inspection outcomes: investment firms have significantly increased their ownership in firms with clean inspection histories, and they have also sold their stakes in companies with substantial

[9]Both of these papers obtain logs of FOIA requests submitted to the FDA by external parties. Descriptive statistics indicate that institutional investors prepared 692 requests, while IBES analysts made 528 requests. Although the FDA fulfilled these requests, I argue that inspections outcomes, on average, reside in managers' private information sets for two main reasons. First, any acquired information likely pertains to only a small subset of inspections. Compared to the number of inspections included in my sample, the number of requests submitted by investors and analysts is relatively small. In addition, the content of the requests likely overlap: some firms will attract more attention due to previous issues such as publicly issued warning letters. Second, it is highly unlikely that there is a short time horizon between the inspection completion date and investors'/analysts' receipt of outcome information. External parties do not know when the FDA will inspect a given firm; therefore, they cannot knowingly submit a request for outcome information immediately after the inspection is complete. Furthermore, they will likely have to wait to receive to receive information from the FDA. As a result, only managers would be aware of inspection outcomes in the window of time immediately surrounding the inspection date.

deficiencies.[10] Rule 10b-5 of the Securities Exchange Act of 1934 aims to protect investors by prohibiting managers from omitting or misrepresenting material facts, such as bad inspection outcomes. Thus, if managers opt to withhold bad inspection outcomes, they could be exposing themselves to litigation risk because investors may be able to claim that share prices were inflated due to withheld information.

When Rule 10b-5 applies to private information, theoretical research predicts that the probability of disclosure increases with the expected litigation costs (Hughes and Sankar [1997]; Trueman [1997]; Dye [2013]). As exemplified by the two Securities Class Action Clearinghouse Case Summaries included in Appendix F, managers have faced shareholder lawsuits after attempting to suppress bad inspection outcomes. These anecdotes address both elements of expected cost: managers should assign a non-trivial probability to a future class-action lawsuit if they elect to remain silent, and any ensuing litigation will result in material costs. Dendreon's $40 million settlement represented 39 percent of its fiscal 2007 operating expenses and the $4.5 million proposed settlement represented 19 percent of Gliatech's fiscal 2000 revenue. Building on this notion, Marinovic and Varas [2016]'s model indicates that when litigation risk is present, managers accelerate the announcement of bad news to minimize legal exposure. Under these circumstances, bad news crowds out good news because the market expects managers to disclose bad news and interprets no news as good news. Consistent with this analytical framework, empirical studies document higher levels of disclosure in litigious environments (Johnson et al. [2001]; Baginski et al. [2002]; Cao and Narayanamoorthy [2011]). In addition, managers may disseminate bad inspection outcomes to deter certain types of litigation (Field, Lowry, and Shu

[10]For example, in early 2012, Millennium discovered that no significant issues were uncovered during an inspection of Regeneron; therefore, it "tripled its ownership in Regeneron to 31,800 shares by March 31, 2012... [and] Regeneron's stock doubled during the first quarter of 2012 to $116.62" (Mullins and Weaver [2013]). Under an opposite set of circumstances, during Genzyme Corp's inspection, officials found problems at the company's primary plant, where it produced a top-selling drug. SAC Capital Advisors acquired this information and reduced its stake from 221,000 shares to 127,000 shares within the quarter; as a result, Genzyme Corp's shares declined 16 percent over a six month period (Mullins and Weaver [2013]). Further, a $4.3 billion buy-out deal collapsed when Fresensius discovered that Akron had failed to meet the FDA's data integrity requirements, which indicated the presence of serious internal control deficits (Feeley, Dolmetsch, and Fineman [2018]).

[2005]) and reduce settlement costs (Skinner [1997]). Basing my predictions on the clear manifestation of litigation risk in this setting, I make the following hypotheses:

Hypothesis 2A: *Litigation risk increases managers' propensity to issue voluntary disclosure.*

Hypothesis 2B: *Litigation risk increases the magnitude of the relation between bad news and the quantity of voluntary disclosure issued.*

Conversely, traditional disclosure theory suggests that managers with sufficiently bad news may attempt to pool with managers who lack news (Dye [1985]; Jung and Kwon [1988]). Extrapolating implications from these models to the FDA setting, I conjecture that managers may encounter a bad inspection outcome and withhold this bad news while they attempt to fix the problems. They may operate under the assumption that they will be able to remediate deficiencies and avoid any further consequences. Baginski et al. [2018] document that managers with career concerns are particularly inclined to adopt this approach. Without any form of disclosure, uninformed investors will assume that the firm did not encounter an inspection (i.e., managers are also uninformed in this regard). Given the market's asymmetric reaction to bad news (Hutton, Miller, and Skinner [2003]; Rogers and Stocken [2005]; Ng, Tuna, and Verdi [2013]), managers' silence may extend until they are uncertain that circumstances will not improve in an attempt to evade stock price declines (Kothari et al. [2009]). If they never reach this juncture, they may be able to permanently suppress the bad news and preserve their self-interests. However, this strategy may fail if the FDA ultimately deems their efforts insufficient and issues a warning letter, or if managers suspect that another party may gain access to their adverse inspection result and publicly expose them.

To protect their personal interests, managers may hesitate to draw attention to bad inspection outcomes. Existing literature finds that the quantity and quality of disclosure tends to be higher during periods of strong firm performance than during periods of weak firm performance (Lang and Lundholm [1993]; Miller [2002]). Managers also prefer to focus on positive notes. Schrand and Walther [2000] find that managers strategically select the lowest permissible prior-period earnings benchmark in order to report an upward trend in their current-period earnings

announcement. Similarly, Miller [2002] shows that after extended periods of consistent earnings increases, managers continue to disclose at elevated levels; however, they shift their focus to positive short-term performance and do not highlight imminent earnings decreases. Taken together, this evidence suggests that managers may be reluctant to disclose bad inspection outcomes because disclosure may cast their firms in a negative light and detract from other positive events or achievements.

In spite of these arguments, a self-dealing strategy could still lead to disclosure of bad inspection outcomes. Prior literature argues that withholding bad news allows managers to shield themselves from the immediate consequences arising from the market's reaction to this adverse event. While they may be able to realize temporary gains (e.g., retain their job and/or maintain high levels of compensation), their long-term reputation and career prospects could be harmed by this approach if they are subsequently exposed (Desai et al. [2006]; Karpoff et al. [2008]; Hazarika et al. [2012]). Therefore, managers could still serve their own best interests by disseminating bad news. As a result, I state the following hypotheses in null form:

Hypothesis 3A: *Self-dealing incentives do not affect managers' propensity to issue voluntary disclosure.*

Hypothesis 3B: *Self-dealing incentives do not affect the magnitude of the relation between bad news and the quantity of voluntary disclosure issued.*

CHAPTER 3

Sample, Data, and Descriptive Statistics

3.1 Sample Selection and Data Sources

I begin construction of my sample by obtaining the FDA's SRO list. Firms are included on this list if they meet either of the following criteria: (1) sales of products regulated by the FDA constitute 10 percent or more of annual gross sales in the organization's previous fiscal year, or (2) an organization that does not have a record of sales of FDA-regulated products has operations that are predominately in fields regulated by FDA, or its research, development, or other business activities are reasonably expected to result in the development of products that are regulated by the FDA (Food and Drug Administration [2018]).

Using ticker symbols and company names, I hand-match firms on this list to Compustat for financial statement data, CRSP for stock data, IBES for analyst following and forecast data, EDGAR for 8-K filing data, and Ravenpack for press release data. For each firm present in either the EDGAR or Ravenpack database, I manually search the FDAzilla repository to obtain information on FDA inspections. This library represents a comprehensive collection of FDA inspection data, and it is used by a wide range of stakeholders including Fortune 500 companies, law firms, insurance companies, banks, and consultants. The information compiled to create this database was requested through FOIA and contains richer content than the FDA posts on its website for public consumption. Table 1, Panel A documents my sample selection procedure. Hand-matching and manual searching allow me to minimize the number of Type 1 errors (i.e., incorrectly indicating that an inspection occurred) in my sample.

While extracting inspection data from the FDAzilla archive, I also consult firms' 10-K filings, specifically Exhibit 21, to identify the names of major subsidiaries and minimize the probability of Type 2 errors (i.e., incorrectly indicating that an inspection did not occur). This step helps to ensure that I attribute inspections to the correct parent firm. If the FDAzilla search engine does not yield any results when I input a given firm name, I assume that this firm did not receive a visit from the FDA authorities. This assumption could be erroneous if the inspection archive is incomplete or I am unable to properly tie firms from the SRO list to the FDAzilla database. The former is unlikely because the purpose of the company is to gather inspection data and providing notably inadequate materials would be undermine its core business model.[11] The latter is possible, but I perform several checks to maximize the completeness of my sample. For example, if the firm did not appear in the database, I attempt to identify the key stem of the name to factor in the possibility that the name was truncated. I also conduct an internet search to ensure that the firm name recorded on the list corresponds to the company's operating name as logged on other corporate documents. Any remaining exclusions represent random errors that would not systematically threaten the validity of my inferences. To my knowledge, there are no correlated omitted variables that would drive both sample inclusion and disclosure choices.

I restrict my sample to a set of observations in which an inspection occurs. Although managers have little control over inspections, the FDA is resource-constrained and thus must optimally select firms to inspect in order to maximize its ability to protect public health. By imposing this restriction, I am able to mitigate endogeneity concerns arising from the FDA's selection of inspection targets. Specifically, my results cannot be explained by an omitted variable that explains both inspection and disclosure choices.

My primary sample includes firm-inspection observations from January 2004 to January 2009. Population of the FDAzilla database begin in 2000; however, Ravenpack coverage did not begin until 2004. As a result, this latter date dictates the start of my primary sample period. My sample period ends in January 2009, as this was when the government introduced the OGI. Although

[11]For example, this library includes both public and private firms; therefore, size would not explain both missing inspection information and disclosure choices.

public disclosure of inspection outcomes was not implemented until May 2011, the FDA publicly acknowledged its commitment to complying with the OGI mandate by widely disseminating its action plan. Throughout its phased approach to becoming more transparent, the FDA heightened awareness about its purpose, operations, and broad range of activities, including inspections. These changes in the regulatory information environment could elicit different disclosure responses from managers when they face a bad inspection outcome. Furthermore, in 2010, FDAzilla was created to "to make government data accessible, usable, and valuable to everyone who needs it" (FDAzilla [2020]) and ultimately made it easier for capital market participants to acquire inspection information. Accordingly, I exclude the transitional period – starting in January 2009 and ending in May 2011 – from my analysis. This decision allows me to isolate a clean sample of inspection observations in which outcomes are private and managers on average, do not expect them to become public information.

To provide additional sample characteristics, I outline inspections by year in Table 1, Panel B and inspections by FDA Center in Table 1, Panel C. Based on this table, inspections generally increase over time and occur most frequently in the Food & Cosmetics and Human Drug Centers.

3.2 Descriptive Statistics

Table 2 reports descriptive statistics for the key variables used in my analyses. All variable definitions are outlined in Appendix A. To proxy for bad news, I use the *Bad Inspection* variable, which is coded as one if the firm receives a Form 483, and zero otherwise. Form 483s are issued in one third of sample inspections. *Disclose_i* is an indicator variable that captures whether a firm files an 8-K or issues a press release in the three months following the end of an inspection. To be included in this measure, a filing must reference both the FDA and inspections, while a press release must cover an FDA inspection-related topic, as tagged by Ravenpack. For 22 percent of inspections, managers issue at least one of these disclosures within three months. *Disclose_n* counts the number of FDA inspection-specific 8-Ks and press releases issued by managers within three months of inspection end date. Conditional on the choice to disclose, the median firm issues one disclosure in the three months subsequent to the completion of an inspection, but 39 percent issue more than one disclosure. A firm may issue more than one disclosure to update investors on its progress with respect to correcting the deficiencies. For example, if fixing the problem was more costly than originally anticipated or changes were made to the action plan to satisfy the FDA, further disclosure my be warranted.

In terms of financial characteristics, the median firm in my sample is profitable, with a median return on assets of 2 percent. Losses occur in 9 percent of the observations. Unwinding the logarithmic transformation reveals that the market capitalization of the median firm is $9.4 billion. Firms in my sample also realize an average book-to-market ratio of 3.82. In the three month window following the conclusion of an inspection, managers also issue below consensus forecasts 26 percent of the time.

CHAPTER 4

Empirical Methodology and Results

4.1 Bad News and Disclosure Choice

4.1.1 Main Specification

To test my prediction that there will be a positive association between bad news and voluntary disclosure, I estimate the following specification:

$$Disclose \quad = \quad \beta_1 Bad\ Inspection\ +\ \sum \beta_k Controls_k\ +\ \lambda\ +\ \gamma\ +\ \theta\ +\ \varepsilon \qquad (1)$$

Disclose takes one of two possible values: (1) *Disclose_i*, which is an indicator variable equal to one if the firm files an 8-K or issues a press release within three months of the inspection end date, or (2) *Disclose_n*, which counts the number of 8-Ks and press releases issued in the three months following the completion of the inspection. To be counted in these measures, the 8-Ks must reference terms, such as FDA and inspection; and, the press releases must cover FDA inspection-related topics. Appendix A provides variable definitions and the specific disclosure inclusion criteria. To compile this list, I scanned Ravenpack's event taxonomy and selected the topics that relate to FDA inspections. Appendix G illustrates several examples of disclosures issued by firms in response to a bad inspection outcome. *Bad Inspection* signals the issuance of a Form 483 and the existence of bad news.

I include a vector of controls including several known determinants of management forecasts. Consistent with prior literature (Miller [2002]; Chen, Matsumoto, and Rajgopal [2011]; Rogers

and Van Buskirk [2013]), I control for market-to-book ratio, firm size, operating performance, profitability, analyst following, returns, stock volatility, and other bad news. All control variables are calculated using financial information from the fiscal quarter prior to the inspection. I also employ a rigorous fixed effects structure, which includes firm (λ), industry-year (γ), and quarter (θ) fixed effects. Standard errors are clustered at the firm level.

Table 3 reports my results on the relationship between inspection outcomes and managers' disclosure choices. Across all specifications, I document significantly positive coefficients on *Bad Inspection*. Specifically, the coefficients of interest from odd-numbered columns indicate that there is a positive relationship between bad inspection outcomes and the probability of disclosure in the subsequent three months. Results from even-numbered columns suggest that bad inspection outcomes are associated with higher levels of disclosure in the three months that follow the end of an inspection. In addition to being statistically significant, these findings are economically significant: the coefficient of 0.0396 on *Bad Inspection* in Column (5) represents 18 percent of the *Disclose_i* mean, and the coefficient of 0.121 on *Bad Inspection* in Column (6) is equal to 34 percent of the *Disclose_n* mean.

Following Hainmueller [2012] and McMullin and Schonberger [2020], I also estimate my specifications with an entropy-balanced sample. This quasi-matching approach allows me to achieve covariate balance by applying a weight to each individual observation such that the distributional properties (i.e., mean and standard deviation) of bad inspection observations match those of clean inspection observations. This approach helps to attenuate concerns related to an omitted correlated variable driving both the incidence of an bad inspection and managers' disclosure choice. Columns (7) and (8) of Table 3 report the results. The coefficient on *Bad Inspection* continues to be significantly positive in both specifications. These results are also economically significant: the coefficient of 0.0431 on *Bad Inspection* in Column (7) represents 20 percent of the *Disclose_i* mean, and the coefficient of 0.121 on *Bad Inspection* in Column (6) is equal to 36 percent of the *Disclose_n* mean. Taken together, these findings are consistent with my

prediction and imply that managers disseminate their private information, even when it is unfavorable.

4.2 Litigation Risk Analysis

In this section, I explore the circumstances under which managers reveal unfavorable prviate information. I use a cross-sectional research design to directly test whether litigation risk motivates managers to disclose their bad news. If this is the case, then I expect that my results will support my second hypothesis: high litigation risk will increase managers' propensity to issue disclosure and increase the magnitude of the relationship between bad news and the quantity of disclosure issued.

I perform this test with two measures of securities litigation risk. First, I construct an industry-based proxy, based on membership in biotechnology, computers, electronics, and retail industries, as described in Francis, Philbrick, and Schipper [1994]. If a firm operates in one of these industries, I place its observations in the high-litigation risk subsample. All other observations are assigned to the low-litigation risk subsample. Second, I compute the ex-ante likelihood that a firm will face 10b-5 litigation. To create this measure, I follow Kim and Skinner [2012] and estimate a logit regression in which the dependent variable is an indicator variable equal to one if the firm is sued in a given quarter, and the independent variables include an array of firm characteristics such as industry membership, firm size, recent performance, share price volatility, return skewness and share turnover from the prior quarter.[12] I use the estimates from this model to calculate the predicted probability of litigation in the next quarter. If the predicted value for a given firm-quarter is higher (lower) than the model median, I classify the corresponding observation as high (low) risk.

Results from these analyses are recorded in Table 4. In Panel A, I use the Francis et al. [1994] industry-membership proxy for litigation risk; and in Panel B, I operationalize Kim and Skinner [2012]'s measure of ex-ante litigation risk. Across all specifications, I find that the *Bad*

[12] Specifically, I employ equation (3) from Kim and Skinner [2012].

Inspection coefficient is only significant in the high litigation risk partitions. Furthermore, all high risk coefficients are significantly larger than the low risk coefficients.[13]

Overall, this evidence suggests that litigation risk is an important factor in managers' decisions to voluntarily disclose bad news. In some instances, managers are incentivized to disclose bad inspection outcomes only when the litigation risk is sufficiently high. In other cases, some disclosure may still occur in low-litigation risk settings, but the amount and likelihood of disclosure is much higher when the litigation risk is also higher.[14]

[13]To test the difference in *BAD_INSPECTION* coefficients across two specifications, I follow Shroff, Verdi, and Yu [2014] and Barth, Landsman, Lang, and Williams [2012] by using a permutation test. I randomly assign cross-sectional classifications (e.g., high versus low, pre versus post, yes versus no, strat versus no strat) and estimate Equation 1 with the pseudo splits. Then, I calculate the difference between the *BAD_INSPECTION* coefficients from the two subgroups. I repeat this procedure 1,000 times to generate a null distribution, which I use to test the significance of the difference in coefficients that I report in Tables 4, 5, 6, 7, 8, 9, 10, 11, and 12.

[14]In untabulated univariate analyses, I find that not all bad outcomes are disclosed in high-litigation settings, while some bad outcomes are disclosed in low-litigation settings. This result could occur for two reasons: (1) there is measurement error in my measures of litigation risk, or (2) there are other incentives associated with disclosure choice. Accordingly, the findings presented in this section demonstrate that litigation risk is a key factor in managers' disclosure decisions, but I include the caveat that litigation risk is not the only factor.

4.3 Inspection Attributes Analysis

4.3.1 Inspection Materiality

My main results suggest that bad inspection outcomes are – on average – sufficiently material to merit subsequent disclosure; however, not all inspections are equal. Given its role as a gatekeeper, the FDA has the authority to authorize or deny product sales. If a firm devotes significant resources to product research and development, a bad inspection outcome could threaten the firm's ability to earn a return on its investment. For example, a bad inspection outcome for a drug company may delay anticipated approvals, but an employee who does not wash his or her hands is unlikely to cause notable harm to a food company. Drawing on this notion of investment at risk, I assign inspections occurring in research-intensive industries (i.e., Medical Devices and Radiological Health, Biologics, and Human Drugs) to the high-materiality group, and all other inspection industries (i.e., Animal Drugs and Food, Foods and Cosmetics, Tobacco Products, and Other) to the low-materiality group. I then assume that the bad inspection outcomes occurring in the highly material subset represent the worst news. If managers are using these disclosures to communicate truly bad news, then the magnitude of the coefficients should be higher when the inspections are more material.

To validate my cross-sectional split, I examine the post-OGI market reaction to bad inspections in each partition. During this post-period, capital market participants can observe inspection outcomes at the end of each month and impound this information into their trading decisions. To calculate market reaction, I cumulate abnormal returns in the last five trading days of the month in which the inspection occurs. Using a t-test, I find that a significantly negative market reaction to bad inspections in my high severity partition. By comparison, the market reacts negatively to inspections in my low materiality partition; however, this reaction is not significantly different from zero. The difference between these market reactions is statistically significant. This test confirms that indeed inspections in the high materiality partition (i.e., inspections in the Medical Devices and Radiological Health, Biologics, and Human Drugs Centers) are more material than those in

the low severity partition (i.e., inspections in the Animal Drugs and Food, Foods and Cosmetics, Tobacco Products, and Other Centers).

I document the findings of my cross-sectional analysis in Table 5. Odd (even) numbered columns report the results from the high- (low-) materiality subsample. The coefficients on *Bad Inspection* are all positive, but they are statistically significant only for high-materiality outcomes. Furthermore, the difference between the high *Bad Inspection* coefficient and the low *Bad Inspection* coefficient is significant for both of my voluntary disclosure measures. This suggests that managers disclose material bad news, but not all bad news. Given that legal exposure is the highest when the underlying news may have the largest impact on investment decisions, the litigation risk mechanism also holds in this case.

4.3.2 Inspection Severity

Next, I consider how the severity of the bad news affects managers' disclosure choices. I assume that the FDA allocates resources to inspections based on its perception of the risks involved. When the FDA expects or encounters more critical issues over the course of the inspection, it will need more inspectors of more time. If managers are making transparent and forthcoming disclosure choices, then I predict that the association between bad news and voluntary disclosure will be will increase with the magnitude of the bad news.

I measure severity based on the duration of the inspection and the number of personnel assigned to the inspection.[15] An inspection is assigned to the high severity partition if its duration is longer than 4 days or its staffing involves more than one FDA employee. All other observations are allocated to the low severity partition. Once again, to validate this cross-sectional split, I perform t-tests of post-OGI abnormal market returns. In general, regardless of the outcome, I find that the market reacts positively to a low severity inspection and negatively to a high severity inspection, with the difference being statistically significant. More specifically, I find that the market reacts

[15]One concern with this measure might be that it captures firm size, rather than inspection severity. Correlation tests indicate that size only explains 9.11 percent of the variation in duration and 9.10 percent of the variation in the number of FDA employees staffed on an inspection. As a result, I conclude that the severity measure is not a purely proxy for firm size.

negatively to both high and low severity bad outcomes, but the reaction for high severity bad inspections is significantly more negative than that of the low severity bad inspections. Combined, this evidence verifies that the market distinguishes between high and low severity inspections based on the duration and staffing of those inspections.

I provide the results of this cross-sectional analysis in Table 6. In line with my prediction, I find that the *Bad Inspection* coefficients are significantly positive in both of the high severity partitions, and the magnitudes of these coefficients are significantly larger than those in the low severity partitions. Taken together, these findings suggest that not only do managers disclose bad news, they also disclose the worst news.

4.4 Impact of a Private to Public Regime Shift

4.4.1 Main Results

In this section, I exploit the implementation of the Open Government Initiative as a regime shift that affected the privacy of inspection outcomes. Under the mandate of this program, the FDA disrupted firms' information environments by beginning to publicly disclose inspection results on a monthly basis. Viewing this change through a theoretical lens, Frenkel et al. [2018] predict that as external sources increase their provision of information, managers will decrease their voluntary disclosures. If the FDA's inspection disclosures serve as a substitute for managers' voluntary disclosures, then the launch of the OGI will alter the costs and benefits of releasing disclosures. Once the inspection outcomes become public information, investors can no longer claim that managers withheld this information; thus, this regime shift could lower the expected legal costs associated with non-disclosure. Prior empirical studies test the opposite set of conditions and find that when analyst coverage decreases, firms compensate by offering more voluntary disclosure (Anantharaman and Zhang [2011]; Balakrishnan, Billings, Kelly, and Ljungqvist [2014]). I hypothesize that by increasing the supply of publicly available information, the OGI downwardly shifts managers' optimal disclosure levels.

I begin my regime shift analysis by comparing inspection attributes in the pre- and post-periods to assess whether the OGI changed the nature of inspections, in addition to the privacy of them. The probability of a bad inspection outcome was 33 percent in the pre-period, and decreased to 31 percent in the post-period. This reduction in bad outcomes is statistically significant. The average duration of inspections increased from 6.29 days to 6.59 days; however, this change is not statistically significant. Finally, the average number of inspectors rose from 1.33 to 1.67, with this increase being statistically significant. Taken together, these changes do not move in a consistent direction nor to they suggest that the OGI systematically changed the rigor

of inspections. Therefore, I conclude that the OGI primarily changed the privacy of inspections, rather than the inspections themselves.[16]

To test my hypothesis, I extend my sample to the end of 2016. I estimate Equation 1 augmented with a *Bad Inspection*×*Post* interaction variable, and I also separately estimate Equation 1 with with pre- and post-regime shift subsets. I present my results in Table 7. In Panel A, I find that there is a significantly positive coefficient on *Bad Inspection* in all columns. This is consistent with my other findings, which suggest that managers disclose bad inspection outcomes when this information resides in their private information sets. I also document a significantly negative coefficient on *Bad Inspection*×*Post*, which indicates that bad news disclosure decreases in the post-period. Furthermore, the sum of *Bad Inspection* and *Bad Inspection*×*Post* is not statistically different from zero. This suggests that on average, managers do not disclose bad inspection outcomes in the post-period. All of these inferences hold when I estimate this specification using an entropy-balanced sample, as reported in columns (3) and (4).

In Panel B, I present the results from my fully interacted models. Columns (1) and (3) repeat the findings from my main specification. Columns (2) and (4) document results from the post-period model and do not report a statistically significant *Bad Inspection* coefficient. Furthermore, the differences between the pre- and post-period *Bad Inspection* coefficients are significantly significant. Once again, this suggests that the OGI diminishes managers' incentives to voluntarily disclose their adverse information.

I interpret the decline in disclosure to suggest that when the FDA publicly releases inspection outcomes, it reduces the expected legal costs of silence to a sufficiently low level, such that investors cannot sue on the basis of withheld information. However, although I do not find a statistical relationship between *Bad Inspection* and voluntary disclosure in the post-period, this does not mean that managers never provide investors with information about their inspection outcomes. Given that *Disclose_i* and *Disclose_n* do not equal zero in the post-period, managers may still disseminate inspection-related news to contextualize or pre-empt the FDA's monthly

[16]Institutional insights suggest that inspection trends do occur over time. I include industry-year fixed effects to absorb the variation attributable to these drifts.

data uploads. Investors may demand information beyond the scope of the FDA's publications to adequately update their valuation expectations; therefore, managers may provide additional information to minimize any lingering legal exposure and satisfy capital market participants.

4.4.2 Litigation Risk Cross-sectional Results

To formally test whether the regime shift lowered litigation risk, I re-perform my pre-period cross-sectional tests on my post-period sample. I report my results in Table 8. Across all specifications, the coefficient on *Bad Inspection* is statistically insignificant. The coefficients in the high litigation columns are higher in magnitude than those in the low columns; however, the difference is only significant for the *Disclose_n* dependent variable. Compared to the pre-period results, the substantially weakened post-period findings suggest that implementation of the OGI dampened the litigation risk disclosure incentive.

4.4.3 Informational Efficiency

Extending this stream of analysis, I use the FDA's implementation of the OGI to examine the market's informational efficiency under voluntary and mandatory disclosure regimes. During the pre-period, when managers choose to disclose inspection results, I find that the market reacts negatively to bad outcome disclosures and positively to clean outcome disclosures; however, this difference is not statistically significant.[17] By contrast, as discussed in Section 2.1, in the post-period, when the FDA discloses inspection outcomes at the end of the month, firms with bad outcomes experience negative returns and firms with clean outcomes experience positive returns. This post-period difference in returns is statistically significant. Although both regimes exhibit qualitatively similar reactions, the quantitative difference is interesting to note and could occur for a number of reasons.

First, during the pre-period, managers are able to maintain control of the narrative that surrounds the announcement of a bad inspection outcome. Anecdotally, as exemplified by the disclosures in Appendix G, managers appear to state that they have received a Form 483, along

[17]For this test, I calculate the cumulative abnormal returns in the 3-day window surrounding the disclosure date.

with the firm's commitment to operating in compliance with FDA regulations. This leaves the reader with the impression that although a problem was discovered, the firm is taking prompt and appropriate actions to remediate the deficiencies, which might moderate the negative reaction to occurrence of a bad inspection outcome. In the post-period, the FDA discloses the inspection outcome; however, it does not outline any steps that the firms are taking to fix the documented issues. While managers could still respond by issuing their own disclosures to minimize the reduction in stock price, my findings suggest that on-average, they do not offer a supplementary commentary to accompany the FDA disclosures. As a result, the market may react more negatively to the FDA disclosures because they represent bad news without an added positive spin.[18]

Second, in the pre-period, managers may use voluntary FDA inspection outcome disclosures as an opportunity to signal their firm's type (Spence [1973], Leland and Pyle [1977]). For example, firms that are more capable of resolving the problems may be more likely to disclose them.[19] Accordingly, the market response to bad inspection disclosures may not significantly differ from clean outcome disclosures because managers temper the bad news by revealing their relatively better type. If managers successfully build an expectation that violations will be swiftly and adequately fixed, the bad outcome may not seem *as* bad. Conversely, in the post-period, the market can use the FDA's monthly publications to observe inspection outcomes for all types of firms. In the case of relatively worse-types, public revelation of a bad inspection outcome may seem worse due to the firm's inability to solve problems and may lead to more negative market reactions. By including all types of firms in the calculation of the market's response to bad news – as opposed to just the better-type firms in the pre-period – this can create a more stark contrast

[18]Presumably, the FDA's monthly publication of inspection outcome alters the costs and benefits of voluntary disclosure. In maximizing their objective functions, firms will consider a variety of factors, in addition to short-window stock returns. These other factors must outweigh the cost of short-term stock price decreases in order to explain the firms' lack of disclosure in the post-period.

[19]This discussion assumes that inspection outcomes are not the sole determinant of firm type and that there is variation in firm type within inspection outcome subsets. For example, there are better and worse firms that experience clean inspection outcomes, and there are better and worse firms that experience bad inspection outcomes.

between bad outcomes and clean outcomes, and allow for the detection of a significantly different market reaction.

Third, the mandatory FDA disclosures might provide the market with more information, such that capital market participants are better able to discriminate between firms. In the pre-period, as illustrated by the excerpts in Appendix G, the market might receive detailed information on disclosed inspections; however, it will not receive any timely information on undisclosed inspections. In the post-period, the market will be able to observe basic details for all inspections disclosed by the FDA. Based on the finding that the market does not distinguish between bad and clean inspection disclosures in the pre-period, but does significantly differentiate in the post-period, the FDA appears to provide the market with incremental information that is used in valuation decisions. Although the relation between bad inspection outcomes and voluntary disclosure disappears in the post-period, and capital market participants may lose some of the detailed inspection-specific information, there is still an overall net information gain because they are able to observe outcomes for the entire set of inspections disclosed by the FDA. Combined with my main finding, this suggests that even when managers disclose bad news under a voluntary disclosure regime, the informational efficiency of the market can be improved by imposing a mandatory disclosure regime to reveal the previously undisclosed, value-relevant information.

While all of these explanations plausibly explain the results that I document, the findings should be interpreted with caution. In performing this market-based analysis, I have a much smaller sample for the pre-period voluntary disclosure tests than I do for the post-period mandatory disclosure tests. Not all firms disclose inspection outcomes in the pre-period; therefore, I can only calculate the cumulative abnormal returns for the ones that do disseminate this information (i.e., I must drop the pre-period observations in which no disclosure occurs). In the post-period, I can calculate cumulative abnormal returns for all inspections in my sample, which means that I have a larger number of observations and more power to detect a statistically significant difference between bad and clean disclosures. Consequently, statistics, rather than economics, may explain the difference between my pre-period and post-period results.

4.5 Disclosure Timeliness

4.5.1 Main Results

Thus far, my study has investigated *if* managers disclose bad news. A related question is *when* managers disclose bad news. By delaying disclosure, managers may reduce its usefulness to investors if the same information ends up aggregated with other firm performance news (e.g., forecasts, earnings announcements). The same incentives affecting managers' choice to disclose also affect the timeliness of such disclosures. Litigation risk induces managers to disclose bad news in a timely manner to limit shareholders' ability to argue that they withheld the information (Skinner [1994]) and to minimize potential settlement costs (Skinner [1997]). Conversely, managers interested in self-dealing may try to delay the disclosure of bad news until they are certain that subsequent events will not reverse or offset the adverse circumstances (Kothari et al. [2009]). As a result, the timing of the disclosure is just as important as the choice.

Untabulated univariate analysis indicates that, conditional on disclosure, the first 8-K or press release is issued within an average of 36 days following a bad inspection, and within an average of 39 days following a clean inspection. This 3-day difference is statistically significant. While this may seem like a long time lag, a firm experiencing a bad inspection outcome likely prioritizes rectifying the deficiencies over immediate disclosure, as it must respond to the FDA within 15 business days. According to Cerulean Associates LLC [2011], "for many companies, those 15 days are a panicked rush". Accounting for this focus when assessing the disclosure delay, managers typically disclose a bad inspection outcome within two weeks of responding to the FDA. In addition, as exemplified by the excerpts in Appendix G, managers tend to make references to their action plan in their disclosures. They would not be able to include details of their response in the 8-K or press release if it was immediately issued after an inspection. Thus, both of these factors explain the delay between the inspection end date and the first disclosure date.

I document my multivariate findings in Table 9. In Panel A, the dependent variable is *Days*, which is the number of days in between the inspection end date and disclosure date. If the firm

does not issue a disclosure, *Days* is set to the maximum number of days in the three month window subsequent to the end of the inspection. In Column (1), using an unmatched sample, I find that the coefficient on *Bad Inspection* is negative and statistically significant. With an entropy-balanced sample, in Column (2) I continue to report a significantly negative coefficient on *Bad Inspection*. Combined, these specifications suggest that bad news accelerates disclosure by two to three days.

4.5.2 Litigation Risk Cross-sectional Results

The litigation risk hypothesis suggests that not only do managers disclose bad news, but they also do so in a timely manner. If managers file 8-Ks and issue press releases in a timely manner to minimize legal exposure, then I predict that their disclosures will be more timely in high litigation risk environments, than in low litigation risk ones. I once again rely on Francis et al. [1994] and Kim and Skinner [2012]'s measures to partition my sample. Using the SIC industry membership measure, I find that managers issues disclosures within 34 days of a bad inspection outcome and within 44 days of a clean inspection outcome. With the ex ante predicted litigation risk measure, I find that managers issue disclosures within 35 days of a bad inspection outcome and within 39 days of a clean inspection outcome. The difference between bad and clean inspection disclosures for both partitions is statistically significant, indicating that managers issue more timely bad news disclosures when they operate in high litigation risk settings.

I also perform cross-sectional analysis on my multivariate timeliness tests and report the results in Table 9, Panel B. With both measures of litigation risk, I find that the coefficient on *Bad Inspection* is negative and statistically significant in the high litigation risk subgroup. In the low risk subgroups, the *Bad Inspection* coefficient is negative, but not statistically significant. I also find that the high risk coefficients are significantly less than the low risk coefficients. All of this evidence suggests that litigation risk motivates managers to disclose bad news in a timely manner.

4.6 Managerial Self-Dealing Analysis

My results suggest that on average, managers voluntarily disclose bad news. However, under certain conditions, managers may be willing to deviate from the norm. In this section, I draw on prior research to identify settings with managerial self-dealing incentives or opportunities. Within these settings, I investigate whether managers change their disclosure choices in ways that would allow them to exploit their information advantage and extract rents from shareholders.

4.6.1 Career Concerns

Prior literature asserts that career concerns arise when managers' performance affects their compensation (Gibbons and Murphy [1992]). To protect their job prospects and financial interests, managers with these concerns may be reluctant to disclose bad news. Instead, they may try to conceal bad inspection outcomes and gamble on their ability to resolve the issues without subsequent detection or leaks of the unfavorable information. Following Baginski et al. [2018], I assume that career concerns are high when any one of the following conditions exist: (1) the CEO is young, (2) the CEO is close to retirement, (3) the CEO was hired from outside the firm, or (4) the CEO was hired within the last year.[20] If none of these criteria apply, I assign the observation to the low-career concerns subsample. If managers are withholding unfavorable information to protect their career trajectories, then I expect the relation between bad news and voluntary disclosure will weaken or disappear in the high-concern cross-sections.

I document my results from these cross-sectional tests in Table 10. I find that the *Bad Inspection* coefficients are positive and significant in all partitions. Furthermore, the coefficients in the high partitions are nearly identical to those in the low partitions. Tests of the statistical

[20](1) Young CEOs have long careers ahead and may be hesitant to reveal bad news if it will negatively affect the labor market's perception of their talent and skills (Gibbons and Murphy [1992]. (2) CEOs close to retirement will have a short horizon remaining with the firm and this diminishes their incentives to act in the best interests of shareholders (Cassell, Huang, and Sanchez [2013]). Thus, they may exhibit less transparent and forthcoming behavior. (3) CEOs hired from outside of the firm may be more likely to face termination if they disclose bad inspection outcomes because investors may be more uncertain about their ability; hence, they may want suppress any bad news to affirm that they are competent and deserving of the position (Gillan, Hartzell, and Parrino [2009]). (4) Newly hired CEOs may also be inclined to hide bad news to make a good initial impression and prevent investors from questioning their ability (Hermalin and Weisbach [2012]).

significance of the small differences confirm that they are indistinguishable. Collectively, the results do not suggest any evidence of managerial self-dealing. Even when career concerns are high, managers continue to voluntarily disclose bad inspection outcomes. Further, the disclosure choices of managers with high career concerns closely mimic those of managers with low concerns. In some cases, managers with high career concerns exhibit more transparent and forthcoming behavior.

4.6.2 Weak Governance

Extant research shows that the strength of a firm's governance practices is inversely related to accounting quality, firms' propensity to issue guidance, and the quantity of voluntary disclosure issued by the firm (Dechow, Sloan, and Sweeney [1996]; Ajinkya, Bhojrah, and Sengupta [2005]). When firm governance is weak, managers may have better opportunities to participate in self-dealing activities (Jensen and Meckling [1976]; Fama and Jensen [1983]; Jensen [1986]) because the firm lacks the mechanisms necessary to flush out this bad news. For example, if the CEO is also the Chairman or the CEO is also on the board, then he or she may be able to exert influence over meeting agendas and discussions. Under these circumstances, CEOs may be able to divert attention away from the inspection outcomes in order to shield their personal interests. Entrenched CEOs can take advantage of their bargaining power and ensure that they work with a friendly board, which allows them to operate autonomously with less monitoring and scrutiny (Hermalin and Weisbach [1998]). When paired with more passive boards, extremely strong CEOs may be more successful in hiding bad inspection outcomes, as the other directors may be less inclined to dig into issues with the intention of uncovering bad news. Following this logic, I argue that if a firm has a dual CEO-Chairman or its CEO is also a board member, then weak governance practices exist. If managers are self-dealing, then I expect the association between bad inspection outcomes and voluntary disclosure will diminish or disappear in the weak governance cross-sections.

Table 11 presents my results from this analysis. In Panel A, my sample is split based on whether the firm has a dual CEO-Chairman; in Panel B, my sample is divided based on whether the CEO

also sits in the board of directors. Across all specifications in both panels, I fail to document any evidence that CEOs nefariously use their power to hide bad news. The coefficient on *Bad Inspection* is significantly positive in all partitions. Although the magnitudes of the coefficients in weak governance subgroups tend to be larger than those in the high partitions, the difference is generally not statistically significant. The findings undermine any conjecture that managers self-deal when opportunities to do so exist, such as when their firm's governance is weak.

4.6.3 Financing Incentives

If a firm is seeking financing for a given project, its manager might suppress bad news to maximize proceeds. Prior literature supports this conjecture by documenting that managers make strategic disclosure decisions surrounding financing events. Lang and Lundholm [2000] show that, in the months preceding a seasoned equity offering, firms increase their disclosure activity to hype their sock. More specifically with respect to bad news, Brockman, Khurana, and Martin [2008] show that firms increase bad news disclosures and decrease good news disclosures prior to repurchasing its own shares. Ertimur, Sletten, and Sunder [2014] find that IPO firms delay the disclosure of bad news during the period following the lockup expiration date to facilitate higher sell prices for pre-IPO shareholders. Similarly, Ge and Lennox [2010] document that firms withhold bad news when they are using their own stock to finance an acquisition. If these findings translate to the FDA setting, then I expect that the probability and levels of disclosure will be lower if managers issue debt or equity in the three months following the inspection.

To test this conjecture, I obtain data on public debt and equity from SDC Platinum and supplement it with debt issuances reported in Dealscan. I partition my sample as follows: if a firm receives financing in the three months following the inspection end date, then that observation is assigned to the high financing incentives subgroup, and if the firm does not receive financing during this window of time – as reported by these two databases – then the observation is allocated to the low financing incentives subgroup. I report my results in Table 12. In all partitions, I find a significantly positive coefficient on *Bad Inspection*. Moreover, the differences

in the high and low financing incentive coefficients are not statistically significant. This indicates that managers do not withhold bad news from finance providers to facilitate the most favorable deal.

4.6.4 Insider Trading

Managers possess superior information about their firm's future prospects. Those interested in self-dealing can use their information advantage to earn excess profits (Piotroski and Roulstone [2005]). In the FDA inspection setting, managers possess an information advantage because, in the pre-period, they are the only ones who have timely access to inspection outcomes. Therefore, in general, if managers are exploiting this advantage and self-dealing, I expect insiders will complete opportunistic trades in the three months following the end of am inspection. As well, more specifically, prior research finds that managers strategically time their trades around disclosure dates (Ke, Huddart, and Petroni [2002]; Billings and Cedergren [2015]). As a result, managers may schedule their inspection disclosures to maximize rent extraction. Accordingly, I also consider two possible ways in which insider trading may interact with a manager's decision to disclose bad news. I report all results in Table 13.

First, in Column (1), I explore whether a bad inspection outcome is associated with any opportunistic insider trading in the three months following the end of the inspection. The dependent variable, *Insider Trade*, is an indicator variable equal to one if an insider executes an opportunistic trade, as defined by Cohen, Malloy, and Pomorski [2012], within three months of the inspection end date, and zero otherwise. The insignificant coefficient on *Bad Inspection* suggests that on average, managers are not exploiting their informational advantage. Similarly, in Column (2), I restrict my sample to non-disclosing observations in the spirit of Blackburne et al. [Forthcoming], who find that a majority of SEC investigations are not disclosed and insiders do not abstain from trading on this private information. In this case, I continue to find an insignificant coefficient on *Bad Inspection*, suggesting that managers are not withholding this information for their own personal gain.

Second, in Column (3), I examine whether managers strategically sell their stocks prior to disclosure. In this case, they could realize a higher selling price before it drops due to the bad news. Accordingly, I capture this type of behavior through my dependent variable, *Strategic Sale*, which is an indicator variable equal to one if an insider completes an opportunistic sale prior to the disclosure in the three month period after the inspection. If there is no disclosure, such a sale can occur at any point in the three month window. With this specification, I once again find an insignificant coefficient on Bad Inspection. This result is consistent Noe [1999] who finds that managers do not initiate inside trades to profit from private information. It also aligns with Li, Wasley, and Zimmerman [2016], as they find that managers uphold their affirmative duty to disclose all material information or abstain from trading in their firms' securities.

Finally, in Column (4), I consider whether managers purchase shares after disclosing bad news. In this type of scenario, managers would disclose a bad inspection out to depress the stock price, and then acquire the shares at a lower price than what would have been possible without dissemination of bad news. In line with this idea, Aboody and Kasznik [2000] find that firms disclose of bad news around stock option award dates to dampen the stock price and enable managers to increase their personal profits by purchasing shares at a lower cost. Cheng and Lo [2006] report a similar finding that managers reveal bad news prior to purchasing shares. To test this conjecture in my setting, I create the *Strategic Purchase* indicator variable, which is equal to one if an insider purchases shares after the inspection disclosure. and zero otherwise. To be clear, if no disclosure occurs within three months of the inspection, then this variable will equal zero. Once again, I find an insignificant coefficient on *Bad Inspection*. This indicates that managers are not using this trading strategy to improve their personal financial position.

Throughout the entire table, I am unable to document any systematic evidence based on their disclosure choices that managers are strategically executing trades. This implies that managers do not jointly use insider trades and voluntary disclosure to self-deal.

4.6.5 Managerial Self-Dealing Discussion and Caveats

The findings from my main specification suggests that on average, managers exhibit transparent and forthcoming behavior. However, this result may not hold under all sets of circumstances. In this section, I aim to identify settings in which managers may be tempted to self-deal. I perform numerous cross-sectional tests to assess whether these incentives affect the relationship between bad news and disclosure. None of my evidence suggests that managers are self-dealing; at least, this behavior is not occurring frequently enough for my tests to detect. Still, misspecification and/or mismeasurement of incentives may also explain why I fail to find evidence that managers are self-dealing. Although I attempt to attenuate these concerns by exploring multiple settings in which self-dealing could occur, I cannot completely rule out this possibility.

Self-dealing could also yield offsetting disclosure outcomes. In some cases, managers may believe that they can indefinitely conceal bad inspection outcomes; therefore, they may withhold this news. In other cases, managers may act in their own interests by disclosing bad inspection outcomes to avoid undermining their reputation and credibility Kaplow and Shavell [1994]. Therefore, my lack of systematic findings could also be explained by these counteracting forces.

4.7 Robustness Testing and Supplementary Discussion

4.7.1 Endogeneity Concerns

Due to resource constraints, the FDA must optimally select firms to inspect in order to maximize its ability to protect public health. Firm fixed effects will absorb any time-invariant factors that may influence the FDA's decision of which sites to inspect. In addition, limiting the sample to firms that are subject to an inspection at some point during my sample period addresses selection concerns relating to which firms the FDA does and does not inspect. A remaining endogeneity concern stems from the possibility that an omitted correlated variable explains both a bad inspection outcome and a manager's disclosure choice.

Throughout the paper, I perform a number of tests to attenuate omitted correlated variable concerns. First, I employ a rigorous fixed effect structure that eliminates any time-invariant firm factors, any time-varying industry explanations, and any quarterly or seasonal alternatives. Second, for my main results, I use both an unmatched and a quasi-matched entropy-balanced sample to estimate my specifications. This reduces the concern that confounding variables explain the bad inspection outcome and the disclosure choice. Third, I report a number of cross-sectional tests that are consistent with managers disclosing bad news in a transparent and timely manner. In order for a correlated omitted variable to threaten the internal validity of my inferences, it would need to explain the main result and align with all of my cross-sectional findings. Finally, I exploit an exogenous regime shift, which means if a correlated omitted variable explains my pre-period result, it must also undergo a change that coincides with the timing of the FDA's implementation of the OGI mandate. Although these strategies do not rule out all plausible alternative explanations, the entire body of evidence strongly supports my inferences. In the following sections, I perform a number of additional robustness tests to further attenuate remaining endogeneity concerns.

4.7.2 Other Bad News Events

In a credible alternative explanation, the managers of a firm that experiences turbulent operating conditions could respond by issuing higher levels of disclosure to communicate this series of

unfavorable events. A bad inspection outcome could be just one of many problems facing the firm at that time. Further, the FDA may have selected the firm for inspection because of this instability. In this example, overall bad news – as opposed to bad inspection outcomes in particular – could be driving the disclosure choices.

I address this concern in three ways. First, I apply filters to my dependent variables to ensure that 8-K filings relate to the FDA and that the press releases discuss inspection-related topics. As a result, my disclosure measures do not capture all bad news; rather, they target a more precise set of communications, tailored to my setting. This creates a much tighter connection between inspection outcomes and subsequent disclosure choices. Other bad news that occurs at the same time as inspections with bad outcomes is unlikely to lead to these types of disclosures.

Second, I include several control variables that capture firm performance. For example, *ROA*, *Loss*, *Returns*, and *Returns Volatility* all reflect elements of general bad news, if it exists. Any other adverse circumstances that drive my results would need to involve non-financial bad news.

Third, I directly control for other bad news by augmenting my vector of control variables with *Other Bad News*, which is an indicator variable equal to one if managers issue a below consensus forecast in the three months following the end of the inspection, and zero otherwise. While this measure will not reflect all bad news, it will capture a broad range of events that are material enough to warrant an update for investors. If a bad FDA inspection outcome is simply proxying for other bad news that motivates disclosure, then including this control variable should eliminate the statistical significance of the *Bad Inspection* coefficient. Given that I document a series of tests throughout the paper that are robust to the inclusion of *Other Bad News*, I conclude that it is unlikely that other bad news explains my results.

4.7.3 Changes Specifications

Endogeneity concerns, specifically those related to omitted correlated variables, could threaten my ability to draw inferences from my analyses. While the existence of a confounding factor that explains all of my results is unlikely, I attempt to attenuate any remaining concerns by estimating

a number of changes specifications. I use Δ *Disclose_i* and Δ *Disclose_n* as dependent variables to capture changes in managers' disclosure choices. Δ *Disclose_i* indicates a firm's shift from a discloser to a non-discloser, or vice versa. Δ *Disclose_n* measures fluctuations in the number of disclosures issued. Since I use a three month (i.e., quarterly) disclosure window, I use two benchmarks to calculate changes in my dependent and control variables: the disclosure choices from the immediately preceding quarter and the disclosure choices from the same quarter in the prior year. Further, I include the lagged value of the dependent variable to control for the firm's prior disclosure history. The benchmark comparison periods are listed at the top of the table.

My results are documented in Table 14. Columns (1) and (3) suggest that bad inspection outcomes motivate managers to switch from non-disclosers to disclosers. The significantly positive coefficients on *Bad Inspection* in Columns (2) and (4) provide evidence that managers respond to bad inspection outcomes by increasing the amount of disclosure they issue on behalf of their firm. For an omitted correlated variable concern to persist, such a variable would need to be correlated with changes in managers' disclosure choices and the occurrence of inspections. A plausible alternative explanation would also need to operate within the confines of my cross-sectional results. All of these requirements help to alleviate any remaining endogeneity concerns.

Collectively, this section's findings are noteworthy because prior literature has shown that managers' voluntary disclosure choices tend to be sticky (Lang and Lundholm [1996]; Anilowski, Feng, and Skinner [2007]; Einhorn and Ziv [2008]). In the FDA inspection setting, I find evidence that managers are willing to revise their previous disclosure choices to communicate bad news to the capital markets. My results do not reconcile with those of Rogers and Van Buskirk [2013], as they show that managers do not change their disclosure choices until after a litigation event occurs. All of my analyses consider post-inspection disclosure choices, but these decisions are likely determined before managers face shareholder lawsuits. Because I use a short-term, one-quarter disclosure window, my findings imply that managers may be taking pre-emptive rather than responsive actions.

4.7.4 Oster Bounds

In creating a research design to assess the relationship between bad news and voluntary disclosure, I aimed to make decisions that would strengthen the internal validity of my inferences and minimize the threat of a correlated omitted variable. However, given that I cannot rule out all plausible alternative explanations, in my final series of tests, I formally assess how unobservable variables could affect my main results. Following Altonji, Elder, and Taber [2005] and Oster [2019]'s partial identification technique, I estimate bounds on my *Bad Inspection* coefficients, as well as the impact unobservable factors would need to have on the *Bad Inspection* coefficients in order to reduce them to zero.

These estimations rely on two key assumptions: (1) the maximum R^2 that could be achieved when the model is specified with a full set of controls, but the dependent variable is measured with error; and (2) the impact that unobservable factors could have on the coefficient of interest, relative to the that of the observable control variables. Consistent with Altonji et al. [2005] and Oster [2019], I assume that $R^2_{max} = min(1.3\hat{R}^2, 1)$ and $\delta = 1$.

Using this approach, I find that unobservable factors would need to be substantial in order to threaten the validity of my results. If I assume that unobservables and observables – including fixed effects – the relationship between bad news and voluntary disclosure (i.e., $\delta = 1$), the estimated coefficient would decrease from 0.0396 to 0.0115 for the *Disclose_i* specification and it would decrease from 0.121 to 0.0678. Accordingly, the true beta for the *Disclose_i* specification lies in the interval [0.0115, 0.0396] and the true beta for the *Disclose_n* specification lies in the interval [0.0678, 0.121]. This means that unobservable factors would need to have an impact that is 1.36 times and 2.04 times that of the observable factors to reduce the *Bad Inspection* coefficients in the *Disclose_i* and *Disclose_n* models, respectively, to zero. Given their rigor and explanatory power, I also re-perform these estimations without fixed effects. In this case, the *Bad Inspection* coefficient decreases from 0.0920 to 0.0872 in the *Disclose_i* model, and decreases from 0.224 to 0.216 in the *Disclose_n* model. This implies that the bounds for the *Bad Inspection* coefficient in the *Disclose_i* model are [0.0872, 0.0920] and the bounds for the same coefficient in the *Disclose_n* model are

[0.216, 0.224]. Again, this indicates that unobservable factors would need to have an impact that is 14.77 times and 19.10 times the impact of the control variables in the *Disclose_i* and *Disclose_n* models, respectively, to reduce the *Bad Inspection* coefficient to zero.

Taken together, these tests highlight two important findings. First, none of the bounds include zero, which means that my inferences are robust to the inclusion of unobservable factors, assuming their impact is symmetric to that of the observable factors. Second, a correlated omitted variable would need to have a considerable impact on the *Bad Inspection* coefficient in order to invalidate my inferences. As a result, although I cannot eliminate all threats to the internal validity, I argue that the existence of such a considerable correlated omitted variable is unlikely.

4.7.5 Data Limitations

Although my data permit direct observation of inspection outcomes, this is just one piece of managers' private information sets that may be immaterial relative to their entire corpus of knowledge. This is unlikely, however, because it is critical for these firms to comply with FDA regulations. If they deviate from applicable laws and the violation is detected, the firm must implement corrective actions. If it does not, the FDA has the authority to impose significant costs that could threaten the business's viability. From an econometric perspective, if this institutional intuition does not hold, then I will be unable to identify a statistically significant relationship between this form of bad news and voluntary disclosure.

Due to the nature of the data, my sample is restricted to firms that operate in FDA-regulated settings. Firms that self-select into these specific industries may be inherently different from the broader population of firms. More specifically, bad news may differentially impact voluntary disclosure in this environment. For this reason, I include the caveat that my results may not generalize beyond this setting.

4.7.6 Clean Inspection Considerations

I focus my analyses on managers' disclosure choices following a bad inspection outcome. In most cases, however, managers experience a clean inspection. I do not classify a good outcome

as *news* for two main reasons. First, according to the descriptive statistics presented in Table 2, clean inspections occur 67 percent of the time in my main sample. This indicates that ex-ante, investors expect the firm to comply fully with all applicable regulations. Accordingly, disclosing a clean inspection would simply confirm investors' priors. Second, if the FDA does not identify any deficiencies, the firm will not be required to incur costs to remediate these issues. For that firm, operations will continue under status quo conditions.

Descriptively, in untabulated univariate tests, I find that managers disclose clean inspection outcomes in some cases; however, the frequency and quantity of these disclosures is significantly less than that of the bad outcome disclosures. This result could reflect the managers' choice to issue confirmatory disclosures. As noted in Clement, Frankel, and Miller [2003], these disclosures corroborate existing market expectations about future performance and aim to reduce uncertainty. The reduced probability and quantity of these confirmatory disclosures, as compared to the bad news ones, makes sense given the typical inconsequential nature of clean inspections.

CHAPTER 5

Conclusion

I examine the association between bad news and managers' voluntary disclosure choices. Adverse events routinely endow managers with unfavorable private information, and they must decide whether to share this news with the capital markets. Prior literature in this area faces a fundamental empirical challenge: managers' private information is often unobservable and difficult to capture. Without observing the existence and content of managers' private information, it is difficult to assess whether managers disclose or withhold bad news. I overcome this challenge by acquiring data on FDA inspection dates and outcomes, which effectively reside in managers' private information sets for a meaningful amount of time.

My primary finding is that bad inspection outcomes are associated with a higher probability of disclosure and higher quantities of disclosure in the following three months. These results are stronger when inspection outcomes are more material or more severe; and, they weaken when the FDA begins publicly releasing inspection outcomes on a monthly basis. In addition to the incidence of managers' disclosures, I also examine the timing. I find that bad inspection outcomes are associated with more timely disclosures than clean inspection outcomes. Taken together, this evidence suggests that managers disclose bad news, and they do so in an accelerated manner.

I also explore the incentives that motivate managers' disclosure choices. My results indicate that high litigation risk increases managers' propensity to issue disclosure, and it also increases the magnitude of the association between bad news and voluntary disclosure. Furthermore, it also prompts managers to disclose this news in a timely manner. With my current tests, I am unable to document evidence suggesting that managers are self-dealing. These findings imply that litigation

risk is a strong incentive in the FDA inspection setting, while the temptation to self-deal is much weaker.

My study contributes to the literature on voluntary disclosure, as I directly observe a complete piece of managers' private information sets. To innovate beyond existing research, I exploit variation in this information and document a variety of cross-sectional results that explain why and when managers disclose bad news. Further, I also extend the literature that investigates connections between incentives and disclosure choices. Using my precise measure of bad news, I provide direct evidence on the incentives that affect disclosure choices and identify incentives that may not strongly influence managers. Taken together, my results show that non-financial government entities – such as the FDA – play a role in shaping managers' disclosure choices.

APPENDICES

APPENDIX A

Variable Descriptions

Table A1: Variable Definitions

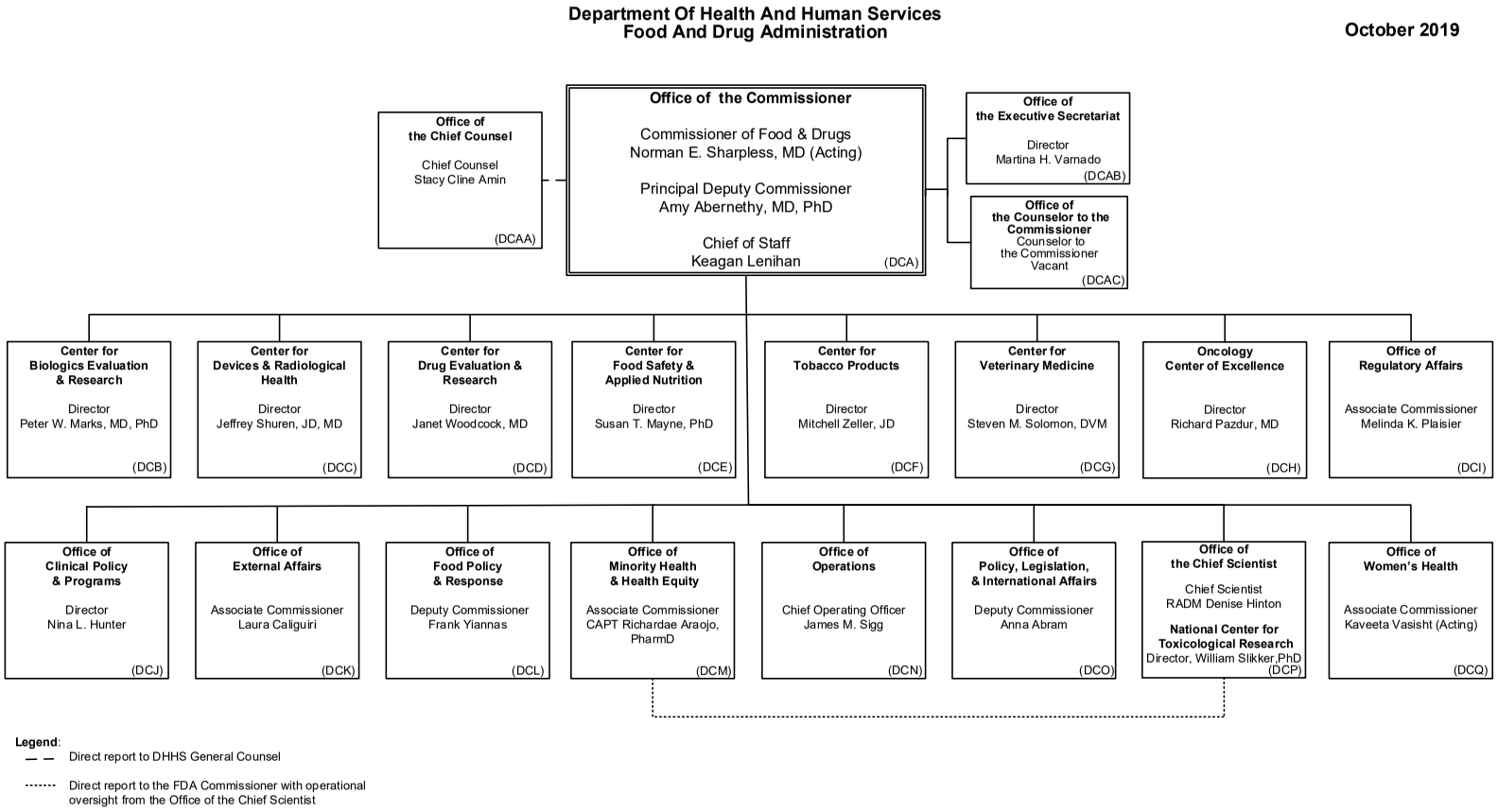
Variable	Description
DEPENDENT VARIABLES	
Disclose_i	An indicator variable equal to one if the firm files an 8-K or issues a press release covering FDA inspection-related topics within three months of the inspection end date, and zero otherwise. An 8-K is counted if it includes at least one word from each of the following categories: (1) 'food and drug administration', 'fda', 'food & drug administration', (2) 'inspection', 'inspected', 'inspectional', 'reinspected', 'inspect'. A press release is counted if Ravenpack attaches one of the following topics to the disclosure: 'product-recall', 'regulatory-product-review' 'regulatory-product-warning', 'regulatory-investigation' 'sanctions', 'clinical trials', 'product-discontinued', or 'product-outage'.
Disclose_n	The total number of 8-Ks and press releases, meeting the above criteria, issued by the firm within three months of the inspection end date.
Days	The number of days between the inspection and the first disclosure. If there is no disclosure, the maximum number days in the disclosure window (i.e., three months) is used.
Inside Trade	An indicator variable equal to one if an opportunistic inside trade, as defined by Cohen et al. [2012], is executed during the three month disclosure window, and zero otherwise.
Strategic Sale	An indicator variable equal to one if an opportunistic inside sale occurs before a disclosure and within three months of the inspection end date, and zero otherwise.
Strategic Purchase	An indicator variable equal to one if an opportunistic inside purchase occurs after a disclosure and within three months of the inspection end date, and zero otherwise.
INDEPENDENT VARIABLE OF INTEREST	
Bad Inspection	An indicator variable equal to one if the firm receives a Form 483 at the end of an inspection, and zero otherwise.

Variable	Description
CONTROL VARIABLES	
MTB	Market value of equity / book value of equity, measured at the fiscal quarter end prior to the inspection.
Size	Natural logarithm of total assets, measured at the fiscal quarter end prior to the inspection.
ROA	Net income divided by total assets, measured at the fiscal quarter end prior to the inspection.
Loss	An indicator variable equal to one if the firm incurs a loss during the fiscal quarter period prior to the inspection, and zero otherwise.
Analyst Following	Log (1 + Number of analysts following the firm in the fiscal quarter prior to the inspection).
Returns	Cumulative returns in the fiscal quarter prior to the inspection.
Returns Volatility	Standard deviation of daily returns in the fiscal quarter prior to the inspection.
Other Bad News	An indicator variable equal to one if managers issue a forecast below the consensus estimate during the three month disclosure window, and zero otherwise.

APPENDIX B

FDA Organizational Chart

Figure B.1: FDA Organizational Chart



APPENDIX C

Sample Form 483

Figure C.1: Sample Form 483

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	10/24/2017-10/26/2017 FEI NUMBER 1417171

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bryan T. Lawson, Plant Manager

FIRM NAME	STREET ADDRESS
The Gillette Company, LLC (subsidiary of Procter & Gamble)	3500 16th St
CITY, STATE, ZIP CODE, COUNTRY North Chicago, IL 60064-1513	TYPE ESTABLISHMENT INSPECTED Manufacturer of Active Pharmaceutical Ingredients

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Computerized analytical systems have not been appropriately validated to ensure that unauthorized access or changes to raw data cannot occur.

Specifically, software used for interpreting analytical test results from (b) (4) does not appear to have been adequately validated prior to implementation. Sequences affected include assay test results for the two most recent batches of PCMX Solution 20%, a bulk human drug intermediate solution manufactured by your firm which contains the active drug ingredient Chloroxylenol. Batch number 1(b) (4) was approved for release on 10/16/2017, and batch number (b) (4) was approved for release on 10/2/2017.

- The process for data archiving has not been proceduralized or validated to ensure that appropriate controls to prevent the loss of data are in place,
- the audit trails for such computerized systems have not been secured against manipulation or deletion from employees that use the system to generate data,
- electronic signatures do not include a reliable time and date stamp,
- and user role restrictions for your firm's chemistry analysts are not configured in accordance with the most recent performance qualification protocol.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher D Leach, Investigator Christopher D Leach Investigator Signed By Christopher D. Leach - S X Date Signed 10-26-2017 11 06 03	10/26/2017

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 1 OF 1 PAGES

APPENDIX D

Excerpts of Form 483 Observations

Pfizer, Inc.: October 15, 2012

Adverse drug experiences that were the subject of post marketing 15-day reports were not promptly investigated.

SOP AEM-01-03 was not followed in that follow-up information for ADEs that are serious and unexpected, including deaths and life threatening events, is not conducted; and deaths are not extensively investigated. Examples include:

- On 4/21/2005, a spontaneous report was received from a physician reporting death (unexpected event); stating that a (b)(4) yr old patient received an incorrect dose of the drug Fosphenytoin Sodium because the labeling did not correctly describe the dose/rate of infusion. Follow-up information was not attempted until 9/25/2012, seven years later. There is also no documentation of an investigation or follow-up attempts to review the labeling in other marketed countries.
- A Pharmacist reported a patient died while talking Sutent. Casualty was assessed as related: the events were serious and unexpected, yet the case was invalidated due to a non-identifiable patient, even though the reporter had first had knowledge that a true patient exists. There were no attempts to conduct follow-up from the pharmacist who reported the event, or from the case processor: Pfizer Medical Information.

Kraft Heinz Foods Company: November 14, 2017

You did not maintain your plant in a clean and sanitary condition and keep your plant in repair. Specifically, we observed the following:

- The metal beam located approximately 2 feet above the (b)(4) Tank is excessively rusted where rust, peeling paint and debris may fall into the open tank containing in-process Ketchup product below. We observed the (b)(4) tank was open to the environment
- The metal beam which runs above the (b)(4) cookers used to cook in-process Ketchup product is rusted, where rust may fall into an open ingredient port used for manual food product additions. The Ketchup is exposed to the environment through the open port.
- A drain pipe in the basement, adjacent to the (b)(4) tank of in-process Ketchup product. We observed a plastic bag containing an unknown liquid and unknown brown substance hanging from this pipe, and the liquid was dripping from the bag. Employees may track this liquid material to the (b)(4) tank area and (b)(4) tank surface, thus creating a potential for Ketchup contamination.

Church & Dwight Co., Inc.: December 10, 2014

The number of qualified personnel is inadequate to perform and supervise the processing of each drug product.

Specifically impacted has been the local Quality Assurance (QA) and Quality Control (QC) staffs.

- Your laboratory and manufacturing investigations are not being investigated, resolved, written up, and closed in a timely manner. There are over 50 open investigations that have not been closed after 120 days, some have been open for over 328 days.
- Your stability samples analysis has fallen behind. Sample analysis is currently being performed two months after the scheduled pull date.
- In 2014 over (b)(4)% of your QC staff and over (b)(4)% of your QA staff were replaced with temporary employees.

Established laboratory control mechanisms are not documented at the time of performance. Electronic records are used, but they do not meet audit trail requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records. Specifically, your firm is using a combination of paper records and an electronic spreadsheet to initiate and track laboratory deviations and out of specification (OOS) investigations. Unique numbers are not assigned to investigations until after the investigations have been completed. Your system does not allow you to audit whether or not all laboratory deviations and OOSs have been investigated.

Varian Medical Systems, Inc.: November 10, 2015

There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. Your firm has a deficient stability program to include:

- No formal written stability program for each of the OTC drug products you manufacture.
- Long Term Stability testing is not performed up to the assigned expiration date.
- Accelerated stability and long term stability samples are not stored in controlled, humidity conditions.

There shall be written procedures for the production and process controls designed to assure that the drug products have the identity, strength, quality, and purity are represented to possess.
All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. However, it was observed that the review/approval of Batch Records and Certificates of Analyses are not all approved by the Quality Unit.

Merck, Sharp & Dohme Corp.: Feburary 6, 2013

The firm has failed to adequately control mold in manufacturing areas including, but not limited to, mold found in Grades A, B critical environments and in adjacent Grade C areas. There have been no less than 160 incidences of mold investigated in Grade A, B, and C manufacturing areas and for air and water samples between August 2010 and December 2012. The Grade A areas include filling, lyophilization and upstream aseptic processing areas where filtration of product does not take place downstream. The majority of investigation reports do not determine a root cause for the presence of mold. Corrective actions are not always performed and often if performed consist of additional cleaning. However, there is a lack of assurance that cleaning is adequate in that mold continues to be isolated in the facility.

Praxair, Inc.: August 8, 2014

An MDR was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would likely to cause or contribute to a death of serious injury if the malfunction were to recur. Specifically,

- Medwatch report (b)(4) (device malfunction) involved a high pressure oxygen cylinder connected to a class 1 medical device, Vantage Grab N Go Pressure Integrated Regulatory that self-ignited and caused a flash fire that ruptured the oxygen cylinder. This incident occurred on 1/8/12, filed on 1/10/12 and was not reported to the FDA until 11/15/2012.

Procedures for corrective and preventive action have not been adequately established.

- Specifically, your procedure titled Corrective Preventive Action Pois 0.414 revised 6/15/2011 does not require the analysis of audit reports, service reports, and product returns to detect product or system quality issues.
- Corrective Preventive Action (Pois O.414) does not require verification or validation of corrective and preventive actions to ensure corrective or preventive actions do not adversely affect the finished device. In addition, it does not mention to ensure information that relates to quality problems are disseminated to those persons who have direct responsible for areas affected by the change, and to submit relevant quality problems and corrective actions for management review.

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not be adequately established. The written MDR procedure does not include an internal system which provides for standardized review process/procedure for determining when an event meets the criteria for reporting.

The evaluation of potential suppliers and contractors was not documented. Specifically a record of the evaluation of contractors and suppliers of Grab N Go pressure flow regulators was not documented. There is no agreement with contractors to notify you of changes in the product or service. Specifically, as the legal manufacturer of Vantage Grab N' Go Pressure Regulators you do not have an agreement with the contractor to notify of any changes to the product or services prior to implementation.

APPENDIX E

Post-Open Government Initiative FDA Public Disclosure of Outcomes

Figure E.1: Post-Open Government Initiative FDA Public Disclosure of Outcomes

District	Legal Name	City	State	Inspection End Date	Center	Project Area	Classification
ATL	Bausch & Lomb Inc- Greenville Solutions Plant	Greenville	SC	5/12/2009	CDRH	Compliance: Devices	VAI
ATL	GlaxoSmithKline	Durham	NC	6/11/2009	CDER	Bioresearch Monitoring	NAI
NYK	Wal-Mart	Johnstown	NY	1/5/2009	CFSAN	Foodborne Biological Hazards	NAI
LOS	AstraZeneca, PLC	San Diego	CA	9/25/2009	CDER	Bioresearch Monitoring	NAI
KAN	Nestle Purina PetCare Co.	Davenport	IA	1/13/2009	CVM	Monitoring of Marketed Animal Drugs, Feed, and Devices	NAI
CIN	Invacare Corporation	Elyria	OH	12/17/2010	CDRH	Compliance: Devices	OAI
FLA	Neurotronics, Inc.	Gainesville	FL	8/31/2010	CDRH	Postmarket Assurance: Devices	NAI
NYK	Avon Products Inc	Suffern	NY	12/30/2010	CDER	Drug Quality Assurance	VAI
NWJ	Pharmachem Laboratories, Inc.	South Hackensack	NJ	9/27/2010	CFSAN	Food Composition, Standards, Labeling and Econ	NAI
NOL	Pepsi Beverage Co., Inc.	Collierville	TN	1/5/2011	CFSAN	Foodborne Biological Hazards	NAI
NWE	The King Arthur Flour Company, Inc.	White River Junction	VT	1/12/2011	CFSAN	Foodborne Biological Hazards	NAI
SEA	Acme United Corporation	Vancouver	WA	2/8/2011	CDER	Drug Quality Assurance	NAI
PHI	Siemens Healthcare Diagnostics, Inc.	Newark	DE	2/9/2012	CDRH	Compliance: Devices	OAI
NWE	Medtronic	Hopkinton	MA	1/25/2012	CBER	Human Cellular, Tissue, and Gene Therapies	NAI
ATL	Krispy Kreme Doughnut Corporation	Raleigh	NC	1/13/2011	CFSAN	Foodborne Biological Hazards	VAI
BLT	Kraft Foods Group, Inc.	Suffolk	VA	8/31/2011	CFSAN	Foodborne Biological Hazards	NAI
BLT	Nestle Waters North America, Inc	Lorton	VA	8/31/2011	CFSAN	Foodborne Biological Hazards	NAI
DEN	Tronox	Green River	WY	2/14/2013	CDER	Drug Quality Assurance	VAI
KAN	Biomat USA Inc	Topeka	KS	1/31/2013	CBER	Blood and Blood Products	NAI
ATL	Hospira a Pfizer Company	Rocky Mount	NC	11/15/2013	CDRH	Compliance: Devices	OAI
FLA	Vitamins Direct (USA), Inc.	West Palm Beach	FL	8/14/2013	CDER	Drug Quality Assurance	OAI
NWJ	Johnson & Johnson Consumer, Inc.	Skillman	NJ	4/10/2013	CDRH	Compliance: Devices	OAI
DET	Terumo Cardiovascular Systems Corporation	Ann Arbor	MI	2/17/2014	CDRH	Postmarket Assurance: Devices	NAI
LOS	Pharma Tech Solutions, Inc	Westlake Village	CA	3/6/2014	CDRH	Compliance: Devices	OAI
KAN	Kraft Heinz Foods Company	Springfield	MO	1/23/2014	CFSAN	Foodborne Biological Hazards	NAI
MIN	Saputo Cheese USA, Inc.	New London	WI	1/9/2014	CFSAN	Foodborne Biological Hazards	NAI
NYK	Koning Corporation	West Henrietta	NY	5/19/2014	CDRH	Project Evaluation: Devices	NAI
MIN	Cargill, Inc	Parker	SD	1/21/2015	CFSAN	Foodborne Biological Hazards	NAI
MIN	Nestle Dreyers Ice Cream - Holmen DSD	Holmen	WI	3/6/2015	CFSAN	Foodborne Biological Hazards	NAI
DET	Eli Lilly and Company	Indianapolis	IN	2/11/2015	CDER	Postmarket Surv. and Epidemiology	NAI
LOS	3M Espe Dental Products	Irvine	CA	1/15/2015	CDRH	Compliance: Devices	NAI
PHI	Precision Medical, Inc.	Northampton	PA	2/10/2015	CDRH	Compliance: Devices	NAI
NWJ	Elite Laboratories Inc.	Northvale	NJ	2/2/2016	CDER	Postmarket Surv. and Epidemiology	OAI
NYK	AJES Pharmaceuticals LLC	Copiague	NY	3/9/2016	CFSAN	Food Composition, Standards, Labeling and Econ	OAI
NYK	Global Health Products Inc	Rochester	NY	6/22/2016	CFSAN	Foodborne Biological Hazards	NAI
SAN	Medisca Inc	Las Vegas	NV	1/15/2016	CDRH	Postmarket Assurance: Devices	NAI
SAN	BloodSource, Inc.	Merced	CA	1/25/2016	CBER	Blood and Blood Products	NAI
CHI	Grace Analytical Lab Inc	Berkeley	IL	1/30/2017	CFSAN	Colors and Cosmetics Technology	VAI
DAL	Texas Biostetic Instruments	Colleyville	TX	1/24/2017	CDRH	Compliance: Devices	NAI
NWJ	Becton Dickinson & Company	Franklin Lakes	NJ	7/6/2017	CDRH	Compliance: Devices	OAI
SEA	Northwest Fresh Foods LLC	Portland	OR	3/9/2017	CFSAN	Foodborne Biological Hazards	OAI

APPENDIX F

Examples of Securities Class Action Lawsuits

Case: Dendreon Corporation
Filing Date: May 24, 2007
Status: Settled

The complaint filed in the action charges Dendreon and certain of its officers and directors with violations of the Securities Exchange Act of 1934. Dendreon is a biotechnology company focused on the development and commercialization of therapies for cancer. Its most advanced product is Provenge (sipuleucel-T), an active cellular immunotherapy for advanced prostate cancer.

Specifically, the complaint alleges that the defendants made false and misleading statements regarding the progress of the Company's Biologics License Application ("BLA") for Provenge. According to the complaint, the FDA conducted a pre-approval Chemistry, Manufacturing and Controls (CMC) inspection of Dendreon's Hanover, New Jersey manufacturing facility in mid-February 2007 and issued to Dendreon what is known as an FDA Form 483, Inspectional Observations Report, which cited various violations of FDA regulations at the Dendreon facility. Pursuant to FDA regulations, the complaint alleges, the issuance of a Form 483 made it highly likely that FDA approval would be delayed substantially past May 15, 2007, the anticipated FDA review date.

According to the complaint, the defendants repeatedly failed to disclose this information to investors and made false and misleading statements, thereby artificially inflating Dendreon's stock price. The complaint further alleges that certain officers and directors traded on this information without disclosing it to the investing public. The complaint alleges that the Company only began disclosing this information as part of its May 9, 2007 announcement that the FDA had issued a Complete Response letter denying approval for Provenge, which letter cited the same CMC issues allegedly known to the defendants in February. As a result of this disclosure, Dendreon stock lost nearly 70 percent of its market value, causing significant losses to investors.

As summarized by the Company's Form 10-Q, beginning on May 24, 2007, four proposed securities class action suits were filed in the United States District Court for the Western District of Washington, on behalf of purchasers of the Company's common stock, purporting to state claims for securities law violations stemming from our disclosures related to Provenge and the FDA's actions regarding our BLA for Provenge. The complaints seek compensatory damages, attorney's fees and expenses. On October 4, 2007, the Court consolidated these actions under the caption McGuire v. Dendreon Corporation, et al., and designated a lead plaintiff. The lead plaintiff designated the complaint filed June 6, 2007 in McGuire, et al. v. Dendreon Corporation, et al., as the operative complaint. On December 21, 2007, the Company and individual defendants jointly filed a motion to dismiss the complaint. By order dated April 18, 2008, the Court granted the motion to dismiss the complaint, holding that plaintiffs failed to plead a claim against the Company or the individual defendants, and allowing plaintiffs thirty days to file an amended complaint. Plaintiffs filed an amended complaint on June 2, 2008, naming Dendreon, our chief executive officer, and a senior vice president as defendants. Defendants filed a motion to dismiss the amended complaint on July 2, 2008. By order dated December 5, 2008, the Court granted the motion to dismiss the allegations against our chief executive officer based on allegedly false or

misleading statements and his sale of Dendreon stock, and denied the remainder of the motion. The Court gave plaintiffs permission to file an amended complaint to reassert their allegations against our chief executive officer, and plaintiffs filed a second amended complaint on January 5, 2009. Defendants filed a motion to dismiss the second amended complaint on January 29, 2009. On May 21, 2009, the Court issued an order granting in part, and denying in part, defendants' motion to dismiss the second amended complaint, and allowing leave to amend. Plaintiffs filed a third amended complaint on June 8, 2009. On June 29, 2009, defendants filed an answer to the third amended complaint. The parties have commenced discovery, and exchanged initial disclosures on July 22, 2009. Trial in this action has been set for October 18, 2010.

On January 14, 2010, the plaintiffs filed a motion to certify the class.

On May 27, 2010, an Order on Motion For Class Certification was granted by the Court.

On September 17, 2010, a Dismissal Order was issued that this action and all claims asserted were Dismissed with prejudice and without costs to any party.

On February 17, 2012, a Final Judgment and Order of Dismissal with Prejudice was entered by the Court.

On March 9, 2012, Order Approving Payments and Distributions from Settlement Fund was entered onto the Court's docket.

Case: Gliatech, Inc.
Filing Date: September 5, 2000
Status: Settled

By the Order and Final Judgment entered on May 13, 2003, the settlement is approved as fair, reasonable, and adequate and the complaint is dismissed with prejudice.

According to the proposed settlement posted on the site dated March 7, 2003, a settlement of $4,500,000 in cash, with interest, was reached on December 5, 2002. A settlement fairness hearing is set for May 13, 2003 for final approval by the court.

The original complaint alleges, that during the Class Period, defendants violated federal securities laws by issuing to the investing public false and misleading statements and press releases concerning the Company's product ADCON-L, its efficacy and the integrity of the clinical data submitted in support of ADCON-L's Food and Drug Administration ("FDA") approval process.

Further, the complaint alleges that on August 28, 2000, Gliatech, Inc., shocked the investing community by announcing that the Boards of Directors of Gliatech and Guilford agreed to a mutual termination of their Merger Agreement, due to Guilford's decision not to pursue the merger based on the FDA's issuance of inspectional observations contained in a Form 483 report, issued by the FDA to Gliatech on August 23, 2000, which identified certain items pertaining to Gliatech's methods of recording and presenting clinical data for ADCON-L submitted to the FDA. Indeed, it was revealed that doctors told Gliatech of their concerns about ADCON-L, such as inflammation and spinal-fluid leakage, as long as a year and a half ago, and the Company did not investigate the concerns and notify the FDA until March 13, 2000. These disclosures contradicted much of the information provided by defendants to the market during the Class Period and caused the Company's common stock to plummet 59 percent on August 29, 2000, or $15 3/16 to $10 3/16 per share.

NOTE: Gliatech was named a defendant in this Action. On May 9, 2002, Gliatech filed a voluntary petition for protection under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Northern District of Ohio, Eastern Division, Case No. 02-15045. All actions against Gliatech have been stayed by operation of the Bankruptcy laws.

APPENDIX G

Excerpts from Bad Inspection Disclosures

Company: Utah Medical Products, Inc
Date: March 4, 2004
Headline: UTMD Reports Conclusion of FDA Inspection

On February 11, Utah Medical Products, Inc. (NASDAQ: UTMD) publicly disclosed a comprehensive inspection of its Utah facility by three FDA inspectors from Minneapolis, Dallas and Denver which began on February 2.

In response to shareholder questions regarding the status of the inspection, UTMD announces that on March 3, the inspection ended with the presentation of seven observations in a Form FDA-483, which the Company reviewed completely with the inspectors. These observations relate to only 6 of more than 150 subsections of the FDA Quality System Regulation (QSR). UTMD is now preparing a written response to the FDA regarding the observations. The inspection, which consumed 56 inspector-days, reviewed many thousands of pages of quality system documents including device history records, procedures, complaints and complaint investigations, nonconformance reports, deviation/ waivers, corrective action reports, process control records including statistical process control parameters, meeting minutes, bills of operation, set-up sheets, calibration reports, process validation records, sterilization records, test reports including raw data and many other documents. Considering the extent of the inspection, UTMD believes the observations are relatively few, easily explained and some not supportable.

At the conclusion of the 2003 inspection by two inspectors for almost three weeks, UTMD received a FDA-483 with 19 observations which relate to specific subsections of the QSR. These observations were explicitly reviewed again in the present inspection. Some of the key previous observations, for example, alleged lack of proper sterilization validation where the Company's same documentation was available to inspectors in 2002 and 2003 inspections, did not reappear on the current FDA-483.

UTMD believes its longstanding position has been vindicated on the basis that the adequacy of UTMD's QSR procedures that have been in existence for years has been verified. There were no current observations to suggest or support concern about the safety or effectiveness of any devices manufactured and distributed by UTMD. This last statement represents to UTMD the continuing confirmation of the effectiveness of the UTMD Quality System that has been in effect since prior to the 2001 inspection which resulted in an FDA Warning Letter, and consistent with the unqualified ISO certifications UTMD has enjoyed since 1994, long before the FDA modified its GMP regulation to conform with the criteria and objectives of the ISO. The ISO standards are quality system standards used by most countries around the world including the U.S.

UTMD advises that its devices are of state of the art quality preferred in particular by sophisticated clinician users, and that its devices conform to the quality and performance represented by UTMD.

Company: Able Laboratories, Inc.
Date: July 8, 2005
Headline: Able Laboratories, Inc. Receives Inspectional Observations from FDA

Able Laboratories, Inc. (Nasdaq: ABRX) today announced that it had received from the FDA a list of Inspectional Observations (Form FDA 483) made by the agency in connection with the events that led to the recall of its products and suspension of manufacturing operations, previously announced on May 23, 2005. The Form 483, along with the Company's response, will be posted on the Company's web site at http://www.ablelabs.com as soon as the Company files its response with the FDA.

The ongoing disruption in the Company's operations caused by its product recall and the suspension of manufacturing activities has had, and will continue to have, a material adverse effect on the Company's results of operations and financial position. The Company intends to continue to work proactively and cooperatively with the FDA to achieve resolution of the outstanding regulatory issues. Able can give no assurance, though, as to if or when it will be able to resolve the regulatory issues with the FDA or resume manufacturing operations. The Company is continuing to review these and related matters with representatives of the FDA and other government agencies and with its consultants, and is evaluating all potential strategic options available to it in light of the regulatory and financial issues it faces, including the possibility of seeking relief under the bankruptcy laws.

Company: CryoLife, Inc.
Date: October 20, 2003
Headline: CryoLife to Respond to Recent FDA Inspection Observation

CryoLife, Inc. (NYSE: CRY), announced today its commitment to promptly respond to an observation made in a recent FDA inspection report (Form 483). The observation requires CryoLife to complete the validation of its processing operations and procedures for decontaminating tissues, written procedures for the prevention of infectious disease contamination during processing, and its anti-microbial solution.

"CryoLife is committed to ensuring the quality and safety of our tissues, making continual improvements to our tissue processing, and fulfilling all FDA requirements and expectations," stated Tom Lynch, VP Regulatory Affairs and Quality Assurance. "The Company will begin its validation study on October 21st and plans to have it completed by year-end. The Company also plans to apply appropriate corrective actions to all processes, procedures and quality systems."

Company: Guidant
Date: September 22, 2005
Headline: Guidant Announces Completion of FDA Inspection of St. Paul Facilities and Responds to FDA's Observations; Company Continues to Work with Stakeholders to Establish Industry Standards for Communicating Device Performance

Guidant (NYSE:GDT) announced today that the U.S. Food and Drug Administration (FDA) has completed its inspection of Guidant's Cardiac Rhythm Management facilities in St. Paul, Minnesota, and has provided Guidant a Form 483, noting several observations of non-compliance, including an observation with commentary on two specific trends in its INSIGNIA(R) and NEXUS(R) families of pacemakers.

Guidant has provided the FDA with a thorough written response to the observations, describing the steps that Guidant has taken and will be taking to address the FDA's observations. In connection with its response, Guidant is issuing a physician communication on two specific trends in its INSIGNIA and NEXUS families of pacemakers. A copy of the physician communication can be found at http://www.guidant.com/physician_communications/insignia-nexus.pdf.

Guidant has taken action to increase the flow of information to physicians and patients on device performance. Recently, Guidant Cardiac Rhythm Management (CRM) published its 2005 Product Performance Report, which may be reviewed at http://www.guidant.com/physician/product_performance_report.pdf. This report includes more specific information than was contained in past such reports. A further enhancement to this report is planned by the end of the year.

In addition, Guidant has now provided physicians with Advisory Updates on its PRIZM(R) 2 DR and CONTAK RENEWAL(R) and RENEWAL 2 devices which were subject to Physician Advisories previously communicated in June. The Advisory Updates include updated rate of occurrence information and results from returned product testing. The Advisory Updates may be found at http://www.guidant.com/physician_communications/.

"Our efforts to provide product performance information in increasing quantity and frequency to physicians and patients is well-underway," said Fred McCoy, president, Cardiac Rhythm Management, Guidant Corporation. "We will work closely with physicians, patients, the Heart Rhythm Society (HRS) and other industry participants and stakeholders on the broad issues highlighted at the recent HRS Policy Conference on Pacemaker and ICD Performance."

Guidant recently announced the formation of an Independent Panel, chaired by Dr. Robert J. Myerburg, Professor of Medicine and Physiology at the University of Miami, to report on ways that Guidant can further enhance capabilities in understanding, detecting and disseminating important product performance information. In addition, the Panel will make public its non-proprietary observations and recommendations regarding these issues that may be useful to others in the device industry, regulatory bodies, and clinical community. The Panel held its first meeting last month. The Panel's goal is to present its complete report within six months.

Company: Eli Lilly and Company
Date: December 19, 2001
Headline: Lilly Reports on Status of FDA Manufacturing Reinspection; Lilly and FDA Discussing New Form 483 Observations and Quality Improvement

Eli Lilly and Company (NYSE:LLY) reported today on the status of the U.S. Food and Drug Administration's (FDA) reinspection of certain Lilly manufacturing facilities in Indianapolis in connection with pending new product approvals for Zyprexa(R) IntraMuscular and Forteo(TM). The FDA has issued a Form 483 outlining 50 additional observations, primarily relating to computer system validation, manufacturing process reviews, and data handling. The company has provided responses to the FDA relative to these observations and, last week, met with agency officials to discuss its plans to address the issues raised.

The approval of Zyprexa IntraMuscular and Forteo as well as additional new products continues to be dependent on resolution of all manufacturing issues to the agency's satisfaction. Therefore, the Zyprexa IntraMuscular and Forteo launch dates are uncertain. Although the timeline for resolution of the issues is difficult to predict, based on information available at this time, the company continues to plan for the launch of Cialis(TM); duloxetine for the treatment of depression, which was recently submitted to the FDA; and atomoxetine beginning in the second half of 2002. The company reiterated its 2002 earnings-per-share expectations of $2.70 to $2.80 and continues to target high-teen earnings-per-share growth for 2003.

"We are absolutely dedicated to achieving the highest standards of quality in order to support the industry's strongest late-stage pipeline," said Sidney Taurel, Lilly chairman, president and chief executive officer. "Therefore, I am committing all the necessary resources of the company to address these issues. We will continue to work closely with the FDA in order to deliver on our promise to bring these innovative new medicines to patients as quickly as possible."

Company: Osteotech, Inc.
Date: October 7, 2001
Headline: Osteotech Announces Completion of FDA Inspection; Resumption of Tissue Processing on Schedule

Osteotech, Inc. (Nasdaq: OSTE) announced today that the Food and Drug Administration ("FDA") completed its inspection on October 4, 2002 relating to the Company's voluntary and temporary suspension of certain of its tissue processing operations and retrieval of certain Base Tissue Segment donor tissue. The Company remains on schedule to resume its tissue processing operations in both of its facilities as previously reported.

At the conclusion of the inspection, the FDA made two observations in a Form 483, which is a document issued during the exit meeting with the Company that specifies objectionable conditions and practices noted by the FDA investigator. The first observation, which contained several sub-parts, related to the preparation, validation and following of written procedures to prevent contamination of tissue during processing. The second observation focused on the specificity of record keeping.

The Company will be putting in place the necessary corrective action programs to address the observations made by the FDA. As stated in the Company's conference call on October 1, 2002 and again in our press release on October 3, 2002, there is no requirement to obtain a license or approval from the FDA before operations at the Shrewsbury or Eatontown facilities can restart. However, some changes to our procedures or systems will be made before operations commence in these facilities. The Company believes that the observations made in the FDA's Form 483, and the corrective actions to be undertaken by the Company, will not prevent the Company from restarting operations at both of the facilities within the timeframes already reported.

Richard W. Bauer, Osteotech's President and Chief Executive Officer commented, "Throughout the Company's 16 year history, we have been inspected by the FDA many times and never received a Form 483 observation. We recognize the seriousness of such an event and are committed to resolving all the issues for which we were cited." Mr. Bauer concluded by saying, "We believe the Company exercised the proper judgment and caution in voluntarily suspending tissue processing and retrieving tissue that had been shipped to clients even though it had passed final sterility testing. We look forward to resuming our processing operations shortly, so we can continue to serve our hospital and surgeon customers and, just as importantly, our tissue recovery clients who have been very supportive of Osteotech during this difficult time."

TABLES

Table 1: Sample Selection and Characteristics

Panel A: Sample Selection Procedures

Total number of firms on SRO list that link to Compustat, CRSP, and IBES	1,107
Total number of firms subject to inspection during my sample period	497
Total number of firms subject to inspection in the pre-period and with required data	189
Total number of firm-inspection observations	4,391
Total number of firms subject to inspection in the post-period and with required data	288
Total number of firm-inspection observations	6,509

Panel B: Inspections by Year

Year	Number	Percent
Pre-Period		
2004	877	8.05
2005	877	8.05
2006	827	7.59
2007	916	8.40
2008	894	8.20
Post-Period		
2011	743	6.82
2012	1,051	9.64
2013	1,224	11.23
2014	1,134	10.40
2015	1,175	10.78
2016	1,182	10.84
Total	10,900	100.00

Panel C: Inspections by FDA Center

Center	Number	Percent
Animal Drugs & Feeds	1,283	11.77
Biologics	429	3.94
Foods & Cosmetics	3,953	36.27
Human Drugs	3,122	28.64
Medical Devices & Radiological Health	2,101	19.28
Tobacco Products	10	0.09
Other	2	0.02
Total	10,900	100.00

Table 2: Summary Statistics

This table presents descriptive statistics for my primary sample, which spans from the beginning of 2004 to the Introduction of the Open Government Initiative in January 2009. All continuous, non-logarithmic variables are winsorized at the 1 percent and 99 percent levels. Variables are defined in Appendix A.

Variable	N	Mean	Std Dev	P25	Median	P75
Disclose_i	4,391	0.22	0.41	0.00	0.00	0.00
Disclose_n	4,391	0.36	0.82	0.00	0.00	0.00
Bad Inspection	4,391	0.33	0.47	0.00	0.00	1.00
Size	4,391	8.71	1.84	7.67	9.15	9.94
ROA	4,391	0.02	0.03	0.01	0.02	0.03
Loss	4,391	0.09	0.28	0.00	0.00	0.00
MTB	4,391	3.82	4.26	1.85	2.78	4.84
Analyst Following	4,391	2.06	1.24	1.10	2.48	3.00
Returns	4,391	0.01	0.14	−0.06	0.01	0.09
Returns Volatility	4,391	0.02	0.01	0.01	0.01	0.02
Other Bad News	4,391	0.26	0.44	0.00	0.00	1.00

Table 3: Association between Inspection Outcomes and Voluntary Disclosure Choices

This table reports the results from estimating Equation 1. In Columns (1), (3), (5), and (7), the dependent variable is *Disclose_i*, which is an indicator equal to one if the firm issues an 8-K or press release related to FDA inspections in the three months following the inspection. In Columns (2), (4), (6), and (8), the dependent variable is *Disclose_n*, which is the sum of 8-Ks and press releases covering FDA inspection topics issued by the firm in the three months following the inspection. In Columns (1) to (6), I use the full unmatched sample to estimate the specification. In Columns (7) and (8), I use an entropy balanced sample to estimate the model. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

		No Matching						Entropy Balanced	
		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Prediction	Disclose_i	Disclose_n	Disclose_i	Disclose_n	Disclose_i	Disclose_n	Disclose_i	Disclose_n
Bad Inspection	+	0.106***	0.247***	0.0920***	0.224***	0.0396***	0.121***	0.0431***	0.131***
		(0.0267)	(0.0562)	(0.0230)	(0.0461)	(0.0127)	(0.0375)	(0.0125)	(0.0276)
Size				0.0785***	0.157***	-0.0311	-0.186	-0.0288	-0.214***
				(0.0288)	(0.0552)	(0.0813)	(0.225)	(0.0328)	(0.0760)
ROA				0.675	0.337	0.475	0.598	0.513	0.651
				(0.696)	(1.538)	(0.642)	(1.346)	(0.369)	(0.721)
Loss				0.201***	0.250**	0.0867**	0.0380	0.0933***	0.0397
				(0.0505)	(0.101)	(0.0384)	(0.0820)	(0.0339)	(0.0651)
MTB				0.00396	0.00664	-0.00201*	-0.00438	-0.00348**	-0.00926***
				(0.00505)	(0.00941)	(0.00119)	(0.00377)	(0.00175)	(0.00281)
Analyst Following				0.0291	0.0305	0.00216	0.00139	0.00248	0.00194
				(0.0307)	(0.0550)	(0.00272)	(0.00587)	(0.00774)	(0.0191)
Returns				0.0517	0.131	0.0746	0.155	0.0741	0.152
				(0.0591)	(0.246)	(0.0655)	(0.244)	(0.0512)	(0.105)
Returns Volatility				4.942**	10.27	3.778	8.899	6.110***	13.11***
				(2.210)	(6.478)	(3.233)	(9.971)	(1.210)	(3.140)
Other Bad News				-0.0162	-0.0135	-0.00101	0.0508	0.00290	0.0634
				(0.0296)	(0.0483)	(0.0161)	(0.0443)	(0.0174)	(0.0387)
N		4391	4391	4391	4391	4391	4391	4391	4391
R^2		0.015	0.020	0.138	0.125	0.470	0.441	0.473	0.438
Firm FE		N	N	N	N	Y	Y	Y	Y
Industry-Year FE		N	N	N	N	Y	Y	Y	Y
Quarter FE		N	N	N	N	Y	Y	Y	Y

Table 4: Cross-sectional Analysis – Litigation

This table reports the results from estimating Equation 1 with high- and low-litigation risk subsamples. In Panel A, litigation risk is measured using SIC codes. An observation is allocated to the high-risk subsample if the firm belongs to an SIC industry identified by Francis et al. [1994]. All other SIC codes are assigned to the low-risk subsample. In Panel B, I split the data based on my estimation of model (3) in Kim and Skinner [2012], which captures a quarterly measure of ex ante litigation risk. If an observation has a predicted value higher (lower) than the pre-period model median, it is classified as high (low) risk. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the High partition is significantly different from the same coefficient in the Low partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. *, **, and *** represent significance at the 10%, 5%, and 1% levels, respectively.

Panel A: Litigation Risk Based on Francis et al. [1994] Industry Membership

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	+	0.0729***	0.00993	0.195***	0.0485
		(0.0236)	(0.0136)	(0.0557)	(0.0315)
N		1641	2750	1641	2750
R^2		0.433	0.500	0.408	0.502
Test Coefficients	High>Low	p-value=0.007		p-value=0.006	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Panel B: Litigation Risk Based on Ex-Ante Predicted Probability Estimate from Kim and Skinner [2012]

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	+	0.0530***	0.0118	0.165***	0.0287
		(0.0176)	(0.0197)	(0.0485)	(0.0308)
N		2384	1918	2384	1918
R^2		0.463	0.540	0.426	0.575
Test Coefficients	High>Low	p-value=0.048		p-value=0.005	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 5: Cross-sectional Analysis – Materiality of Inspections

This table reports the results from estimating Equation 1 with high- and low-materiality subsamples. An inspection is assigned to the high-materiality subset if it relates to Medical Devices and Radiological Health, Biologics, Human Drugs. Conversely, an inspection is allocated to the low-materiality subset if it relates to Animal Drugs and Feeds, Foods and Cosmetics, Tobacco Products, or Other. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the High partition is significantly different from the same coefficient in the Low partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. *, **, and *** represent significance at the 10%, 5%, and 1% levels, respectively.

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	+	0.0533***	0.00307	0.158***	0.00255
		(0.0176)	(0.0123)	(0.0464)	(0.0128)
N		2345	2017	2345	2017
R^2		0.407	0.494	0.384	0.657
Test Coefficients	High>Low	p-value=0.020		p-value=0.003	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 6: Cross-sectional Analysis – Severity of Inspections

This table reports the results from estimating Equation 1 with high- and low-severity subsamples. An inspection is classified as high severity if its duration is longer than four days or if its staffing involves more than one FDA employee. Any observations not meeting either criteria are assigned to the low partition. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the High partition is significantly different from the same coefficient in the Low partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	+	0.0487**	0.0169	0.170***	0.0659*
		(0.0212)	(0.0170)	(0.0574)	(0.0389)
N		1896	2379	1896	2379
R^2		0.473	0.467	0.434	0.428
Test Coefficients	High>Low	p-value=0.097		p-value=0.034	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 7: Regime Shift

This table compares pre- and post-regime shift disclosure choices. Panel A presents the results from estimating Equation 1, augmented with a *Post* variable. *Post* is an indicator variable equal to one if the inspection occurs after May 26, 2011, and zero otherwise. Columns (1) and (2) use an unmatched sample for estimation, and columns (3) and (4) use an entropy-balanced sample. The Test Sum and Test P-Value rows report the results of testing whether the sum of *Bad Inspection* and *Bad Inspection*×*Post* is significantly different from zero. Panel B presents the results from estimating a fully interacted Equation 1 with pre- and post-regime shift samples. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the Pre-Period partition is significantly different from the same coefficient in the Post-Period partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

Panel A: Regime Shift Specification with Post Interaction

		No Matching		Entropy Balanced	
		(1)	(2)	(3)	(4)
	Prediction	*Disclose_i*	*Disclose_n*	*Disclose_i*	*Disclose_n*
Bad Inspection	+	0.0295**	0.107***	0.0303**	0.122***
		(0.0142)	(0.0398)	(0.0129)	(0.0286)
Bad Inspection×*Post*	–	-0.0375**	-0.0935*	-0.0370**	-0.120***
		(0.0181)	(0.0533)	(0.0163)	(0.0378)
N		10900	10900	10900	10900
R^2		0.451	0.460	0.464	0.466
Test Sum F-Stat		0.44	0.36	0.46	0.01
Test Sum P-Value		0.507	0.551	0.450	0.940
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Panel B: Fully Interacted Model and Coefficient Comparison

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	Pre-Period	Post-Period	Pre-Period	Post-Period
Bad Inspection	+	0.0396***	-0.00304	0.121***	0.0145
		(0.0127)	(0.0108)	(0.0375)	(0.0240)
N		4391	6509	4391	6509
R^2		0.470	0.493	0.441	0.532
Test Coefficients	Pre-Period>Post-Period	p-value=0.013		p-value=0.004	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 8: Regime Shift Cross-sectional Analysis – Litigation

This table reports the results from estimating Equation 1, in the post-period, with high- and low-litigation risk subsamples. In Panel A, litigation risk is measured using SIC codes. An observation is allocated to the high-risk bucket if the firm belongs to an SIC industry identified by Francis et al. [1994]. All other SIC codes are assigned to the low-risk subsample. In Panel B, I estimate a quarterly measure of ex ante litigation risk following model (3) in Kim and Skinner [2012]. If an observation has a predicted value higher (lower) than the post-period model median, it is classified as high (low) risk. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the High partition is significantly different from the same coefficient in the Low partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

Panel A: Litigation Risk Based on Francis et al. [1994] Industry Membership

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	+	0.0128	-0.0149	0.0528	-0.0149
		(0.0194)	(0.0124)	(0.0380)	(0.0273)
N		2123	4386	2123	4386
R^2		0.479	0.369	0.488	0.394
Test Coefficients	High>Low	p-value=0.113		p-value=0.082	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Panel B: Litigation Risk Based on Ex-Ante Predicted Probability Estimate from Kim and Skinner [2012]

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	+	0.0113	-0.0109	0.0522	-0.0315
		(0.0155)	(0.0143)	(0.0342)	(0.0265)
N		3343	3060	3343	3060
R^2		0.530	0.474	0.543	0.466
Test Coefficients	High>Low	p-value=0.170		p-value=0.041	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 9: Timeliness of Disclosure

This table reports on the timeliness of management's voluntary disclosure decisions. Panel A presents the results of estimating Equation 1, with *Days* as the dependent variable. Column (1) reports the results of using an unmatched sample to estimate the specification, and column (2) uses an entropy-balanced sample. Panel B presents the results of litigation-based cross-sectional tests. Columns (1) and (2) use SIC codes to measure litigation risk. An observation is allocated to the high-risk subsample if the firm belongs to an SIC industry identified by Francis et al. [1994]. All other SIC codes are assigned to the low-risk subsample. Columns (3) and (4) I split the data based on my estimation of model (3) in Kim and Skinner [2012], which captures a quarterly measure of ex ante litigation risk . If an observation has a predicted value higher (lower) than the pre-period model median, it is classified as high (low) risk. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the High partition is significantly different from the same coefficient in the Low partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

Panel A: Pooled Timeliness Tests

		No Matching	Entropy Balanced
		(1)	(2)
	Prediction	*Days*	*Days*
Bad Inspection	–	-2.794**	-2.764***
		(1.176)	(0.842)
N		4369	4369
R^2		0.402	0.399
Controls		Y	Y
Firm FE		Y	Y
Industry-Year FE		Y	Y
Quarter FE		Y	Y

Panel B: Cross-sectional Litigation Timeliness Tests

		SIC Membership		Ex Ante Litigation Risk	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	–	-5.230**	-0.703	-3.879**	-0.404
		(2.363)	(1.014)	(1.849)	(1.032)
N		1628	2741	2363	1917
R^2		0.366	0.436	0.402	0.480
Test Coefficients	High<Low	p-value=0.005		p-value=0.027	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 10: Cross-sectional Analysis – Career Concerns

This table reports the results from estimating Equation 1 with high- and low-career concerns subsamples. An observation is allocated to the high-career concerns subset if it meets any one of the following criteria: (1) the CEO was hired from outside of the firm, (2) the CEO was hired in the past year, (3) the CEO is young (i.e. the CEO is 52 years old or younger, which represents an age in the lower quartile of the sample), or (4) the CEO is retiring (i.e., the CEO is 63 years old or older). All other observations are assigned to the low-career concerns subsample. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the High partition is significantly different from the same coefficient in the Low partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	?	0.0422*	0.0411***	0.126**	0.129***
		(0.0213)	(0.0132)	(0.0617)	(0.0335)
N		1873	2467	1873	2467
R^2		0.512	0.492	0.485	0.486
Test Coefficients	?	p-value=0.478		p-value=0.469	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 11: Cross-sectional Analysis – Weak Governance

This table reports the results from estimating Equation 1 using subsamples of data with and without indicators of weak governance. In Panel A, an observation is assigned to the Yes subset if the firm's CEO is also the Chairman of the Board, and No otherwise. In Panel B, an observation is allocated to the Yes subset if the firm's CEO is also on the Board of Directors, and No otherwise. The Test Coefficients row reports whether the coefficient on *Bad Inspection* in the Yes partition is significantly different from the same coefficient in the No partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

Panel A: Dual CEO-Chairman

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	Yes	No	Yes	No
Bad Inspection	?	0.0239*	0.0492**	0.0742**	0.164***
		(0.0139)	(0.0190)	(0.0296)	(0.0517)
N		2552	1781	2552	1781
R^2		0.505	0.533	0.463	0.535
Test Coefficients	?	p-value=0.158		p-value=0.054	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Panel B: CEO on the Board of Directors

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	Yes	No	Yes	No
Bad Inspection	?	0.0322**	0.0648***	0.112**	0.140***
		(0.0156)	(0.0205)	(0.0432)	(0.0293)
N		3313	1035	3313	1035
R^2		0.481	0.535	0.449	0.566
Test Coefficients	?	p-value=0.155		p-value=0.391	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 12: Cross-sectional Analysis – Financing Incentives

This table reports the results from estimating Equation 1 with high- and low-financing incentives subsamples. An observation is assigned to the high financing incentives partition if the firm issues equity or debt in the three months following the inspection end date. If the firm does complete an equity or debt offering, then the observation is allocated to the low incentives partition. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

		Disclose_i		*Disclose_n*	
		(1)	(2)	(3)	(4)
	Prediction	High	Low	High	Low
Bad Inspection	?	0.0390**	0.0382***	0.133***	0.0773**
		(0.0165)	(0.0138)	(0.0456)	(0.0340)
N		2894	1450	2894	1450
R^2		0.489	0.466	0.459	0.480
Test Coefficients	?	p-value=0.465		p-value=0.155	
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 13: Cross-sectional Analysis – Insider Trading

This table reports the results from estimating Equation 1 with dependent variables that capture opportunistic insider trades. In column (1), the dependent variable is *Insider Trade*, which is an indicator variable equal to one if an opportunistic trade, as defined by Cohen et al. [2012], is executed in the three month disclosure window, and zero otherwise. In column (2), the dependent variable is *Insider Trade*, but the estimation sample is restricted to non-disclosers. In column (3), the dependent variable is *Strategic Sale*, which is an indicator variable equal to one if an opportunistic inside sale occurs before a disclosure and within three months of the inspection end date, and zero otherwise. In column (4), the dependent variable is *Strategic Purchase*, which is an indicator variable equal to one if an opportunistic inside purchase occurs after a disclosure and within three months of the inspection end date, and zero otherwise. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

		(1)	(2)	(3)	(4)
	Prediction	*Insider Trade*	*Insider Trade*	*Strategic Sale*	*Strategic Purchase*
Bad Inspection	?	-0.0146	-0.00579	-0.0118	-0.000834
		(0.0128)	(0.0136)	(0.0146)	(0.00215)
N		4391	3427	4391	4391
R^2		0.597	0.639	0.536	0.113
Controls		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

Table 14: Changes Specification

This table reports the results from estimating Equation 1 with change variables. Columns (1) and (2) calculate change as the value for the current quarter minus the value from the prior quarter. Columns (3) and (4) calculate change as the value for the current quarter minus the value from the same quarter in the prior year. Variable definitions are provided in Appendix A. All continuous variables are winsorized at the 1% and 99% levels. Standard errors are clustered by firm and reported in parentheses. ***, **, and * represent significance at the 10%, 5%, and 1% levels, respectively.

		Prior Quarter		Same Quarter Prior Year	
		(1)	(2)	(3)	(4)
	Prediction	$\Delta Disclosure\_i$	$\Delta Disclosure\_n$	$\Delta Disclosure\_i$	$\Delta Disclosure\_n$
Bad Inspection	+	0.0396***	0.115***	0.0436***	0.117***
		(0.0122)	(0.0370)	(0.0129)	(0.0383)
N		4372	4372	4363	4363
R^2		0.578	0.677	0.553	0.623
Δ Controls		Y	Y	Y	Y
Lagged Disclosure Level		Y	Y	Y	Y
Firm FE		Y	Y	Y	Y
Industry-Year FE		Y	Y	Y	Y
Quarter FE		Y	Y	Y	Y

BIBLIOGRAPHY

ABOODY, D. AND R. KASZNIK (2000): "CEO stock option awards and the timing of corporate voluntary disclosures," *Journal of Accounting and Economics*, 29, 73 – 100.

AJINKYA, B., S. BHOJRAH, AND P. SENGUPTA (2005): "The Association between Outside Directors, Institutional Investors and the Properties of Management Earnings Forecasts," *Journal of Accounting Research*, 43, 343–376.

AKIN GUMP STRAUSS HAUER & FELD LLP (2017): "A Client's Guide to FDA Inspections," https://www.akingump.com/images/content/6/0/v2/60179/DRAFT-2-FDA-Inspections-LETTER-Brochure-090517.pdf Accessed October 27, 2018.

ALTONJI, J., T. E. ELDER, AND C. R. TABER (2005): "Selection on Observed and Unobserved Variables: Assessing the Effectiveness of Catholic Schools," *Journal of Political Economy*, 113, 151–184.

ANANTHARAMAN, D. AND Y. ZHANG (2011): "Cover Me: Managers' Responses to Changes in Analyst Coverage in the Post-Regulation FD Period," *The Accounting Review*, 86, 1851–1885.

ANILOWSKI, C., M. FENG, AND D. J. SKINNER (2007): "Does earnings guidance affect market returns? The nature and information content of aggregate earnings guidance," *Journal of Accounting and Economics*, 44, 36 – 63.

BAGINSKI, S. P., J. L. CAMPBELL, L. A. HINSON, AND D. S. KOO (2018): "Do Career Concerns Affect the Delay of Bad News Disclosure?" *The Accounting Review*, 93, 61–95.

BAGINSKI, S. P., J. M. HASSELL, AND M. D. KIMBROUGH (2002): "The Effect of Legal Environment on Voluntary Disclosure: Evidence from Management Earnings Forecasts Issued in U.S. and Canadian Markets." *Accounting Review*, 77, 25.

BALAKRISHNAN, K., M. B. BILLINGS, B. KELLY, AND A. LJUNGQVIST (2014): "Shaping Liquidity: On the Causal Effects of Voluntary Disclosure," *The Journal of Finance*, 69, 2237–2278.

BAO, D., Y. KIM, G. M. MIAN, AND L. N. SU (2019): "Do Managers Disclose or Withhold Bad News? Evidence from Short Interest," *The Accounting Review*, 94, 1–26.

BARTH, M. E., W. R. LANDSMAN, M. LANG, AND C. WILLIAMS (2012): "Are IFRS-based and US GAAP-based accounting amounts comparable?" *Journal of Accounting and Economics*, 54, 68 – 93.

BILLINGS, M. B. AND M. C. CEDERGREN (2015): "Strategic silence, insider selling and litigation risk," *Journal of Accounting and Economics*, 59, 119 – 142.

BLACKBURNE, T., J. D. KEPLER, P. J. QUINN, AND D. J. TAYLOR (Forthcoming): "Undisclosed SEC Investigations," *Management Science*.

BROCKMAN, P., I. K. KHURANA, AND X. MARTIN (2008): "Voluntary disclosures around share repurchases," *Journal of Financial Economics*, 89, 175 – 191.

CAO, Z. AND G. S. NARAYANAMOORTHY (2011): "The Effect of Litigation Risk on Management Earnings Forecasts," *Contemporary Accounting Research*, 28, 125–173.

CASSELL, C. A., S. X. HUANG, AND J. M. SANCHEZ (2013): "Forecasting without Consequence? Evidence on the Properties of Retiring CEOs' Forecasts of Future Earnings," *The Accounting Review*, 88, 1909–1937.

CERULEAN ASSOCIATES LLC (2011): "FDA 15-Day Post-Inspection Response Window Produces Panic or Success," https://ceruleanllc.com/article/fda-15-day-inspection-response-window/ Accessed on July 10, 2020.

CHEN, S., D. MATSUMOTO, AND S. RAJGOPAL (2011): "Is silence golden? An empirical analysis of firms that stop giving quarterly earnings guidance," *Journal of Accounting and Economics*, 51, 134 – 150.

CHEN, T. (2018a): "What's the Big Deal with Form FDA 483s?" https://blog.fdazilla.com/2018/10/pharma-medical-devices-fsma-whats-the-big-deal-with-form-fda-483s/ Accessed April 10, 2018.

——— (2018b): "A Bad 483 Could Cost a Company Millions," https://blog.fdazilla.com/2018/08/what-does-getting-an-483-or-warning-letter-really-cost-you/ Accessed April 11, 2018.

——— (2018c): "Who Can See Form FDA 483s, and Where Do I Get Them?" https://blog.fdazilla.com/2018/07/who-can-see-form-fda-483s-and-where-do-i-get-them/ Accessed April 10, 2018.

CHENG, Q. AND K. LO (2006): "Insider Trading and Voluntary Disclosures," *Journal of Accounting Research*, 44, 815–848.

CLEMENT, M., R. FRANKEL, AND J. MILLER (2003): "Confirming Management Earnings Forecasts, Earnings Uncertainty, and Stock Returns," *Journal of Accounting Research*, 41, 653–679.

COHEN, L., C. MALLOY, AND L. POMORSKI (2012): "Decoding Inside Information," *The Journal of Finance*, 67, 1009–1043.

DECHOW, P. M., R. G. SLOAN, AND A. P. SWEENEY (1996): "Causes and Consequences of Earnings Manipulation: An Analysis of Firms Subject to Enforcement Actions by the SEC*," *Contemporary Accounting Research*, 13, 1–36.

DESAI, H., C. E. HOGAN, AND M. S. WILKINS (2006): "The Reputational Penalty for Aggressive Accounting: Earnings Restatements and Management Turnover," *The Accounting Review*, 81, 83–112.

DUFLO, E., M. GREENSTONE, R. PANDE, AND N. RYAN (2013a): "What Does Reputation Buy? Differentiation in a Market for Third-Party Auditors," *The American Economic Review*, 103, 314–319.

——— (2013b): "Truth-telling by Third-party Auditors and the Response of Polluting Firms: Experimental Evidence from India*," *The Quarterly Journal of Economics*, 128, 1499–1545.

——— (2018): "The Value of Discretion in the Enforcement of Regulation: Experiment Evidence and Structural Estimates from Environmental Inspections in India," Working Paper.

DYE, R. (2013): "Voluntary Disclosure and Duty to Disclose," Working Paper.

DYE, R. A. (1985): "Disclosure of Nonproprietary Information," *Journal of Accounting Research*, 23, 123–145.

——— (2017): "Optimal disclosure decisions when there are penalties for nondisclosure," *The RAND Journal of Economics*, 48, 704–732.

EINHORN, E. AND A. ZIV (2008): "Intertemporal Dynamics of Corporate Voluntary Disclosures," *Journal of Accounting Research*, 46, 567–589.

ENACHE, L., L. LI, AND E. RIEDL (2018): "The Disclosure of Good versus Bad News: Evidence from the Biotech Industry," Working Paper.

ERTIMUR, Y., E. SLETTEN, AND J. SUNDER (2014): "Large shareholders and disclosure strategies: Evidence from IPO lockup expirations," *Journal of Accounting and Economics*, 58, 79 – 95.

FAMA, E. F. AND M. C. JENSEN (1983): "Separation of Ownership and Control," *The Journal of Law and Economics*, 26, 301–325.

FDAZILLA (2020): "About Us," https://govzilla.com/about/ Accessed on July 9, 2020.

FEELEY, J., C. DOLMETSCH, AND J. FINEMAN (2018): "Akorn Plunges After Judge Backs Fresenius Exit From Deal," https://www.bloomberg.com/news/articles/2018-10-01/akorn-fresenius-ruling-template-hold-for-feeley-greenlight Accessed October 29, 2018.

FIELD, L., M. LOWRY, AND S. SHU (2005): "Does disclosure deter or trigger litigation?" *Journal of Accounting and Economics*, 39, 487 – 507.

FOOD AND D. ADMINISTRATION (2018): "What does FDA inspect?" https://www.fda.gov/aboutfda/transparency/basics/ucm194888.htm Accessed April 10, 2018.

FOOD AND DRUG ADMINISTRATION (2011): "Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data," http://wayback.archive-it.org/7993/20171101215210/https://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212110.pdf Accessed on June 8, 2020.

——— (2017a): "FDA at a Glance," https://www.fda.gov/media/104402/download July 9, 2020.

——— (2017b): "FDA Transparency Initiative Overview," https://www.fda.gov/about-fda/transparency/transparency-initiative Accessed on June 8, 2020.

——— (2018): "Listing of Significantly Regulated Organizations," https://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm079670.htm Accessed on April 10, 2018.

——— (2018a): "Laws Enforced by FDA," https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/default.htm Accessed: October 29, 2018.

——— (2018c): "Inspection Citation," https://www.fda.gov/ICECI/Inspections/ucm346077.htm Accessed April 7, 2018.

——— (2020a): "Inspections Database Frequently Asked Questions," https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions#updates Accessed: July 9, 2020.

——— (2020b): "VAI 90 Day Decisional Letter," https://www.fda.gov/media/113124/download Accessed: July 9, 2020.

FRANCIS, J., D. PHILBRICK, AND K. SCHIPPER (1994): "Shareholder Litigation and Corporate Disclosures," *Journal of Accounting Research*, 32, 137–164.

FRENKEL, S., I. GUTTMAN, AND I. KREMER (2018): "The Effect of Exogenous Information on Voluntary Disclosure and Market Quality," Working Paper.

GARGANO, A., A. G. ROSSI, AND R. WERMERS (2016): "The Freedom of Information Act and the Race Toward Information Acquisition," *The Review of Financial Studies*, 30, 2179–2228.

GE, R. AND C. LENNOX (2010): "Do acquirers disclose good news or withhold bad news when they finance their acquisitions using equity?" *Review of accounting studies*, 16, 183–217.

GIBBONS, R. AND K. J. MURPHY (1992): "Optimal Incentive Contracts in the Presence of Career Concerns: Theory and Evidence," *Journal of Political Economy*, 100, 468–505.

GILLAN, S. L., J. C. HARTZELL, AND R. PARRINO (2009): "Explicit versus Implicit Contracts: Evidence from CEO Employment Agreements," *The Journal of Finance*, 64, 1629–1655.

GOVERNMENT ACCOUNTABILITY OFFICE (2009): "FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs," https://www.gao.gov/new.items/d09581.pdf Accessed October 29, 2018.

GRAHAM, J. R., C. R. HARVEY, AND S. RAJGOPAL (2005): "The economic implications of corporate financial reporting," *Journal of Accounting and Economics*, 40, 3 – 73.

GROSSMAN, S. J. (1981): "The Informational Role of Warranties and Private Disclosure about Product Quality," *The Journal of Law & Economics*, 24, 461–483.

GROSSMAN, S. J. AND O. D. HART (1980): "Takeover Bids, The Free-Rider Problem, and the Theory of the Corporation," *The Bell Journal of Economics*, 11, 42–64.

HAINMUELLER, J. (2012): "Entropy Balancing for Causal Effects: A Multivariate Reweighting Method to Produce Balanced Samples in Observational Studies," *Political Analysis*, 20, 25–46.

HAZARIKA, S., J. M. KARPOFF, AND R. NAHATA (2012): "Internal corporate governance, CEO turnover, and earnings management," *Journal of Financial Economics*, 104, 44 – 69.

HERMALIN, B. E. AND M. S. WEISBACH (1998): "Endogenously Chosen Boards of Directors and Their Monitoring of the CEO," *The American Economic Review*, 88, 96–118.

——— (2012): "Information Disclosure and Corporate Governance," *The Journal of Finance*, 67, 195–233.

HUGHES, P. AND M. SANKAR (1997): "The Impact of Litigation Risk on Discretionary Disclosure," Working Paper.

HUTTON, A. P., G. S. MILLER, AND D. J. SKINNER (2003): "The Role of Supplementary Statements with Management Earnings Forecasts," *Journal of Accounting Research*, 41, 867–890.

JENSEN, M. C. (1986): "Agency Costs of Free Cash Flow, Corporate Finance, and Takeovers," *The American Economic Review*, 76, 323–329.

JENSEN, M. C. AND W. H. MECKLING (1976): "Theory of the firm: Managerial behavior, agency costs and ownership structure," *Journal of Financial Economics*, 3, 305 – 360.

JOHNSON, M. F., R. KASZNIK, AND K. K. NELSON (2001): "The Impact of Securities Litigation Reform on the Disclosure of Forward-Looking Information by High Technology Firms," *Journal of Accounting Research*, 39, 297–327.

JUNG, W.-O. AND Y. K. KWON (1988): "Disclosure When the Market Is Unsure of Information Endowment of Managers," *Journal of Accounting Research*, 26, 146–153.

KAPLOW, L. AND S. SHAVELL (1994): "Optimal Law Enforcement with Self-Reporting of Behavior," *Journal of Political Economy*, 102, 583–606.

KARPOFF, J. M., D. S. LEE, AND G. S. MARTIN (2008): "The consequences to managers for financial misrepresentation," *Journal of Financial Economics*, 88, 193 – 215.

KASZNIK, R. AND B. LEV (1995): "To Warn or Not to Warn: Management Disclosures in the Face of an Earnings Surprise." *The Accounting Review*, 70, 113 – 134.

KE, B., S. HUDDART, AND K. PETRONI (2002): "What Insiders Know About Future Earnings and How They Use It: Evidence from Insider Trades," *Journal of Accounting and Economics*, 35, 315–346.

KIM, I. AND D. J. SKINNER (2012): "Measuring securities litigation risk," *Journal of Accounting and Economics*, 53, 290 – 310.

KLEIN, A., T. LI, AND B. ZHANG (2017): "Do Analysts Use the Freedom of Information Act to Improve Stock Recommendations and Forecast Accuracy?" Working Paper.

KOTHARI, S. P., S. SHU, AND P. D. WYSOCKI (2009): "Do Managers Withhold Bad News?" *Journal of Accounting Research*, 47, 241–276.

LANG, M. AND R. LUNDHOLM (1993): "Cross-Sectional Determinants of Analyst Ratings of Corporate Disclosures," *Journal of Accounting Research*, 31, 246–271.

LANG, M. H. AND R. J. LUNDHOLM (1996): "Corporate Disclosure Policy and Analyst Behavior," *The Accounting Review*, 71, 467–492.

——— (2000): "Voluntary Disclosure and Equity Offerings: Reducing Information Asymmetry or Hyping the Stock?*," *Contemporary Accounting Research*, 17, 623–662.

LEHMANN, J. (2013): "FDA Warning Letters and Form 483 - What's the Difference?" http://www.imarcresearch.com/blog/bid/280993/fda-warning-letters-and-form-483-what-s-the-difference Accessed April 18, 2018.

LELAND, H. E. AND D. H. PYLE (1977): "Informational Asymmetries, Financial Structure, and Financial Intermediation," *The Journal of Finance*, 32, 371–387.

LI, E., C. WASLEY, AND J. ZIMMERMAN (2016): "The Disclose or Abstain Incentive to Issue Management," *Journal of Law, Finance Accounting*, 1, 187–233.

MACHER, J. T., J. W. MAYO, AND J. A. NICKERSON (2011): "Regulator Heterogeneity and Endogenous Efforts to Close the Information Asymmetry Gap," *The Journal of Law and Economics*, 54, 25–54.

MARINOVIC, I. AND F. VARAS (2016): "No news is good news: voluntary disclosure in the face of litigation." *RAND Journal of Economics (Wiley-Blackwell)*, 47, 822 – 856.

MCMULLIN, J. L. AND B. SCHONBERGER (2020): "Entropy-balanced accruals," *Review of accounting studies*, 25, 84–119.

MILLER, G. S. (2002): "Earnings Performance and Discretionary Disclosure," *Journal of Accounting Research*, 40, 173–204.

MULLINS, B. AND C. WEAVER (2013): "Open-Government Laws Fuel Hedge-Fund Profits," *The Wall Street Journal*.

NAGAR, V. (1999): "The Role of the Manager's Human Capital in Discretionary Disclosure," *Journal of Accounting Research*, 37, 167–181.

NAGAR, V., D. NANDA, AND P. WYSOCKI (2003): "Discretionary disclosure and stock-based incentives," *Journal of Accounting and Economics*, 34, 283 – 309.

NG, J., I. TUNA, AND R. VERDI (2013): "Management forecast credibility and underreaction to news," *Review of Accounting Studies*, 18, 956 – 986.

NOE, C. F. (1999): "Voluntary disclosures and insider transactions," *Journal of Accounting and Economics*, 27, 305 – 326.

ORSZAG, P. (2009): "Open Government Directive," https://obamawhitehouse.archives.gov/open/documents/open-government-directive Accessed on July 9, 2020.

OSTER, E. (2019): "Unobservable Selection and Coefficient Stability: Theory and Evidence," *Journal of Business & Economic Statistics*, 37, 187–204.

PIOTROSKI, J. AND D. ROULSTONE (2005): "Do Insider Trades Reflect Both Contrarian Beliefs and Superior Knowledge About Future Cash Flow Realizations?" *Journal of Accounting and Economics*, 39, 55–81.

ROGERS, J. AND A. VAN BUSKIRK (2013): "Bundled forecasts in empirical accounting research," *Journal of Accounting and Economics*, 55, 43 – 65.

ROGERS, J. L. AND P. C. STOCKEN (2005): "Credibility of Management Forecasts." *The Accounting Review*, 80, 1233 – 1260.

SCHRAND, C. M. AND B. R. WALTHER (2000): "Strategic Benchmarks in Earnings Announcements: The Selective Disclosure of Prior-Period Earnings Components," *The Accounting Review*, 75, 151–177.

SHROFF, N., R. S. VERDI, AND G. YU (2014): "Information Environment and the Investment Decisions of Multinational Corporations." *Accounting Review*, 89, 759 – 790.

SKINNER, D. J. (1994): "Why Firms Voluntarily Disclose Bad News," *Journal of Accounting Research*, 32, 38–60.

——— (1997): "Earnings disclosures and stockholder lawsuits," *Journal of Accounting and Economics*, 23, 249 – 282.

SOLOMON, D. AND E. SOLTES (2019): "Is Not Guilty the Same as Innocent? Evidence from SEC Financial Fraud Investigations," Working Paper.

SPENCE, M. (1973): "Job Market Signaling," *The Quarterly Journal of Economics*, 87, 355–374.

TRUEMAN, B. (1986): "Why do managers voluntarily release earnings forecasts?" *Journal of Accounting and Economics*, 8, 53 – 71.

——— (1997): "Managerial Disclosures and Shareholder Litigation," *Review of Accounting Studies*, 2, 181–199.

UNGER, B. (2018): "Interval Between Inspection and Warning Letters Decreasing," https://blog.fdazilla.com/2018/03/948/ Accessed April 9, 2018.

VERRECCHIA, R. E. (1983): "Discretionary disclosure," *Journal of Accounting and Economics*, 5, 179 – 194.

YANG, H. I. (2012): "Capital market consequences of managers' voluntary disclosure styles," *Journal of Accounting and Economics*, 53, 167 – 184.

YERMACK, D. (1997): "Good Timing: CEO Stock Option Awards and Company News Announcements," *The Journal of Finance*, 52, 449–476.