Operational Externalities of Intense Scrutiny over Financial Reporting Controls

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Abstract

In this study, we examine how intense scrutiny over financial reporting controls affects operating control outcomes. Increasing emphasis on internal controls over financial reporting (ICFR) might require firms to modify resource allocations within control systems, such that the quality of operating controls could improve or deteriorate. Using a sample of firms subject to FDA inspections, we find that introducing intense scrutiny leads to improvements in operating controls, as evidenced by lower probabilities of regulatory deficiencies. Resource availability helps firms enhance the observed benefits, while resource constraints force firms to focus on financial reporting controls, at the expense of their regulatory compliance. Our results suggest that intensified ICFR scrutiny facilitates a complementary relationship between financial reporting and operating controls: firms implement system-wide changes that advance both functions. Identifying this positive externality is important because many stakeholders question whether the benefits of the increased ICFR focus introduced by the Sarbanes-Oxley Act (SOX) outweigh the costs.

I. Introduction

Since the Sarbanes Oxley Act of 2002 (SOX) mandated disclosures about and audits of internal controls over financial reporting (ICFR), ICFR has been subject to intense scrutiny. Precipitated by the revelation of a number of high-profile corporate frauds, SOX was a response to intense demand for capital market reforms by investors, regulators, legislators, and employees. However, while the internal control provisions of SOX focused on ICFR, internal control systems also comprise important processes designed to achieve operational and compliance objectives (COSO 2013). How external scrutiny over ICFR has affected operational controls that do not relate to or rely on financial reports, such as inventory quality and product safety controls, is relatively unknown. Increasing stakeholder focus on ICFR has the potential to help compliance and operational controls if investments in ICFR have spillover benefits throughout the control system or harm them if managers divert resources to respond to ICFR scrutiny. We examine how ICFR scrutiny affects resource allocations within control systems by specifically examining how variation in ICFR scrutiny affects Food and Drug Administration (FDA) good manufacturing practices and related inspection findings.

We study effects of intense ICFR scrutiny on operational controls generally, and particularly FDA-related operational controls for two reasons. First, debate continues as to whether overall benefits of ICFR regulation exceed costs 20 years after the passage of SOX. Three regulatory exemptions provide relief from ICFR audits for over half of small public issuers based on arguments that resources spent complying with ICFR disclosure requirements and audits would be better invested elsewhere. Indeed, prior work suggests that unaudited mandatory disclosures of ICFR may be cost beneficial substitutes for ICFR audits of small firms (Kinney and Shepardson 2012). Thus, understanding the full landscape of effects of ICFR scrutiny on control systems

remains important. Second, effects of ICFR scrutiny are particularly important when affected operational controls have public health implications. Understanding how regulatory focus on ICFR has affected resource allocations within control systems is important to fully understanding effects of ICFR regulation more broadly and helps address claims that ICFR compliance may have overwhelmingly detrimental effects.

To examine our research question, we estimate differences in FDA control deficiencies between mandatory ICFR disclosure regimes with varying levels of scrutiny. Prior research finds direct improvements to ICFR associated with both audited and unaudited ICFR disclosures (e.g., Kinney and Shepardson 2011; Schroeder and Shepardson 2016). Thus, we expect increasing ICFR scrutiny will increase ICFR-related resource requirements, in turn affecting operating controls as firms either (1) improve control systems generally, thus also improving operating controls or (2) divert resources from operating controls to improve ICFR, thus harming operating controls.

Increased ICFR scrutiny could lead to improvements in operational controls if scrutiny leads to improvements in complementary controls or overall improvements in control systems. Prior work that finds firms with high quality ICFR experience better operational outcomes such as better M&A decisions (Caplan et al. 2018; Harp and Barnes 2018; Kravet et al. 2018), improved operational efficiency (Cheng et al. 2018), increased innovation (Dambra and Gustanfson 2021; Miller et al. 2022), and more accurate management guidance (Feng et al. 2009) is supportive of spillover benefits of high quality ICFR into other corporate functions. In addition to effects of high quality ICFR, a recent study also finds that the presence of an ICFR audit, or high external scrutiny, is associated with greater operational efficiency (Imdieke et al. 2023). However, much of this work relies on ICFR-driven improvements in financial reports causing improved operational decision making; the spillover path to controls that do not require financial information in their performance

is less obvious. On one hand, firms that invest in or focus on ICFR may experience improvements in operational controls if ICFR focus leads to a culture of compliance (Altamuro et al. 2021), or an enhanced understanding of how high-quality controls and monitoring systems are designed. Additionally, many firms responded to SOX by investing in internal audit, either via hiring or outsourcing, which could also benefit operational control oversight (BioPharm International 2005).[1] Thus, allocating resources to ICFR in response to scrutiny may lead to improved operational controls and decreased likelihood of FDA inspection findings.

Alternatively, firms may focus on ICFR to the detriment of other controls. With increased ICFR focus, more managerial and internal auditor effort may be required to comply with ICFR requirements, taking time away from operational controls. Also, if control system investments are substitutive, resource constrained firms may delay operational control investments when ICFR scrutiny is high. Thus, ICFR scrutiny may be associated with lower-quality operational controls and increased likelihood of FDA deficiencies.

We identify three changes in ICFR scrutiny in 2004 and 2007 to address our research question: (1) the implementation of mandatory management disclosures of ICFR under SOX 404(a) combined with ICFR audits under SOX 404(b) for accelerated filers in 2004 (large increase); (2) the implementation of mandatory management disclosures of ICFR under SOX 404(a) without concurrent audit for non-accelerated filers in 2007 (small increase); and (3) the relaxation of ICFR auditing standards, also in 2007 (small decrease). We examine the effects of these changes in ICFR scrutiny on firm-year-inspection outcomes. Using a pre-/post-design, we first test whether the large increase is associated with differences in FDA inspection outcomes.

[1] The risk consulting and internal audit segment of Robert Half International (i.e., Protiviti) reported a 265% increase in revenue between the years ended 2003 and 2004, which they attributed primarily to SOX compliance engagements (https://www.sec.gov/Archives/edgar/data/315213/000119312505035210/d10k.htm).

Second, we use a difference-in-differences design comparing differences in FDA inspection outcomes between firms experiencing this large increase as compared to firms with no required disclosures in either period, and further limit our treatment sample firms to small accelerated filers to obtain a more comparable sample. Next, we test whether the small increase for non-accelerated filers (small decrease for accelerated filers) is associated with differences in FDA inspection outcomes, and also compare differences between these two groups. Finally, we examine whether any changes in outcome differ between the relatively larger and smaller scrutiny regimes to provide additional evidence as to effects of changes in external scrutiny of ICFR on operational controls.

We find the large increase in ICFR scrutiny is associated with decreased likelihood of FDA deficiencies as compared to the pre-mandatory disclosure period and using both the full sample and small firm difference-in-differences designs. We identify a marginally significant decrease in FDA inspection findings post the 2007 small increase in ICFR scrutiny for non-accelerated filers and an increase for the accelerated filers experiencing a small decrease in scrutiny. Further, we identify a decreased likelihood of FDA deficiencies post small increase as compared to small firms experiencing the concurrent small decrease. In combination, our results are consistent with increased scrutiny upon first time audited ICFR disclosure (a stark increase to scrutiny) leading to improvements in operational controls with additional evidence that smaller changes in ICFR scrutiny also affect operational controls in a complementary manner.

Next, using three measures of resource availability (i.e., firm age, firm size, and cash flow), we expect and find a decrease in FDA deficiencies with increased resource availability. Similarly, we find evidence that distressed and loss firms are limited in their ability to make control improvements as beneficial effects of high scrutiny are moderated in these subsets of firms. Further, higher quality auditors should be associated with greater ICFR scrutiny. We find evidence

that the increased scrutiny associated with Big 4 auditors amplifies benefits associated with external scrutiny. In summary, we find external scrutiny of ICFR is associated with improvements to operational controls. Benefits are moderated by resource availability, suggesting that firms with greater resources enjoy incremental spillover benefits to ICFR scrutiny and that firms under financial distress are unlikely to devote sufficient resources to experience benefits outside of ICFR.

Our study contributes to literature on externalities of ICFR scrutiny. Prior work concludes that when ICFR is high quality, improved financial reporting leads to spillover benefits (e.g., Feng et al. 2009; Caplan et al. 2018; Cheng et al. 2018; Dambra and Gustafson 2018; Harp and Barnes 2018; Kravet et al. 2018; Miller et al. 2018). Most recently, Imdieke et al. 2023 find that ICFR audits improve operational efficiency. Our study complements this literature by providing evidence of operating control improvements that do not rely on financial reports in their performance. Further, we provide improved specification via direct examination of operational controls, rather than financial measures of operational performance directly affected by ICFR.

We also add to literature that examines economic consequences of mandatory disclosure. Prior studies have shown that mandatory disclosure yields benefits including a lower cost of capital (e.g., Lambert et al. 2007; Shroff et al. 2017), increased liquidity (Bushee and Leuz 2005), and investment efficiency (Biddle et al. 2009; Cheng et al. 2013; Shroff et al. 2014). We augment this work by showing that mandatory disclosure of firms' financial reporting control quality has positive spillover effects on firms' operating controls and compliance with other regulation. In this way, our study answers Leuz and Wysocki's (2016) call for more research on the externalities of mandatory disclosure regulation. FDA inspections have direct implications for public health and general welfare; therefore, our outcome of interest is important and extends beyond traditional capital market consequences typically explored in prior studies.

Finally, we contribute to recent literature investigating the interaction of disclosure practices and FDA regulation. Down (2022) shows that FDA deficiencies influence managers' voluntary disclosures and Enache et al. (2022) find that the FDA approval process affects disclosure choices. Further, Down et al. (2022) find that mandatory disclosure of FDA inspection outcomes curbs lead arrangers' ability to exploit informational advantages over participant lenders in syndicated loans and Aghamolla and Thakor (2021) document when private firms must disclose clinical trial progress, they are more likely to go public. While these studies consider disclosure of FDA-related information, we flip the analysis and assess how mandatory ICFR disclosures and related scrutiny affect firms' ability to operate in accordance with FDA regulations.

II. Background, Regulatory Environment, and Hypothesis Development

Internal Controls and the Regulatory Environment for U.S. Public Issuers

Internal controls are broadly defined as processes that help managers achieve objectives. The COSO Framework covers three categories of objectives: operations objectives that promote effectiveness and efficiency of operations, reporting objectives that promote the quality of internal and external financial and non-financial reporting, and compliance objectives that help ensure adherence to laws and regulations (COSO 2013).

Since 1981, U.S. public firms have been required to maintain a system of internal controls in response to the Foreign Corrupt Practices Act (FCPA) (U.S. Congress 1977). While the FCPA was enacted primarily to curb foreign corruption and bribery, it contains accounting provisions that require companies to maintain a system of internal controls. Both the U.S. Department of Justice and the Securities and Exchange Commission (SEC) have enforcement authority over the FCPA, with the SEC having authority over civil actions against public issuers. However, prior to 2002, the SEC brought only 15 FCPA-related enforcement actions against issuers, none of which

related solely to controls outside of those related to foreign bribery (i.e., while the charges frequently include fraudulent reporting, in all cases there was some form of inappropriate payment or bribery). Thus, external enforcement and scrutiny of internal controls was low.

Subsequently, SOX was passed in July of 2002 in response to the revelation of a number of high-profile frauds. The primary objective of SOX can be found in its preamble: "to protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws, and for other purposes" (U.S. Congress 2002). As one mechanism to improve disclosure, multiple provisions of SOX focused firms on internal controls.

SOX Section 302, first required for all public issuers in 2003, requires quarterly management certifications and disclosures about the quality of and changes in disclosure controls. Section 404(a) requires that firms assess and disclose annually whether ICFR are designed and operating effectively and was implemented for accelerated filers (i.e., firms with more than $75 million in public float) in 2004 and non-accelerated filers in 2007. Finally, Section 906 allows for criminal penalties and fines of up to $5 million and imprisonment for up to 20 years for willful misrepresentation in periodic reports, increasing litigation risk for all public issuers. Thus, not only are managers required to assess the quality of controls and report their findings, they also have disclosure accuracy incentives to avoid legal liability. In summary, management disclosure requirements provide incentives for managers to improve controls to avoid capital market consequences of disclosing ineffective controls and avoid SEC sanction for inaccurate disclosures.

Internal Control Oversight Regimes

Internal controls generally, and management certifications and assessments about disclosure controls and ICFR, specifically, are monitored by the SEC. As noted above, while the SEC was granted authority to enforce violations of the FCPA, they have not frequently exercised

this authority. Thus, there was very little threat of FCPA / ICFR enforcement prior to 2019, and thus minimal regulatory pressure from this channel exists, even post 2002.

Much of the monitoring authority over issuer ICFR has been allocated to auditors, and thus we focus on auditor-related scrutiny in examining whether external scrutiny of ICFR affects operational controls.[2] Auditors directly oversee client internal controls and related disclosures in two ways: they monitor all unaudited 302 and 404(a) disclosures for material misstatements of fact and audit ICFR for accelerated filers. Indirectly, auditors also understand and may test internal controls in the performance of their annual financial statement audits.

SOX 404(a) disclosures with ICFR audits

In 2004, all accelerated filers began providing managements' assessment of ICFR in compliance with SOX 404(a) and auditors concurrently began performing audits of ICFR in accordance with SOX 404(b). While all mandatory control disclosures have some amount of auditor oversight, the amount of auditor scrutiny involved in an ICFR audit is extensive.

The output of a Section 404(b) ICFR audit is a report providing reasonable assurance that about the existence of material weaknesses in ICFR, where material weaknesses are defined as deficiencies that could lead to a material misstatement of the financial statements (PCAOB 2007). ICFR audits are effort intensive and costly, with prior research showing that audit fees increased 74% upon the initial implementation of ICFR audits in 2004 under Auditing Standard No. 2 (e.g., Ghosh and Pawlewicz 2009). In addition to increases in fees, ICFR audits were associated with higher material weakness disclosure rates (Kinney and Shepardson 2011) and improved internal

[2] We recognize that others monitor ICFR, and that in addition to explicit monitoring, reputation and litigation risk each influence managerial decisions with respect to ICFR and mandatory disclosures. We assume that more rigorous auditor oversight is likely correlated with increased reputation and litigation risks incremental to auditor involvement.

control system quality (Schroeder and Shepardson 2016), consistent with increased auditor effort and managerial ICFR-related resource allocation as compared to the pre-ICFR audit period.

In response to the high cost of ICFR audits, public companies lobbied for a relaxation of auditing standards, which ultimately resulted in the issuance of Auditing Standard No. 5 (AS5) in 2007. AS5 was intended to provide a top-down audit approach which would decrease audit cost while maintaining audit effectiveness (PCAOB 2007). Prior work finds that AS5 led to decreased audit fees (Krishnan et al. 2011) and a corresponding decrease in internal control system quality (Schroeder and Shepardson 2016), consistent with decreased auditor scrutiny of and managerial investment in ICFR. In sum, any audits of ICFR are associated with increased external scrutiny over unaudited disclosures, but the level of scrutiny decreased when AS5 was issued in 2007.

SOX 404(a) disclosures with limited auditor involvement

Beginning in 2007, non-accelerated filers with less than $75 million in public float began disclosing results of unaudited management assessments of ICFR under SOX 404(a). The auditor has no requirement to provide assurance (i.e., an audit) with respect to any SOX 302 disclosures or 404(a) disclosures for non-accelerated filers. However, AS 2710 (previously AU 550) requires the auditor's consideration of other information contained in published documents that also contain an auditor's opinion and provides guidance about appropriate auditor actions when the auditor determines that the disclosures are materially inconsistent with information appearing in the financial statements or contain a material misstatement of fact. Kinney and Shepardson (2011) note, "even without an ICFR audit, [AS 2710] requires auditor actions that may cause management to disclose material weaknesses…under SOX 302 or 404(a)" (pg. 421). Thus, there is some auditor scrutiny of ICFR in the absence of an ICFR audit, though arguably less than in an audited regime.

Hypothesis Development

Absent external regulation of controls, companies allocate resources to controls based on expected benefits such as improved operations and lower cost of capital. Resources can include investments in information systems, allocation of personnel across specific tasks and objectives, and allocation of individual personnel time to control performance and oversight. Regulatory risk affects resource allocation decisions by altering control investment benefits, in turn affecting focus on and resources allocated to the regulated controls. Prior work examines how varying levels of ICFR scrutiny affect ICFR as intended. We posit how altering regulatory scrutiny over ICFR affects other important controls, namely controls over operational effectiveness and efficiency.

ICFR scrutiny can have beneficial, detrimental, or no effects on operational controls. High external scrutiny over ICFR may have beneficial effects on operational controls if ICFR focus leads managers to implement dual purpose process level controls, improve monitoring mechanisms within the control system, and enhance focus on compliance (i.e., tone at the top) more generally. Dual purpose controls allow managers to achieve process-level objectives that relate to overlapping categories. For example, controls implemented to ensure the reliability of inventory estimates reported in financial statements can also improve operational efficiency by streamlining purchasing processes (Feng, Li, and McVay 2015). Companies may also realize control benefits across multiple control system functions of ERP system upgrades in response to SOX (BioPharm International.com 2005). As noted above, an important component of many control systems is an internal audit department that monitors whether controls are operating as designed. Investments in internal audit were extensive concurrent with the large increase in scrutiny. Protiviti, the risk consulting and internal audit segment of Robert Half International, reported a 265% increase in revenue between 2003 and 2004, which they attributed primarily to

SOX compliance engagements. Clearly, corporate investments in internal audit made in response to ICFR scrutiny can have beneficial effects over operating and compliance controls as well. Finally, managerial tone regarding compliance may be affected by external scrutiny. Prior work shows that tone at the top is important for the operation of high-quality controls (Altamuro et al. 2021). If managers respond to ICFR scrutiny by communicating the importance of compliance, firms may also experience complementary benefits in operational controls.

Alternatively, ICFR scrutiny may lead to lower quality operational controls if fewer resources are allocated to them. Because SOX requires that firms expend resources to assess the quality of ICFR and acquire ICFR audits (for accelerated filers), managers have additional incentives to invest in and focus on ICFR in the post-SOX period, which may lead to operational control problems if resources, such as manager and internal auditor effort, are re-allocated from those previously used for operational control compliance. Also, if investment allocations are substitutive within the control system, resource constrained firms may delay improvements to operational controls to invest in ICFR when scrutiny is high.

Because prior work and theory suggest increased scrutiny over ICFR could lead to differing effects on operational controls, we state our first hypothesis in the null:

H1: External scrutiny over internal controls over financial reporting will not affect the quality of operational controls.

Further, we posit that any effects of ICFR scrutiny on operational controls will be moderated by resource availability. We expect that the availability of more resources to the firm will serve to relax constraints on control system improvements such that more resources should lead to better operational control outcomes, regardless of whether scrutiny serves to help or harm operational controls. If high scrutiny periods are associated with better operational controls, we expect this effect to be amplified by increasing resources. Conversely, if high scrutiny periods are

associated with worse operational controls, we expect this detrimental effect to decline as resources increase. Said differently, firms will be more constrained in their ability to improve ICFR and operational controls jointly as resource availability declines. We state our second hypothesis in the alternative form:

H2: Resource availability is (constraints are) associated with improved (declining) operational control outcomes.

III. Method and Experimental Design

We use three changes in mandatory ICFR disclosure (i.e., 2004 implementation of audited ICFR disclosures for accelerated filers and the 2007 concurrent introduction of unaudited ICFR disclosures for non-accelerated filers and the relaxation of ICFR scrutiny under AS5 for accelerated filers) to examine whether ICFR scrutiny is associated with operational control quality. Due to the unique nature of the control failure data, we next discuss the regulatory environment related to our operational outcome.

FDA Inspections Institutional Background

The FDA protects, promotes, and advances public health by ensuring that food, drugs, biological products, medical devices, animal feeds, tobacco products, cosmetics, and radiation-emitting products are safe. FDA-regulated goods account for nearly 20 cents of every dollar spent by U.S. consumers, translating into oversight of more than $1 trillion of product each year.

In fulfilling this critical oversight role, the FDA performs facility-level inspections to verify that manufacturers and processors of regulated goods are complying with applicable legislation, such as the Federal Food, Drug, and Cosmetic Act of 1938. In 2019, approximately 260,000 facilities were registered with the FDA (FDA 2019), and about 36,000 of them were inspected. While inspections are required every two years for certain higher-risk industries such as drugs and

biologics[3], stipulated inspection intervals do not exist for lower-risk entities. Thus, the FDA uses discretion in deciding which sites to examine, based on their estimates of public health risks.

The FDA takes a process-based approach to monitoring that focuses largely on internal controls that ensure high quality manufacturing practices. Internal controls must be designed and implemented to ensure that products are manufactured according to relevant specifications. In this setting, control failures can lead to devastating consequences. For example, if firms do not adhere to strict protocols in the manufacturing of a drug, it might not treat the targeted ailment or the recipient may experience unintended side effects. Firms must have appropriate procedures, which have been validated and are followed throughout the course of operations, that increase the likelihood of high-quality outputs. Further, firms establish quality control practices to identify problems that occur during daily operations, allowing them to investigate and correct problems quickly. By inspecting manufacturing and quality control processes, the FDA gains assurance over the quality of manufactured products while not directly inspecting the quality of the output.

Inspection manuals provide insights into what controls are evaluated, and underscore the importance of effective operating controls in maintaining compliance with FDA regulations. For example, at a food processing facility, FDA personnel confirm that "computerized systems used to control, monitor or record functions that may be critical to the safety of a food product [are] checked for accuracy at intervals of sufficient frequency to provide assurance that the system is under control". At a medical device establishment, FDA staff will ensure control and monitoring procedures are followed by visiting the shop floor and "reviewing work instructions, product acceptance criteria and results, [and] control charts". Across all industries, an effective internal

[3] FDA resource constraints have historically prevented the FDA from meeting these targets.

control system will help reduce the likelihood of inspection deficiencies, or deviations from current good manufacturing practices (cGMPs) as prescribed by law.

FDA staff communicate inspection outcomes to management during a close-out meeting and they issue a Form 483 that outlines any identified deficiencies that must be rectified. If the inspectors do not discover any deficiencies, then a Form 483 is not issued. Within 15 days of receipt of a Form 483, management must respond to the FDA, outlining specific corrective actions that will address the noted violations, and the timeline of remediation. If the FDA is not satisfied with managers' efforts and compliance issues persist, further enforcement actions may be imposed. We use the receipt of a Form 483 to capture our construct of operational controls. Given the tight link between our proxy and construct, we believe that the FDA inspection setting is a powerful laboratory to test the relationship between ICFR scrutiny and operational controls.

Data and Sample Selection

Given that we exploit changes in ICFR scrutiny at two dates, we construct two samples to identify the impact of each change. Table 1 details our sample selection procedure. Our first sample includes firm-years from January 1, 2001 to November 14, 2007; and our second sample covers firm-years from November 15, 2004 to December 31, 2011. The 2001 to 2004 period captures a time when no ICFR audits were performed for either accelerated or non-accelerated filers. Our large increase in external scrutiny occurred in 2004 when management assessments and ICFR audits commenced for accelerated filers. Our small increase in external scrutiny occurred in 2007 when non-accelerated filers began issuing unaudited ICFR disclosures. Finally, the post-2007 period represents a relatively small decrease in external scrutiny for accelerated filers as ICFR auditors transitioned to a top-down audit approach under Auditing Standard No. 5.

For our first (second) regime sample, we begin with 85,068 (102,784) firm-year-inspection observations that result from the merging of Compustat with FDA inspection-level data[4], which was obtained through a FOIA request.[5] A firm-year-inspection unit of observation allows us to fully exploit the richness of the data and incorporate inspection-level variation in our tests. When we merge these observations with Audit Analytics, we lose 31,712 (39,312) observations. Then, we drop firm-year observations that are either not subject to an inspection or could not have plausibly been subject to an inspection.[6] We exploit the FDA's Significantly Regulated Organizations ("SRO") list to identify firms that could have been inspected. A publicly-traded firm is an SRO if it meets one of the following criteria: (1) sales of products regulated by the FDA constitute 10 percent or more of annual gross sales in the 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 (FDA (2018)). In this step, we also drop firms that are clearly not manufacturers or processors of FDA-regulated goods, such as financial institutions, utilities, and service-based companies. Combined, these filters result in a loss of 34,488 (39,246) observations.

Finally, we lose 2,426 (3,537) observations due to missing data, and we also drop 4,428 (4,181) observations in transitional years. The initial years might not fully reflect the true capability of the regulation, as auditors and managers require time to fully adjust to the change. Two practical reasons support our decision to exclude transitional years. First, there was a degree

[4] We perform a fuzzy matching procedure to link the company names listed in the FDA dataset to those listed in Compustat. We also rely on Exhibit 21 data to ensure that subsidiaries are attributed to the proper parent firm.
[5] We requested a listing of all inspections between January 1, 2000 and December 31, 2021.
[6] To be clear, our sample consists of three types of observations: (1) firms that are inspected at time t, (2) firms that are not inspected at time t, but are inspected at some point during our FOIA period, and (3) firms not inspected at time t, but listed on the FDA's SRO list.

of uncertainty surrounding how to implement ICFR audits. As such, a learning period was needed before auditors were able to execute "high-quality" ICFR audits. Second, firms with a public float of less than $700 million received a 45-day extension from the SEC (SEC 2004). Although only 20 percent of eligible firms used the exemption, 50 percent of these firms disclosed ineffective internal controls and did not have control audits completed until the second quarter of 2005. As a result, these firms did not begin to remediate internal control issues until the second quarter of 2005 at the earliest. For exemption firms, the 2005 fiscal year represents a time of significant adaptation and only a partial year of internal control audits, which is why it is important to drop these observations from our sample. While these exempted firms do not represent the majority, they do represent the ones for which the regime shift has the greatest potential to affect change.

After a number of extensions, SOX 404(a) took effect for non-accelerated filers on December 15, 2007 without concurrent ICFR audits. For accelerated filers, AS5 was implemented on November 15, 2007. Although adjustments are less stark under SOX 404(a) and AS5 we continue to drop the transition years in order to remain consistent across tests.[7]

In subsample analysis, we restrict observations to those with less than $150 million in market capitalization. This improves the internal validity of our difference-in-differences research design, as our non-accelerated filers serve as a better counterfactual for this group of accelerated filers for our large increase tests, and vice versa for our small changes tests. Therefore, our tests rely on two samples: (1) all accelerated filers, and (2) a size-restricted subset of accelerated filers.

Empirical Models

To test the impact of ICFR scrutiny on operational control quality, we follow the research design in Schroeder and Shepardson (2016). In all of our analyses, our dependent variable is *FDA*

[7] We reperform our primary analyses including the transition years and find similar results.

DEFICIENCY, an indicator variable equal to one if the inspection results in a Form 483 during the fiscal year, zero otherwise. *AF* (*NAF*) is an indicator variable equal to one if the firm is an accelerated filer (a non-accelerated filer), subject to the large increase (small increase) change, and zero otherwise. The value of the *REGCHG* variable depends on the time period and sample.

In our initial tests, we focus on firms affected by the regulatory changes. Our variable of interest is *REGCHG*, which captures the pre- to post-period change in the propensity to receive an FDA inspection deficiency. We estimate the following OLS specification for each of the shifts:

$$FDA\ DEFICIENCY = \beta_0 + \beta_1 REGCHG + \sum \beta_k\ CONTROLS + INDUSTRY\ FE + \varepsilon \qquad (1)$$

In our subsequent tests, we use a difference-in-differences (DiD) research design. In this design, we estimate the following OLS model for each of the regime changes:

$$FDA\ DEFICIENCY = \beta_0 + \beta_1 FILER + \beta_2 REGCHG + \beta_3 FILER \times REGCHG + \sum \beta_k\ CONTROLS_k + INDUSTRY\ FE + YEAR\ FE + \varepsilon \qquad (2)$$

When we examine the effect of the large increase in external scrutiny, we use our sample of observations between January 1, 2001 and November 14, 2007, excluding the transitional year as discussed previously. We replace *REGCHG* with $REGCHG_{06\text{-}07,}$ which is an indicator variable that takes the value of 1 for fiscal years ending after November 14, 2004 – when accelerated filers first began complying with SOX 404(a) and (b) – and zero during the pre-control audit period. Accordingly, the $REGCHG_{06\text{-}07}$ variable will capture the change in going from a no audit regime to a relatively high scrutiny audited disclosure regime. We replace *FILER* with *AF* and our variable of interest is $REGCHG_{06\text{-}07} \times AF$, as it compares the differences in Form 483 incidence for accelerated filers to the same differences observed for non-accelerated filers. We use non-accelerated filers as the counterfactual group because they were not subject to the internal control audits, but still experience similar time-varying factors that will influence FDA inspections.

In our tests of the small increase in ICFR scrutiny, we rely on our second sample of observations between November 15, 2004 and December 31, 2011, once again excluding the transitional period. We replace *REGCHG* with $REGCHG_{09\text{-}11}$, an indicator variable equal to one for the fiscal years ending after December 15, 2007 – when SOX 404(a) became effective for non-accelerated filers – and zero for the fiscal years ending prior to this date. With the $REGCHG_{09\text{-}11}$ variable, we capture the impact of going from a non-disclosure to a disclosure regime in which there is a relatively smaller increase in external scrutiny over internal controls, or going from the stricter AS2 to the integration and top-down focused AS5 (small decrease). We replace *FILER* with *NAF* and our variable of interest is $REGCHG_{09\text{-}11} \times NAF$, as it compares the differences in Form 483 incidence observed for non-accelerated filers to the same differences for accelerated filers. Our control group consists of accelerated filers that experience no change in ICFR mandatory disclosure requirements but do experience a small decrease in external audit intensity.

Control Variables

We include a vector of controls that are known determinants of firms' internal control quality (e.g., Ashbaugh-Skaife et al., 2007; Doyle et al., 2007, Feng et al., 2015). To begin, we control for firm complexity with the natural logarithm of business segments (*LNBSEG)*, and the existence of foreign sales (*FOREIGN)*, as firms with a wider scope of operations are more likely to encounter difficulty in implementing consistent procedures. Alternatively, in this highly regulated space, firms might selectively expand only when processes are sound and scalable.

Firms undergoing periods of significant change – as measured by involvement in mergers and acquisitions (*M&A)*, high sales growth (*GROWTH*), high growth potential (*MBR*), and restructuring activities (*RESTRUCTURE*) are more likely to experience challenges in maintaining appropriate controls as the business changes. That said, given that the FDA functions as a

gatekeeper for this industry, growth might only be permitted for firms that have demonstrated their compliance with the cGMP (i.e., the FDA might deny product approvals for firms with known compliance issues). Similarly, firms with volatile sales (*STD_SALES*) or cash flows (*STD_CFO*) might experience fluctuations in internal control quality.

A firm's age, size, and financial resources are also likely to influence the quality of internal controls. Older firms (*AGE*) are expected to have more established procedures. Larger firms (*SIZE*) benefit from economies of scale and have more resources to invest in controls. These firms also employ more people, meaning that they can better implement proper segregation of duties. However, these firms are also more likely to operate at a larger number of sites, meaning that the probability of inspection is higher than firms that are smaller and manufacture goods at fewer locations. Financial distress (*ZMIJ_SHUM*) and recurring losses (*PERC_LOSS*) might prevent firms from making adequate investments in internal controls, as the firms may not have the resources and managers may need to focus on the essential business operations. Alternatively, these could also be newer firms that have recently received product approvals – and have passed the corresponding inspections – but have not yet realized profitability. We also control for the speed at which firms can convert their accrual accounts into cash (*OP_CYCLE*), as this can free up resources to improve controls.

We include a number of controls that measure the firm's asset structure. Some assets such as computer systems, may enhance internal controls by automating procedures or making it difficult to circumvent established policies. Other assets may reflect the extent to which firms need to divert capital away from internal controls and towards other areas of the business, such as research and development. As such, we control for the accounts receivable and inventory as a percentage of total assets (*ARINV*), net property, plant, and equipment as a percentage of total

assets (*CAP_INTENSITY*), intangible assets as a percentage of total assets (*INT_INTENSITY*), and a lack of intangible assets (*NO_INT*).

Our final set of controls absorbs variation specific to the audit setting. Auditor size and client size are highly correlated and internal control quality differs between small and large clients. We control for this systematic difference with an indicator variable equal to one if the firm engages as Big 4 auditor, and zero otherwise (*BIGN*). In addition, we include the natural log of audit fees (*FEES*) as auditors increase effort and charge higher fees when internal controls are weaker.

IV. Results

Descriptive Statistics

Table 2, Panel A provides the mean FDA deficiency incidence by year and filer type. Accelerated filers have a higher incidence of FDA deficiencies as compared to non-accelerated filers. This is not surprising as accelerated filers tend to be larger firms with more sites inspected.

Table 2, Panels B and C provide descriptive statistics for the key variables used in our analyses. Many of the control variables differ across filer type and time period, underscoring the need to perform multivariate analyses that include determinants of firms' internal control quality. The highest Form 483 incidence occurs for accelerated filers in the pre-ICFR audit period. This deficiency rate significantly decreases for accelerated filers after the large increase in ICFR scrutiny. We note a small and statistically significant increase in FDA deficiencies with the small increase in ICFR scrutiny. When compared to the pre-ICFR audit period, Form 483 incidence in the lower scrutiny audit regime is still significantly lower for accelerated filers. In terms of non-accelerated filers, we observe fluctuations in Form 483 incidence when SOX 404(a) becomes effective and this group experiences changes in the mandatory disclosure requirements, consistent with the small increase in scrutiny.

In Table 2, Panel D, we report results of univariate difference-in-difference tests. With the large increase in ICFR scrutiny, accelerated filers experienced an 11 percent decrease in the probability of Form 483 receipt, relative to non-accelerated filers. This change is significant and represents 46% of the pre-ICFR scrutiny mean deficiency rate. Upon the small increase in ICFR scrutiny for non-accelerated filers and concurrent small decrease in external scrutiny for accelerated filers, we observe that non-accelerated filers experience a 3% decrease in deficiencies while accelerated filers experience an 8% increase in deficiencies, generating a total DiD change of 11%. Once again, this is significant as it represents 27% (33%) of pre-ICFR scrutiny period mean deficiency probability for non-accelerated (accelerated) filers. These results provide initial evidence that ICFR scrutiny exhibits a complementary relationship with operating controls.

Multivariate Results

Test of H1: Large Increase in External ICFR Scrutiny

Table 3 reports the results of our analysis that examines the impact of the large increase in ICFR scrutiny on operating control outcomes. In Column 1, we estimate Equation 1 with a sample restricted to accelerated filers subject to ICFR audits in the post period. With this pre/post analysis, we find a significant, negative coefficient on $REGCHG_{06\text{-}07,}$ suggesting that a spillover effect occurs: ICFR scrutiny not only benefits the financial reporting controls, but also helps firms to improve their operating controls.

In Column 2 and 3, we estimate Equation 2 with a sample of all firms for both filing types and a size-restricted sample that includes non-accelerated filers and accelerated filers with a market capitalization of less than $150 million, respectively. Even when we incorporate a benchmark group of firms that allows us to control for broader macroeconomic and regulatory changes, we continue to document a significant, negative coefficient on $REGCHG_{06\text{-}07} \times AF$.

Our results in this section are statistically and economically significant. The coefficients of interest range from -.04 to -0.15, representing 17 to 63 percent of the pre-ICFR audit deficiency rate, respectively. The coefficient on $REGCHG_{06\text{-}07} \times AF$ is much higher in the size-restricted sample; however, this is expected, as the regulation has the most potential to affect change in small firms, as compared to larger firms with relatively stronger pre-existing control systems.

Test of H1: Small Changes in External ICFR Scrutiny

In Table 4, we document effects on operating controls of the small increase in scrutiny associated with unaudited ICFR disclosures for non-accelerated filers and small decrease in ICFR scrutiny for accelerated filers related to the change in auditing standards. In Column 1, we estimate Equation 1 with a sample of non-accelerated filers that experienced the small increase in ICFR scrutiny as a result of the first-time ICFR management assessments and disclosures without a corresponding ICFR audit. We document a significant, negative coefficient on $REGCHG_{09\text{-}011}$, indicating that a small increase in scrutiny translates to an improvement in operational outcomes. Column 2 presents results for the small decrease in scrutiny among accelerated filers as a result of the change in auditing standards. We document a significant and positive coefficient on $REGCHG_{09\text{-}011}$, suggesting that the decrease in scrutiny also spilled over onto operational controls.

Next, we consider how the non-accelerated filers responded to the increase in ICFR scrutiny relative to a benchmark group of firms that did not experience a change in disclosure, but did encounter a small decrease in external scrutiny. Accordingly, in Column 2 and 3, we estimate Equation 2 with our all firms sample and our size-restricted sample, respectively. We find negative and significant coefficients on $REGCHG_{09\text{-}11} \times NAF$ in both samples.

Pairing the findings for the accelerated and non-accelerated filers suggests that a small increase in scrutiny for non-accelerated filers and a small decrease for accelerated filers combine

to generate a significant effect. When we compare the coefficient from the large increase in scrutiny (i.e., Table 3, Column 1) to the smaller increase (i.e., Table 4, Column 1), we find that smaller changes in scrutiny lead to significantly smaller changes in FDA operational deficiencies.

Taken together, our results suggest that ICFR scrutiny complements operating control outcomes, as higher levels of external ICFR scrutiny are associated with lower probabilities of operational deficiencies. Next, we consider factors that might mediate or moderate this relationship. In the following tests, we utilize our DiD specification with the size-restricted sample. We augment Equation 2 by adding a triple interaction variable – as well as the lower order interactions – to partition our sample.

Test of H2: Resource Availability

A firm's access to resources might impact how it adapts to changes in scrutiny. We use three measures to proxy for the construct of resource availability: firm age (*AGE*), firm size (*BIGFIRM),* and cashflow (*CASHFLOW*). Older firms are more established and can draw on experience adapting to change, as well as their established resource pools. Larger firms are more likely to have higher levels of resources (e.g., financial, capital, and/or human resources) to devote to internal controls. High levels of cash flow help firms acquire resources needed to make necessary changes within their organization.

We conjecture that firms with more resources can better adapt to ICFR disclosure requirements and external scrutiny. Our results documented in Table 5 are consistent with this prediction. Across all measures, we find that firms with high levels of resources successfully adjust to the large increase in scrutiny; and consequently, achieve higher levels of improvements in operating controls.

Test of H2: Resource Constraints

Along similar lines, firms in financial distress might focus on ensuring that the business continues to operate, and they might not have the bandwidth to devote capital to internal controls. We capture financial distress using two measures: an indicator variable (*DISTRESS*), equal to one if the firm has a score in the top decile of the Zmijewski and Shumway measure, zero otherwise; and, *PERC_LOSS*, the percentage of losses from the previous three fiscal years. We predict that financial distress will moderate the positive impact of scrutiny on operating control outcomes.

We provide our results in Table 6. As predicted, in Columns 1 and 2, we document significant, positive coefficients on both $REGCHG_{06\text{-}07} \times AF \times DISTRESS$ and $REGCHG_{06\text{-}07} \times AF \times PERC\_LOSS$. In Columns 3 and 4, we find qualitatively and quantitatively similar results for the second regime shift. These findings suggest that financial distress limits the ability of firms to make investments that also yield spillover benefits for their operating control systems.

Additional Analyses

In this section, we consider other factors that might impact firms' ability to adapt to ICFR scrutiny. We also present additional analyses to assess the robustness of our main results and to attenuate remaining endogeneity concerns.[8]

Audit Quality

Engaging a Big 4 auditor provides firms with expertise that might help firms achieve multiple control objectives. For example, higher quality auditors might suggest improvements that benefit both financial reporting and operational outcomes. We test this conjecture and present results in Table 7. Under both increases in ICFR scrutiny, we find Big 4 auditors are associated

[8] It is important to note that in order for a correlated omitted variable to threaten the internal validity of our main results, it will need to correlate with both the high and low scrutiny change shocks, as well as our cross-sectional partitions. Although this is unlikely, we address the remaining concerns below.

with fewer FDA deficiencies. Because Big 4 auditors also provide greater scrutiny over internal controls than less well-qualified auditors, this analysis also provides a complementary specification of scrutiny.

ICFR and Operational Control Overlap

The FDA inspects firms in six broad industry groupings (i.e., FDA Centers): (1) Food and Cosmetics, (2) Human Drugs, (3) Medical Devices and Radiological Health, (4) Animal Drugs and Feeds, (5) Biologics, and (6) Tobacco Products. Each grouping has specific regulations and inspection guidelines. In this section, we perform exploratory analysis to determine which of the major centers – with sufficient observations to analyze – are driving our documented results. We expect that our results will be the strongest where there is the highest potential for overlap between the controls required for operations and financial reporting (i.e., in the Medical Devices Center), as well as where controls can be automated through computerized systems (i.e., in the Food and Cosmetics Center).

We re-estimate Equation 2 with subsamples restricted to observations in which an inspection occurs and relates to the respective Center[9] and present our results in Table 8. We begin by examining Medical Devices in Column 1 of Panels A and B. Financial statement auditors' expertise can easily transfer to the quality controls required by the FDA for this specific group of firms. For example, there is a high potential for spillover with the management review requirements and the routine quality audits that must be performed. Given the extent of overlapping concepts, the persistent negative coefficients on $REGCHG_{06\text{-}07} \times AF$ *and* $REGCHG_{09\text{-}11} \times NAF$ in the Medical Device subsamples is consistent with our ex-ante expectation.

[9] Over time, firms can experience inspections that focus on different FDA Centers. To cleanly identify Center-specific effects, we restrict our sample to observations in which an inspection occurs because then we know the appropriate Center with certainty.

In the Food and Cosmetics partitions, we expect that the scope for automation will drive our findings. Larger firms in our first regime shift likely have more automated, computerized systems involved in their production processes, as compared to the smaller firms in our second regime shift. Such technology is costly and requires significant resources/investments that are more financially feasible for large firms. Systems-based controls implemented in the financial reporting environment can also be applicable in the operational environment; therefore, the spillover is much more natural in automated processes than in manual processes. Consistent with this notion, we document a significant negative coefficient on $REGCHG_{06\text{-}07} \times AF$; however, $REGCHG_{09\text{-}11} \times NAF$ is insignificant in Panel B.

Types and Severity of FDA Deficiencies

In addition to investigating the likelihood of operational deficiencies, the FDA data also allows us to explore the types and severity of deficiencies. Based on the information received via our FOIA request, the FDA releases citations (i.e., the specific observations in which the firm's practices deviate from the prescribed regulation) for about half of the inspections in which a Form 483 is issued. Thus, in these tests, we restrict our sample to observations in which an inspection occurs, and we drop bad outcome observations for which we do not have citation details. We re-estimate Equation 2 with a number of new dependent variables, and report the results in Table 9.

We construct a number of new dependent variables to examine how inspection outcomes evolve with the changes in financial reporting scrutiny. *N_CITATIONS* captures the number of citations documented by FDA personnel. To capture the spillover construct, we build *RELATED*, which is equal to one if the short description of a citation includes any of the following terms that have clear links to financial reporting control concepts: control, procedure, record, report, review, approval, audit, assurance, SOP, protocol, design, quality control, Q.C., QC, management, verif*,

QAU, quality, process, corrective, preventative, validation. To estimate the gravity of the outcome, we create two measures by using the FDA's post-inspection classification of outcomes[10]: *ACTION,* which is an indicator variable equal to one if further action is needed from the firm, as revealed through the receipt of a VAI or OAI classification, and *SEVERITY,* which is a count variable equal to three if the inspection receives an OAI classification, two if the inspection receives a VAI classification, and one if the inspection receives an NAI classification. Finally, we marry our spillover and severity measures to assess the impact of external scrutiny on the magnitude of issues closest to the financial reporting function by creating *RELATED_ACTION* and *RELATED_SEVERITY*[11].

With these measures, we document four key findings. First, although the regime shifts both reduce the probability of experiencing a bad outcome, conditional upon receiving a Form 483, the total number of issues is not impacted. Second, external scrutiny is associated with an improvement in the aspects of operations that are most similar to financial reporting. Third, although there is no change in citation count, the severity of citations exhibits a negative relationship with external scrutiny. Finally, neighboring areas of operations benefit not only from a reduced incidence of problems, but also the severity of issues detected.

[10] After an inspection is completed, the FDA reviews all of the documentation and classifies the inspection accordingly. In the data, we can see that each citation is placed in one of three possible categories: (1) NAI, which means that the issue is minor, the firm's response is sufficient, and further regulatory action is not justified; (2) VAI, which means that the problem is more significant; however, it is expected that the firm can take the necessary actions to manage the issue; and (3) OAI, which means that the issue is severe and further regulatory action might be imminent. We use these insights to construct two severity measures.

[11] *RELATED_ACTION*, which is an indicator variable equal to one if the inspection results in a citation in close proximity to financial reporting concepts, and receives an inspection classification of VAI or OAI. *RELATED_SEVERITY*, which is a count variable equal to three when a related issue is identified and the inspection receives a classification of OAI, two when a related issue is noted and the inspection receives a VAI classification, and one when a related issue is found and the inspection is classified as NAI.

Entropy Balancing

Our main specification relies on a DiD research design in which non-accelerated filers are used as a benchmark group compared to the size-restricted group of accelerated filers. Despite constraining the sample according to size, there could still be systematic differences between accelerated and non-accelerated filers. To mitigate this concern, we follow Hainmueller (2012) and McMullin and Schonberger (2020) and re-estimate Equation 2 for both regime shifts using entropy-balanced samples, allowing us to weight individual observations to ensure the means of accelerated filers match those of non-accelerated filers. Table 10, Columns 1 and 2, present the results of this analysis. We continue to document negative coefficients on $REGCHG_{06\text{-}07} \times AF$ and $REGCHG_{09\text{-}11} \times NAF$. This indicates that our findings are not confounded by remaining differences between accelerated and non-accelerated filers after imposing the size-constraint.

Inspection Restricted Sample

In our primary analyses, we include firms that could plausibly be inspected by the FDA at any given point in time. A concern with this approach is that inspected and non-inspected firms could differ. In order for this to confound our results, the FDA selection decisions and inspection outcomes would need to correlate with the regime shifts, which is unlikely given that the FDA's decisions are unlikely to move in lockstep with regulators overseeing financial markets. Nonetheless, we restrict our sample to observations in which an inspection occurs during the fiscal year and re-estimate Equation 2 for both the regime change samples. The results are reported in Table 10, Columns 3 and 4, respectively. Our results continue to hold, indicating they are not driven by the FDA's selection of which firms to inspect.

Firms in All Periods

Our tests use two samples that span two different time periods, leading to sample composition change concerns. To address this concern, we limit both samples to firms that show up in all three periods: Pre-AS2, AS2, and AS5/SOX 404(a). We re-estimate Equation 2 with this additional sample constraint and we present our results in Table 10, columns 5 and 6. Results continue to hold.

Transition Periods Included

In our main analyses, we excluded transitional periods from our sample. To assess the impact of this decision on our results, we re-estimate Equation 2 including the transitional periods. In Columns 7 and 8, we continue to document significantly negative effects.

Oster Tests

We employ Oster (2019) and Altonji et al. (2005)'s partial identification approach to assess the impact of unobservables on our main results. In order to reduce our coefficients of interest to zero, unobservables would need to have an impact equal to -5.01 times[12] (3.14 times) the impact of the observables included in our large increase (small change) specifications, which is unlikely.

Logit Specification

Finally, given that our main dependent variable of interest is dichotomous, we also estimate a logit DiD specification. We continue to find significant, negative coefficients on $REGCHG_{06\text{-}07} \times AF$ and $REGCHG_{09\text{-}11} \times NAF$.

V. Conclusion

In this study, we examine whether intense external scrutiny over financial reporting controls affects firms' attention to operational and compliance controls. While increased scrutiny

[12] A negative delta indicates that the impact of the unobservables would need to occur in a direction opposite to that of the observable variables included in our specification.

could encourage managers to allocate their time and resources towards financial reporting controls, and away from operating controls, managers may also react to the increase in ICFR scrutiny by improving the overall control systems, such that both financial reporting and operating controls benefit. This is an important topic to examine because SOX 404 has received significant criticism, with many stakeholders questioning whether benefits exceed compliance costs. We investigate the possibility of operational spillover effects that might arise as a result of changes in ICFR scrutiny.

Our results suggest that mandatory ICFR disclosures, and the corresponding increases in external scrutiny, lead to improvements in operating controls. Resource availability helps firms increase the observed benefits, while resource constraints force firms to place more emphasis on ICFR, at the expense of their regulatory compliance. We also find that a number of other factors influence spillover effects such as auditor quality, tangible and intangible investments, and the extent of the overlap the financial reporting and operating control systems.

We contribute to literature that assesses benefits of ICFR regulation by showing that more intense scrutiny improves other aspects of the control system. By documenting that improved compliance with FDA regulations follows ICFR disclosures, we also add to the literature that investigates the economic consequences of mandatory disclosure. Finally, we contribute to the literature that explores the relationship between firms' disclosures and FDA regulation. Prior work focuses on the FDA-related content in disclosures; however, we extend this work by assessing whether ICFR scrutiny affects firms' compliance with FDA regulation. Taken together, our findings suggest that the benefits of SOX 404 extend beyond financial reporting and should be of interest to a wide audience of stakeholders such as regulators, managers, investors, and auditors.

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APPENDIX A
Variable Definitions

Variable	Description
Dependent Variables:	
FDA DEFICIENCY	An indicator variable equal to one if the firm receives a Form 483 during the fiscal year, and zero otherwise.
N_CITATIONS	The number of releasable citations documented during an inspection.
RELATED	An indicator variable equal to one if any of the citation short descriptions contain one of the following key words: control, procedure, record, report, review, approval, audit, assurance, SOP, protocol, design, quality control, Q.C., QC, management, verif*, QAU, quality, process, corrective, preventative, validation, and zero otherwise.
ACTION	An indicator variable equal to one if any of the citations have an inspection classification of VAI or OAI, and zero otherwise.
RELATED_ACTION	An indicator variable equal to one if *RELATED*=1 for any of the citations and their corresponding inspection classification is VAI or OAI, and zero otherwise.
SEVERITY	A count variable equal to 3 if the inspection classification is OAI, 2 if the inspection classification is VAI, 1 if the inspection classification is NAI, and zero otherwise.
RELATED_SEVERITY	A count variable equal to 3 if the inspection classification is OAI and *RELATED*=1, 2 if the inspection classification is VAI and *RELATED*=1, 1 if the inspection classification is NAI and *RELATED*=1, and zero otherwise.
Independent Variables of Interest:	
AF	An indicator variable coded as 1 if the firm receives a SOX 404(b) internal control audit opinion in the prior year, and 0 otherwise (obtained from Audit Analytics) for firm-quarter observations after November 15, 2004. Prior to November 15, 2004, coded as 1 if the firm's market value of equity is greater than $75M, and 0 otherwise.
NAF	An indicator variable coded as 1 if the firm does not receive a SOX 404(b) internal control audit opinion in the prior year, and 0 otherwise (obtained from Audit Analytics) for firm-quarter observations after November 15, 2004. Prior to November 15, 2004, coded as 1 if the firm's market value of equity is less than $75M, and 0 otherwise.
REGCHG_0607	An indicator variable coded as 1 if the observation is between November 15, 2004 and November 14, 2007, and 0 if the observation is between January 1, 2001 and November 14, 2004.
REGCHG_0911	An indicator variable coded as 1 if the observation is between December 15, 2007 and December 31, 2011, and 0 if the observation is between November 15, 2004 and December 14, 2007.

Variable	Description
Other Variables:	
BSEG	Natural logarithm of one plus the total reported business segments as available from the Compustat Segment file.
FOREIGN	An indicator variable coded as 1 if the firm has foreign operations (FCAQ), and 0 otherwise.
GROWTH	Total assets (AT) as of year *t* less total assets as of year *t-1* scaled by year *t-1* assets.
ARINV	The sum of end-of-year accounts receivable (RECT) and inventory (INVT) scaled by total assets (AT).
MERGER	An indicator variable coded as 1 if the firm discloses any M&A activity during the previous three fiscal years, and 0 otherwise (obtained from Compustat footnote file).
RESTRUCTURE	An indicator variable coded as 1 if the firm experiences any restructuring activity during the previous three fiscal years, and 0 otherwise.
STD_SALE	Natural logarithm of the standard deviation of sales (SALE) from operations during the previous three years, with a minimum of two years.
STD_CFO	Natural logarithm of the standard deviation of cash flows (OANCF) from operations during the previous three years, with a minimum of two years.
OP_CYCLE	Natural log of the operating cycle, calculated as the sum of 360/cost of goods sold turnover (COGS/INVT average) and 360/sales turnover (REVT/RECT average).
INT_INTENSITY	Intangible asset intensity, measured as R&D plus advertising divided by sales.
NO_INT	An indicator variable coded as 1 if *INT_INTENSITY* is equal to 0, and 0 otherwise.
CAP_INTENSITY	Capital asset intensity measured as net property, plant, and equipment (PPENT) divided by total assets (AT).
SIZE	Natural log of total assets (AT).
PERC_LOSS	The percentage of reported losses (NI) during the previous three years.
MBR	Market-to-book ratio, calculated as market capitalization (CSHO × PRCC) divided by book value (AT - LT).
BIGN_AA	An indicator variable coded as 1 if firm is audited by a Big 4 audit firm, and 0 otherwise (obtained from Audit Analytics).
ZMIJ_SHUM	The Zmijewski measure of financial distress using the coefficients from Shumway (2001).
FEES	Natural logarithm of total audit fees (obtained from Audit Analytics).
AGE	Natural logarithm of firm age.
CASHFLOW	Cash flows from operations divided by average total assets.
DISTRESS	An indicator variable coded as 1 if the observation is in the decile of *ZMIJ_SHUM* that represents the highest risk of bankruptcy, and 0 otherwise.

TABLE 1
Sample Selection

	Large Increase Sample (January 1, 2001 to November 14, 2007)	Small Changes Sample (November 15, 2004 to December 31, 2011)
All available U.S. Compustat firm-year-inspection observations for the respective fiscal periods	85,068	102,784
Less: Observations that do not merge with Audit Analytics database	(31,712)	(39,312)
Less: Observations that are not listed on the FDA's Significantly Regulated Organizations list or not subject to an FDA inspection, and observations that relate to companies that are not primarily manufacturers and/processors of FDA-regulated products (e.g., financial institutions, utilities, service-based firms)	(34,488)	(39,246)
Less: Observations with missing values for the remaining control variables necessary to run the multivariate analyses	(2,426)	(3,537)
Less: Transition year observations after regime change	(4,428)	(4,181)
Total available observations for the main multivariate analyses	12,014	16,598

TABLE 2
Descriptive Statistics and Univariate Difference-in-Differences

Table 2 provides descriptive statistics for the dependent and control variables used in our multivariate analyses. In Panel A, we report the mean *FDA DEFICIENCY* by year and filer type. In Panels B and C, we provide the means and median values for each variable and separate the statistics by regime period. In Panel D, we report the univariate difference-in-differences results for the two regime shifts. In Panel A, we include all observations for each year. In Panels B and C, we exclude the transitional years and only include the observations that are used in the following multivariate analyses. All continuous, non-logarithmic variables are winsorized at the 1st and 99th percentiles. Variable definitions can be found in Appendix A. * (#) indicates a significant difference between each of the regime shifts at two-tailed p-values ($p < 0.10$) using a t-test for comparison of mean values and a Wilcoxon rank sum test for comparison of median values.

Panel A: FDA Deficiency Means by Year and Filer Group (Including Transition Years)

FDA DEFICIENCY	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Accelerated Filers	0.28	0.24	0.22	0.19	0.22	0.18	0.19	0.20	0.21	0.24	0.20
Non-accelerated Filers	0.15	0.12	0.09	0.10	0.15	0.13	0.09	0.09	0.11	0.09	0.11

Panel B: Means and Medians by Filer Group for Large Increase in Scrutiny Regime Shift

	Pre-REGCHG_0607				Post-REGCHG_0607			
	AF (n=7589)		NAF (n=980)		AF (n=3141)		NAF (n=304)	
Variable	Mean	Mdn	Mean	Mdn	Mean	Mdn	Mean	Mdn
FDA DEFICIENCY	0.24	0.00	0.11	0.00	0.17*	0.00#	0.12	0.00
BSEG	1.17	1.39	0.98	0.69	1.18	1.39	0.94*	0.69#
FOREIGN	0.21	0.00	0.11	0.00	0.29*	0.00#	0.15*	0.00#
GROWTH	0.16	0.08	0.06	-0.01	0.13*	0.08#	0.27*	0.07#
ARINV	0.25	0.24	0.31	0.27	0.28*	0.27	0.32	0.30
MERGER	0.40	0.00	0.18	0.00	0.21*	0.00#	0.13*	0.00
RESTRUCTURE	0.34	0.00	0.16	0.00	0.58*	1.00#	0.16	0.00#
STD_SALE	5.65	5.79	1.34	1.26	5.74*	6.09#	0.94*	1.00#
STD_CFO	4.35	4.35	0.63	0.57	4.35	4.44	0.49	0.57#
OP_CYCLE	4.45	4.46	4.83	4.83	4.46	4.49	4.88	4.90#
INT_INTENSITY	0.18	0.01	0.66	0.03	0.17	0.02#	0.71	0.05
NO_INT	0.25	0.00	0.28	0.00	0.21*	0.00#	0.20*	0.00#
CAP_INTENSITY	0.34	0.31	0.26	0.21	0.29*	0.27#	0.18*	0.12#
SIZE	8.09	8.41	3.35	3.20	8.18*	8.31#	3.30	3.31#
PERC_LOSS	0.15	0.00	0.55	0.67	0.12*	0.00	0.48*	0.33#
MBR	4.32	2.81	3.17	1.52	3.87*	2.78#	4.41*	2.71#
BIGN_AA	0.98	1.00	0.64	1.00	0.95*	1.00#	0.28*	0.00#
ZMIJ_SHUM	-2.82	-2.80	-2.28	-2.42	-2.99*	-2.86#	-2.64*	-3.14#
FEES	14.01	14.02	11.69	11.56	14.88*	14.88#	11.94*	11.91#
AGE	3.26	3.50	2.68	2.64	3.35*	3.58#	2.75*	2.77#

TABLE 2 (CONTINUED)

Panel C: Means and Medians by Filer Group for Small Changes in Scrutiny Regime Shift

	Pre-REGCHG_0911				Post-REGCHG_0911			
	AF (n=6702)		NAF (n=1171)		AF (n=8109)		NAF (n=616)	
Variable	Mean	Mdn	Mean	Mdn	Mean	Mdn	Mean	Mdn
FDA DEFICIENCY	0.19	0.00	0.13	0.00	0.22*	0.00#	0.10*	0.00#
BSEG	1.17	1.39	0.96	0.69	1.10*	1.39#	0.95	0.69
FOREIGN	0.31	0.00	0.16	0.00	0.33*	0.00#	0.16	0.00
GROWTH	0.13	0.08	0.20	0.06	0.13	0.06#	0.11*	0.02#
ARINV	0.25	0.22	0.31	0.28	0.25	0.21	0.32	0.30
MERGER	0.26	0.00	0.21	0.00	0.22*	0.00#	0.18	0.00
RESTRUCTURE	0.58	1.00	0.30	0.00	0.62*	1.00#	0.19*	0.00#
STD_SALE	5.73	5.99	2.60	2.03	6.12*	6.11#	1.43*	1.39#
STD_CFO	4.32	4.48	1.84	1.32	4.89*	4.78#	0.84*	0.80#
OP_CYCLE	4.47	4.47	4.77	4.77	4.46	4.48	4.78	4.86
INT_INTENSITY	0.20	0.02	0.55	0.03	0.13*	0.02#	0.53	0.05#
NO_INT	0.21	0.00	0.22	0.00	0.22	0.00	0.19*	0.00#
CAP_INTENSITY	0.30	0.27	0.24	0.22	0.29*	0.27#	0.18*	0.13#
SIZE	8.18	8.43	4.85	4.14	8.62*	8.79#	3.49*	3.38#
PERC_LOSS	0.14	0.00	0.39	0.33	0.15*	0.00#	0.55*	0.67#
MBR	4.03	3.01	4.06	2.71	3.90*	2.62#	3.62	1.59#
BIGN_AA	0.96	1.00	0.56	1.00	0.95*	1.00#	0.25*	0.00#
ZMIJ_SHUM	-2.97	-2.95	-2.72	-2.80	-2.92*	-2.94#	-2.62*	-3.09
FEES	14.93	14.98	12.63	12.32	15.02*	15.06#	12.24	12.16#
AGE	3.30	3.53	2.86	2.89	3.44*	3.71#	2.79*	2.83

Panel D: Univariate Difference-in-Differences (DiD)

	Difference in Means Large Increase in Scrutiny			Difference in Means Small Changes in Scrutiny		
	AF	NAF	DiD	NAF	AF	DiD
FDA DEFICIENCY	-0.10	0.01	-0.11*	-0.03	0.08	-0.11*

TABLE 3
Large Increase in Scrutiny for Accelerated Filers and Differences in FDA Deficiencies

This table reports the effect of a large change in scrutiny on FDA deficiencies. We estimate Equation 1 and present the results for each sample. In Column (1), we use a sample restricted to accelerated filers. In Column (2), we include all observations. In Column (3), we include all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

	FDA DEFICIENCY (1)	*FDA DEFICIENCY* (2)	*FDA DEFICIENCY* (3)
REGCHG_0607	**-0.04*** **		
	(-5.33)		
AF		0.03	0.06
		(1.05)	(1.27)
REGCHG_0607 × AF		**-0.04****	**-0.15****
		(-2.04)	**(-2.38)**
BSEG	0.01	0.01	0.01
	(1.22)	(1.65)	(0.27)
FOREIGN	0.01	0.01	-0.06
	(0.63)	(0.57)	(-1.45)
GROWTH	-0.03***	-0.03**	-0.01
	(-2.91)	(-2.20)	(-1.24)
ARINV	-0.13	-0.09	-0.02
	(-1.58)	(-1.29)	(-0.42)
MERGER	0.00	0.01	-0.01
	(0.15)	(0.47)	(-0.28)
RESTRUCTURE	0.00	0.02	0.08***
	(0.18)	(1.11)	(4.00)
STD_SALE	-0.01*	-0.01**	-0.01
	(-1.76)	(-2.56)	(-0.98)
STD_CFO	0.01	0.01	0.01
	(0.54)	(0.84)	(0.39)
OP_CYCLE	0.03	0.02	0.01
	(1.32)	(1.25)	(0.92)
INT_INTENSITY	-0.02***	-0.01***	-0.01
	(-5.52)	(-4.57)	(-1.56)
NO_INT	-0.01	0.00	-0.06*
	(-0.21)	(-0.09)	(-1.84)
CAP_INTENSITY	0.11**	0.10***	0.04
	(2.58)	(3.37)	(0.41)
SIZE	0.03***	0.02**	0.02
	(3.17)	(2.16)	(1.57)

TABLE 3 (CONTINUED)

PERC_LOSS	-0.04*	-0.05**	-0.10***
	(-1.89)	(-2.59)	(-3.40)
MBR	0.00	0.00*	0.00
	(1.39)	(1.94)	(0.92)
BIGN_AA	-0.04**	-0.04**	-0.06***
	(-2.58)	(-2.44)	(-2.94)
ZMIJ_SHUM	0.00	-0.01**	0.01
	(-0.64)	(-2.11)	(1.26)
FEES	-0.01**	0.00	0.05**
	(-2.31)	(-0.30)	(2.49)
AGE	0.00	0.00	0.00
	(-0.01)	(-0.24)	(-0.03)
CONSTANT	0.11	-0.04	-0.46**
	(1.47)	(-0.32)	(-2.22)
Sample	AF=1	DiD, ALL	DiD, MVE<150 | AF=0
Industry FE	Y	Y	Y
Year FE	N	Y	Y
Observations	10730	12014	1877
Adjusted R^2	0.07	0.07	0.06

TABLE 4
Small Changes in Scrutiny and Differences in FDA Deficiencies

This table documents the impact of small changes in scrutiny on FDA deficiencies. We estimate Equation 1 and present the results of using different samples. In Columns (1) and (4), we use a sample restricted to non-accelerated filers, and accelerated filers, respectively. In Columns (2) and (5), we include all observations. In Columns (3) and (6), we include all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

	FDA DEFICIENCY (1)	*FDA DEFICIENCY* (2)	*FDA DEFICIENCY* (3)	*FDA DEFICIENCY* (4)
REGCHG_0911	**-0.03***	**0.03****		
	(-1.72)	**(2.26)**		
NAF			-0.01	0.02
			(-0.48)	(1.30)
REGCHG_0911 × NAF			**-0.06****	**-0.10*****
			(-2.41)	**(-3.09)**
BSEG	0.08***	0.00	0.01	0.07**
	(3.97)	(0.20)	(0.93)	(2.70)
FOREIGN	-0.01	0.02*	0.02	-0.01
	(-0.64)	(1.70)	(1.29)	(-0.28)
GROWTH	0.00	0.00	-0.01	-0.01*
	(-0.25)	(-0.15)	(-0.31)	(-1.78)
ARINV	0.07	-0.19**	-0.13*	0.05
	(1.21)	(-2.21)	(-1.69)	(1.24)
MERGER	-0.02	0.00	0.00	-0.03
	(-0.52)	(0.27)	(0.59)	(-1.21)
RESTRUCTURE	-0.04**	0.01	0.01	-0.04*
	(-2.23)	(0.94)	(0.77)	(-1.96)
STD_SALE	-0.01	0.00	0.00	-0.01
	(-0.64)	(0.27)	(-0.32)	(-0.72)
STD_CFO	0.00	0.01	0.00	-0.01*
	(0.11)	(1.17)	(0.78)	(-1.97)
OP_CYCLE	0.01	0.04**	0.04*	0.00
	(0.45)	(2.14)	(1.94)	(0.30)
INT_INTENSITY	0.00	-0.02***	-0.01***	-0.00**
	(-0.47)	(-2.80)	(-2.92)	(-2.52)
NO_INT	0.01	-0.01	-0.01	0.00
	(0.64)	(-0.61)	(-0.40)	(0.22)
CAP_INTENSITY	0.08	0.00	0.01	0.08
	(0.73)	(-0.01)	(0.15)	(0.78)
SIZE	0.02	0.00	0.01*	0.04***
	(1.43)	(0.62)	(1.70)	(3.06)

TABLE 4 (CONTINUED)

PERC_LOSS	0.00	-0.04**	-0.04**	-0.02
	(0.42)	(-2.22)	(-2.41)	(-0.48)
BIGN_AA	-0.06***	-0.05***	-0.05***	-0.06***
	(-3.09)	(-3.75)	(-3.00)	(-5.61)
ZMIJ_SHUM	-0.02**	-0.01***	-0.02***	-0.01
	(-2.56)	(-2.90)	(-4.26)	(-0.74)
FEES	0.03**	0.00	0.00	0.01
	(2.40)	(-0.00)	(0.50)	(1.29)
AGE	0.01	0.00	-0.01	0.00
	(0.28)	(-0.37)	(-0.83)	(0.01)
CONSTANT	-0.52***	-0.03	-0.07	-0.28*
	(-3.10)	(-0.30)	(-0.66)	(-1.89)
Sample	NAF=1	AF=1	DiD, ALL	DiD, MVE<150 | AF=0
Industry FE	Y	Y	Y	Y
Year FE	N	N	Y	Y
Observations	1784	14810	16598	2243
Adjusted R^2	0.03	0.06	0.06	0.04

TABLE 5
Resource Availability and Differences in FDA Deficiencies

This table documents the impact of resource availability on the relationship between changes in scrutiny and FDA deficiencies. We estimate all specifications using the sample consisting of all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. In Columns (1), (2), and (3), we focus on the time period surrounding the "large increase" in external scrutiny. In Columns (4), (5), and (6), we focus on the time period surrounding the "small changes" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

	FDA DEFICIENCY	*FDA DEFICIENCY*	*FDA DEFICIENCY*	*FDA DEFICIENCY*	*FDA DEFICIENCY*	*FDA DEFICIENCY*
	(1)	(2)	(3)	(4)	(5)	(6)
AF	0.06	0.03	-0.14			
	(1.22)	(1.00)	(-1.59)			
REGCHG_0607 × AF	-0.18***	0.05	0.60**			
	(-3.38)	(0.62)	(2.46)			
REGCHG_0607 × AF × CASHFLOW	**-0.24*** **					
	(-3.69)					
REGCHG_0607 × AF × BIGFIRM		**-0.24*** **				
		(-2.87)				
REGCHG_0607 × AF × AGE			**-0.26*** **			
			(-2.96)			
NAF				0.04***	-0.03	0.01
				(3.00)	(-0.42)	(0.07)
REGCHG_0911 × NAF				-0.12***	0.06*	-0.32**
				(-3.00)	(1.89)	(-2.04)
REGCHG_0911 × NAF × CASHFLOW				**-0.20*** **		
				(-3.37)		
REGCHG_0911 × NAF × BIGFIRM					**-0.25** **	
					(-2.21)	
REGCHG_0911 × NAF × AGE						**0.08**
						(1.58)
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Controls	Y	Y	Y	Y	Y	Y
Industry FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y	Y
Observations	1877	1877	1877	2243	2243	2243
Adjusted R^2	0.07	0.07	0.07	0.04	0.05	0.04

TABLE 6
Resource Constraints and Differences in FDA Deficiencies

This table documents the effect of financial distress on the relationship between changes in scrutiny and FDA deficiencies. We estimate all specifications using the sample consisting of all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. In Columns (1), (2), and (3), we focus on the time period surrounding the "large increase" in external scrutiny. In Columns (4), (5), and (6), we focus on the time period surrounding the "small changes" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

	FDA DEFICIENCY (1)	*FDA DEFICIENCY* (2)	*FDA DEFICIENCY* (3)	*FDA DEFICIENCY* (4)
AF	0.05**	0.06		
	(2.12)	(1.17)		
REGCHG_0607 × AF	-0.28***	-0.17***		
	(-3.83)	(-2.81)		
REGCHG_0607 × AF × PERC_LOSS	**0.28****			
	(2.26)			
REGCHG_0607 × AF × DISTRESS		**0.17***		
		(1.70)		
NAF			0.07**	0.03***
			(2.51)	(2.85)
REGCHG_0911 × NAF			-0.23**	-0.11***
			(-2.45)	(-3.26)
REGCHG_0911 × NAF × PERC_LOSS			**0.25****	
			(2.08)	
REGCHG_0911 × NAF × DISTRESS				**0.11****
				(2.21)
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Controls	Y	Y	Y	Y
Industry FE	Y	Y	Y	Y
Year FE	Y	Y	Y	Y
Observations	1877	1877	2243	2243
Adjusted R^2	0.07	0.06	0.04	0.04

TABLE 7
Audit Quality and Differences in FDA Deficiencies

This table documents the effect of audit quality on the relationship between changes in scrutiny and FDA deficiencies. We estimate all specifications using the sample consisting of all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. In Column (1), we focus on the time period surrounding the "large increase" in external scrutiny. In Column (2), we focus on the time period surrounding the "small changes" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

	FDA DEFICIENCY (1)	*FDA DEFICIENCY* (2)
AF	-0.02	
	(-0.36)	
REGCHG_0607 × AF	-0.01	
	(-0.21)	
REGCHG_0607 × AF × BIGN_AA	**-0.19****	
	(-2.64)	
NAF		-0.01
		(-0.48)
REGCHG_0911 × NAF		-0.04
		(-1.16)
REGCHG_0911 × NAF × BIGN_AA		**-0.12*****
		(-3.58)
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Controls	Y	Y
Industry FE	Y	Y
Year FE	Y	Y
Observations	1877	2243
Adjusted R^2	0.06	0.04

TABLE 8
FDA Centers and Differences in FDA Deficiencies

This table documents relationship between changes in scrutiny and FDA deficiencies within FDA Centers. We estimate all specifications using the sample consisting of all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. In each column, we further restrict the sample to observations in which an inspection occurs and pertains to the noted FDA Center. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

Panel A: Large Increase in Scrutiny

	FDA DEFICIENCY (1)	*FDA DEFICIENCY* (2)	*FDA DEFICIENCY* (3)	*FDA DEFICIENCY* (4)
AF	0.11	0.04	-0.10**	-0.99***
	(0.99)	(0.64)	(-2.55)	(-10.89)
REGCHG_0607 × AF	**-0.32*** **	**-0.34** **	**-0.07**	**3.14*** **
	(-4.19)	**(-2.55)**	**(-0.77)**	**(10.61)**
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
FDA Center	Medical Devices	Food & Cosmetics	Human Drugs	Animal Drugs & Feeds
Controls	Y	Y	Y	Y
Industry FE	N	N	N	N
Year FE	Y	Y	Y	Y
Observations	214	360	80	121
Adjusted R^2	0.09	0.04	0.27	0.45

TABLE 8 (CONTINUED)

Panel B: Small Changes in Scrutiny

	FDA DEFICIENCY (1)	*FDA DEFICIENCY* (2)	*FDA DEFICIENCY* (3)	*FDA DEFICIENCY* (4)
NAF	0.03	0.21**	0.23	0.32
	(0.42)	(2.43)	(1.06)	(1.24)
REGCHG_0911 × NAF	**-0.13****	**0.03**	**-0.37**	**-0.89**
	(-2.95)	**(0.43)**	**(-1.79)**	**(-1.50)**
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Controls	Y	Y	Y	Y
Industry FE	N	N	N	N
Year FE	Y	Y	Y	Y
Observations	267	451	148	104
Adjusted R^2	0.05	0.06	0.09	0.24

TABLE 9
Differences in Types and Severity of FDA Deficiencies

This table documents how changes in scrutiny affects the types and severity of FDA deficiencies. We estimate all specifications using the sample consisting of all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. In Panel A, we focus on the time period surrounding the "large increase" in external scrutiny. In Panel B, we focus on the time period surrounding the "small change" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

Panel A: Large Increase in Scrutiny

	N_CITATIONS	*RELATED*	*ACTION*	*RELATED_ACTION*	*SEVERITY*	*RELATED_SEVERITY*
	(1)	(2)	(3)	(4)	(5)	(6)
AF	0.87*	0.09**	0.06***	0.08**	0.15***	0.18**
	(1.84)	(2.83)	(3.21)	(2.51)	(3.49)	(2.65)
REGCHG_0607 × AF	**0.15**	**-0.10*****	**-0.12*****	**-0.09*****	**-0.22****	**-0.11***
	(0.50)	**(-3.81)**	**(-4.51)**	**(-3.96)**	**(-2.35)**	**(-1.80)**
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Restriction	Inspection=1	Inspection=1	Inspection=1	Inspection=1	Inspection=1	Inspection=1
Controls	Y	Y	Y	Y	Y	Y
N_Citations Control	N	Y	Y	Y	Y	Y
Industry FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y	Y
Observations	636	636	636	636	636	636
Adjusted R^2	0.11	0.54	0.55	0.53	0.6	0.58

TABLE 9 (CONTINUED)

Panel B: Small Changes in Scrutiny

	N_CITATIONS	*RELATED*	*ACTION*	*RELATED_ACTION*	*SEVERITY*	*RELATED_SEVERITY*
	(1)	(2)	(3)	(4)	(5)	(6)
NAF	-1.45*	0.02	0.05	0	0.08	-0.06
	(-2.01)	(0.87)	(1.59)	(-0.15)	(0.95)	(-1.11)
REGCHG_0911 × NAF	**1.29**	**-0.16*****	**-0.14****	**-0.15*****	**-0.28*****	**-0.28*****
	(1.55)	**(-6.12)**	**(-2.70)**	**(-4.95)**	**(-3.53)**	**(-5.70)**
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Restriction	Inspection=1	Inspection=1	Inspection=1	Inspection=1	Inspection=1	Inspection=1
Controls	Y	Y	Y	Y	Y	Y
N_Citations Control	N	Y	Y	Y	Y	Y
Industry FE	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y	Y
Observations	859	859	859	859	859	859
Adjusted R^2	0.05	0.48	0.42	0.41	0.5	0.48

TABLE 10
Robustness Analysis

In this table, we present the results of our robustness tests. We estimate all specifications using the sample consisting of all non-accelerated filers and accelerated filers with a market value of equity less than $150 million. In Column (1), we perform entropy balancing to ensure that the mean values of the AF observations match those of the NAF observations. In Columns (1) and (2), we perform entropy balancing to ensure that the means of the NAF observations match those of the AF observations. In Columns (3) and (4), we further restrict our sample to consist only of observations in which an inspection occurs during the given fiscal year. In Columns (5) and (6), we constrain our sample to include only firms that appear in all three regime periods. In Columns (7) and (8), we include the transitional period observations. The t-statistics reported in parentheses are based on standard errors clustered at the industry level. ***, **, * indicates significance at the 0.01, 0.05, and 0.10 levels, respectively. All variables are defined in Appendix A.

	FDA DEFICIENCY Entropy Balanced (1)	*FDA DEFICIENCY* Entropy Balanced (2)	*FDA DEFICIENCY* Inspection-Restricted (3)	*FDA DEFICIENCY* Inspection-Restricted (4)	*FDA DEFICIENCY* Firms in All Periods (5)	*FDA DEFICIENCY* Firms in All Periods (6)	*FDA DEFICIENCY* Transition Included (7)	*FDA DEFICIENCY* Transition Included (8)
AF	0.05		0.05		0.04		0.07	
	(1.13)		(1.01)		(1.11)		(1.62)	
REGCHG_0607 × AF	**-0.17*** **		**-0.31*** **		**-0.16* **		**-0.11*** **	
	(-3.80)		**(-4.64)**		**(-1.88)**		**(-2.88)**	
NAF		0.01		0.08**		0.02		0.04**
		(0.57)		(2.22)		(0.80)		(2.22)
REGCHG_0911 × NAF		**-0.09** **		**-0.21*** **		**-0.08** **		**-0.08*** **
		(-2.26)		**(-3.33)**		**(-2.33)**		**(-4.46)**
Sample	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0	DiD, MVE<150 | AF=0
Controls	Y	Y	Y	Y	Y	Y	Y	Y
Industry FE	Y	Y	Y	Y	Y	Y	Y	Y
Year FE	Y	Y	Y	Y	Y	Y	Y	Y
Observations	1877	2243	798	982	1336	1519	2845	2769
Adjusted R^2	0.13	0.08	0.20	0.10	0.06	0.05	0.05	0.05