# 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 the quality of internal controls over financial reporting (ICFR), there has been intense external scrutiny over financial reporting controls. However, internal control systems comprise processes that not only achieve financial reporting objectives, but operational and compliance objectives as well (COSO 2013). Specifically, there are important controls that do not relate to or rely on the quality of financial reports. For example, inventory quality and product safety controls are not directly related to financial reporting, but are essential to operational performance for manufacturing firms. As managers make decisions about the type and strength of controls to implement, shifting stakeholder focus to ICFR has the potential to either help (complementary effect) or harm (substitution effect) controls related to compliance and operational functions. We study 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 close to 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 may be 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 examine differences in FDA control deficiencies between mandatory ICFR disclosure regimes with varying levels of external scrutiny, compared to similar firms with no change in required disclosures. 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 variation in ICFR scrutiny will cause firms to allocate more resources to ICFR, 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 this conjecture. 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 the ICFR focus leads to an overall culture of compliance (Altamuro et al. 2021). Additionally, improvements to process-

level and monitoring-related ICFR can directly affect operational controls when controls achieve or oversee multiple objectives. Thus, allocating resources to ICFR in response to scrutiny may lead to improved operational controls and decreased likelihood of FDA inspection findings.

Alternatively, resource constraints may lead firms to 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 investment allocations are substitutive, resource constrained firms may delay operational control improvements when ICFR scrutiny is high. Thus, ICFR scrutiny may be associated with low-quality operational controls and increased likelihood of FDA deficiencies.

There was little external scrutiny of U.S. public issuer internal controls until SOX required audited management assessments and public disclosure of ICFR quality for accelerated filers beginning in 2004, resulting in a "large increase" in external scrutiny, and non-accelerated filers began providing unaudited disclosures in 2007, resulting in a "small increase" in external scrutiny. We use these two increases in ICFR scrutiny to examine effects on FDA inspection outcomes. Using a pre-/post-design, we first test whether the "large increase" in external scrutiny is associated with differences in FDA inspection outcomes. Second, we use a difference-in-differences design comparing differences in FDA inspection outcomes between firms experiencing this "large increase" in scrutiny as compared to firms with no required disclosures in either period ("no change"), and further limit our treatment sample firms to small accelerated filers to obtain a more comparable sample of firm-years. Next, we test whether the "small increase" in ICFR scrutiny for non-accelerated filers is associated with differences in FDA inspection outcomes, and also compare differences between firms experiencing this "small increase" in external scrutiny to firms that experience no change in ICFR disclosure requirements but do experience a small decrease in

external audit intensity ("small decrease" in scrutiny). 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 that the large increase in ICFR scrutiny is associated with decreased likelihood of FDA deficiencies as compared to the pre-mandatory ICFR disclosure period. Using the small firm difference-in-differences design, the likelihood of FDA deficiencies significantly decreases between firms experiencing the large increase in scrutiny as compared to firms experiencing no change. We identify no difference in FDA inspection findings post the 2007 small increase in ICFR scrutiny for non-accelerated filers, but do find a decreased likelihood of FDA deficiencies post small increase as compared to small firms experiencing a concurrent small decrease in scrutiny associated with a relaxation of auditing standards. In combination, our results are consistent with increased scrutiny upon first time audited ICFR disclosure (a stark increase to scrutiny) leading to spillover benefits, with additional evidence that smaller increases / decreases in scrutiny of ICFR also affect operational controls in a complementary manner.

Next, using two measures of resource availability (i.e., firm age and cash flow), we expect and find a decrease in FDA deficiencies with increased resource availability in tests of the large increase in scrutiny with weaker evidence associated with the small increase in scrutiny. Similarly, we find evidence that distressed firms are limited in their ability to make control improvements as beneficial effects of high scrutiny are moderated in distressed 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 the benefits associated with external scrutiny. In summary, we find that 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 in M&A (Caplan et al. 2018; Harp and Barnes 2018; Kravet et al. 2018), operational efficiency (Cheng et al. 2018), innovation (Dambra and Gustafson 2018; Miller et al. 2018) and management guidance (Feng et al. 2009). Our study complements this literature by providing evidence of improvements to operating controls that likely do not rely on financial reports in their performance.

We also add to literature that examines economic consequences of mandatory disclosure. Prior studies have shown that mandatory disclosure yields benefit 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 controls has positive spillover effects on firms' operating controls and compliance with non-financial regulation.

Finally, we contribute to the literature that specifically investigates the interaction of disclosure practices and FDA regulation. Down (2022) shows that FDA deficiencies influence managers' voluntary disclosure decisions and Enache et al. (2022) find that firms increase disclosure as their products advance through the FDA approval process. In the syndicated loan setting, Down et al. (2022) document that mandatory disclosure of FDA inspection outcomes curbs lead arrangers' ability to exploit their informational advantage over participant lenders. Aghamolla and Thakor (2021) also document when private firms are required to disclose clinical trial progress, they are more likely to go public. While these studies consider firms' disclosure of FDA-related information, our study adds to this literature by flipping the analysis: we assess how ICFR

disclosures – and the resultant scrutiny – affects 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 include requirements for companies to maintain a system of internal controls. Both the US 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 company 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 included fraudulent reporting, in all cases there was some form of inappropriate payment or bribery included in the action). Thus, external enforcement and scrutiny of internal controls was low.

Subsequently, SOX was passed with overwhelming bipartisan support 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, which states "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 corporate disclosure, multiple provisions of SOX focused managers on internal controls.

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.[1] 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 no material weaknesses in ICFR exist, 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 97% upon the initial implementation of ICFR audits in 2004 under Auditing Standard No. 2 (e.g., Kinney and Shepardson 2011). In addition to increases in fees, ICFR audits were associated with higher material weakness disclosure rates (Kinney and Shepardson 2011) and improved internal 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

[1] 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.

while maintaining audit effectiveness (PCAOB 2007). Prior work finds that AS5 led to decreased audit fees (Krishnan et al. 2011) and a corresponding decrease 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 providing unaudited management assessments of ICFR under SOX 404(a). The auditor has no requirement to provide positive 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 the 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 detrimental, beneficial, 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). 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 may be made in response to ICFR scrutiny, but 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 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, in the post-SOX period managers have additional incentives to invest in and focus on ICFR, which may lead to operational control problems if resources are re-allocated from those previously used for operational control compliance. For

example, with increased ICFR focus, more manager and internal auditor effort may be required to comply with ICFR requirements, taking time away from operational control oversight. 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 two changes in mandatory ICFR disclosure (i.e., 2004 implementation of audited ICFR disclosures for accelerated filers and the 2007 joint introduction of unaudited ICFR disclosures non-accelerated filers and the relaxation ICFR scrutiny under AS5 for accelerated

filers) to examine whether differences in ICFR scrutiny are 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 to occur every two years for certain higher-risk industries such as drugs and biologics, stipulated inspection intervals do not exist for lower-risk entities.[2] Thus, the FDA uses their discretion in deciding which sites to examine, using an approach based on the estimated significance of public health risks.

The FDA takes a process-based approach to monitoring (as compared to an output-based approach), that focuses largely on the internal controls implemented to ensure high quality manufacturing practices. Internal controls must be designed and implemented to ensure that products are manufactured according to the 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

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

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. Said differently, if the manufacturing and quality process can be deemed effective, there is increased assurance that the output of the process will be high quality.

Inspection manuals provide insights into what aspects of the firm 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 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. When inspectors observe practices that deviate from the relevant regulations and lead to the issuance of a Form 483, there is a risk that the firm's products may not conform to the standards that protect public health and safety. In order for such a problem to exist, either the firm did not establish appropriate internal controls, or the internal controls failed to operate effectively. 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 two increases in ICFR scrutiny, we construct two samples to cleanly 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 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 AS5 audit approach.

For our first (second) regime sample, we begin with 69,892 (75,665) observations from Compustat. When we merge these observations with Audit Analytics, we lose 29,872 (33,221) observations. We link these observations to the FDA inspection database. To facilitate this process,

we use the FDA's Significantly Regulated Organizations ("SRO") list. 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)). Any firm on the list could be inspected by the FDA during our sample periods.

We hand-match firms that are on the SRO list to Compustat. For each matched firm, we manually search the FDAzilla database for its inspection history. This inspection database was compiled by submitting a large number of Freedom of Information Act requests. It provides information on the duration, staffing, and outcomes of inspections, among other data points. We drop 33,754 (34,630) firms that do not conduct business in the FDA regulatory environment.

Finally, we lose 713 (481) observations due to missing data, and we also drop 1,470 (1,433) 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 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 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 material weaknesses in 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.

In subsample analysis, we restrict our accelerated filer group to those with less than $150 million in market capitalization. This improves the internal validity of our difference-in-difference research design, as our non-accelerated filers serve as a better counterfactual for this group of accelerated filers for our AS2 tests, and vice versa for our AS5/404(a) 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_DEFICIENCY*, an indicator variable equal to one if the firm receives 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 AS2 (SOX 404(a)) regulation 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 firms' 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:

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

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 change in external scrutiny over internal controls. 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 across business segments or countries. Alternatively, in this highly regulated space, firms might selectively expand only when their processes and systems 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 the quality of firms' 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 their 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. There tends to be a correlation between auditor size and client size, and internal control quality differs between small and large clients. Accordingly, 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 logarithm of audit fees (*FEES*) as auditors increase their effort and charge higher fees when internal controls are weaker. Management or auditors might also disclose the

existence of a material weakness under SOX 404(b), SOX 404(a), or SOX 302. We include an indicator variable equal to one if a material weakness disclosure is made at year-end or during the fiscal year to control for financial-reporting related problems within the firm (*MW*).

## 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, Panel B provides 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. Across the three distinct periods, the highest incidence of Form 483 issuance occurs for accelerated filers in the pre-ICFR audit period. This deficiency rate significantly decreases for accelerated filers with the large increase in ICFR scrutiny. We note a small, but statistically insignificant, increase in FDA deficiencies with the small increase in ICFR scrutiny. When compared to the pre-ICFR audit period, the incidence of Form 483 issuance in the lower scrutiny audit regime is still significantly lower for accelerated filers. In terms of non-accelerated filers, we observe fluctuations in the incidence of FDA deficiencies 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 C, we report the results of univariate difference-in-difference tests across. With the large increase in ICFR scrutiny, accelerated filers experienced a 7 percent decrease in the probability of encountering an inspection deficiency, relative to non-accelerated filers. This change

is significant and represents 27% 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 5% decrease in deficiencies, relative to accelerated filers. Once again, this is significant, as this represents 56% of the pre-ICFR scrutiny period mean deficiency probability. These results provide initial evidence that ICFR scrutiny exhibits a complementary relationship with operating control outcomes.

**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. 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 -0.08 to -0.17, representing 30 to 65 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 Increase in External ICFR Scrutiny*

In Table 4, we document effects on operating controls of the small increase in scrutiny associated with unaudited ICFR disclosure requirements 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 constrained 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 an insignificant, but negative coefficient on $REGCHG_{09\text{-}011}$, indicating that unaudited ICFR disclosures might not have a significant impact on operating control outcomes.

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 a negative, but statistically insignificant, coefficient on $REGCHG_{09\text{-}11} \times NAF$ in the all firms sample, and a significant, negative coefficient on the same variable in the size-restricted sample. This finding suggests that a small increase in scrutiny for non-accelerated filers and a small decrease in scrutiny for accelerated filers combine to generate a significant effect. When we compare the coefficients from the ICFR audited disclosures (high scrutiny) analysis to those documented for the smaller changes in scrutiny in the second regime change, 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 two measures to proxy for the construct of resource availability: firm age (*AGE*) and cashflow (*CASHFLOW*). Older firms are more established and can draw on experience adapting to change, as well as their established resource pools. High levels of cash flow help firms gain access to resources needed to make necessary changes within their organization.

We conjecture that firms with more resources can better adapt to ICFR disclosure requirements, as well as the corresponding increases in external scrutiny. Our results documented in Table 5 are consistent with this prediction. Across both 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. We find weaker evidence with the smaller increase in scrutiny, which indicates that external scrutiny helps firms allocate resources in a manner that allows them to maximize the benefits across the firm.

*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 $REGCHG_{06\text{-}07} \times AF \times PERC\_LOSS$. These findings suggest that financial distress limits the ability of firms to make investments that also yield spillover benefits for their operating control systems. In Columns 3 and 4, we find qualitatively similar results and they are once again weaker. This suggests that a lower scrutiny regime forces firms to draw lower levels of resources away from operational controls and toward ICFR controls.

**Additional Analyses**

In this section, we consider other factors that might impact firms' ability to adapt to ICFR scrutiny. We also present additional analysis to assess the robustness of our main result and to attenuate remaining endogeneity concerns.[3]

*Audit Quality*

Engaging a Big 4 auditor provides firms with expertise and assistance in navigating the regime changes that might help firms allocate their resources in a way that facilitates the maximization of multiple objectives. For example, higher quality auditors might be better able to suggest improvements that will benefit both financial reporting and operational outcomes. We test this conjecture and present our results in Table 7. Under both increases in ICFR scrutiny, we find that Big 4 auditors are able to support their clients in adapting to the new regulatory requirements,

[3] 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.

while also helping them achieve improvements in operational control outcomes. Because Big 4 auditors can also be seen as providing greater scrutiny over internal controls than less well-qualified auditors, this analysis also measures an alternative specification of scrutiny that complements our primary analysis.

*Tangible and Intangible Capital Investments*

Given that FDA regulated firms manufacture and/or process goods, there are often significant capital investments required to enter this market. Food production facilities rely on plants and machinery, and drug companies invest in research and development. In some cases, tangible property, plant, and equipment capture investments firms have made in their operating systems. Conversely, if firms must commit significant resources to research and development (i.e., intangible assets), then they might prioritize investments in operating control systems. These types of investment decisions can impact the influence of scrutiny on operating control outcomes.

In adjusting to the higher scrutiny regimes, firms with high levels of tangible capital investments might be in a better position to adapt to the change: firms having better technology might better respond to increased scrutiny and reap additional benefits by enhancing their operational controls. In Table 8, Columns 1 and 3, we document a significant, negative coefficients on $REGCHG_{06\text{-}07} \times AF \times CAP\_INTENSITY$ and $REGCHG_{09\text{-}11} \times NAF \times CAP\_INTENSITY$. This suggests that high levels of property, plant, and equipment provides firms with the infrastructure to realize improvements in both financial reporting and operating controls.

That said, in Column 2, we document a significant positive coefficient on $REGCHG_{06\text{-}07} \times AF \times INT\_INTENSITY$. Investments in intangible assets are unlikely to contribute to the strength of the firm's internal control system. Further, these types of investments will likely consume much of the firm's resource pool, potentially leaving little left over for investments in internal controls.

In Column 4, we do not find a significant coefficient on $REGCHG_{09\text{-}11} \times NAF \times INT\_INTENSITY$. This suggests that a lower scrutiny regime prevents firms from having to draw on their operational control resources in order to meet the demands of ICFR reporting.

*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 its own regulations and inspection guidelines specific to the industry's risks.

Given the potential overlap between the principles needed to establish adequate quality control systems and those needed for high quality ICFR, device manufacturers might be more affected by the changes in external scrutiny, as compared to other firms where ICFR-related concepts may play a smaller role in operating control outcomes. For example, financial statement auditors' expertise might not transfer as well to sanitation requirements for food manufacturers, as it would to the management reviews and quality audits required for device manufacturers. Consistent with this conjecture, we predict that the increased scrutiny imposed under both ICFR disclosure regime changes might help device manufacturers improve their operational outcomes.

We present our results in Table 9. In Columns 1 and 2, we document a significant, negative coefficients on $REGCHG_{06\text{-}07} \times AF \times DEVICE$ and $REGCHG_{09\text{-}11} \times NAF \times DEVICE$, which indicates that the increased ICFR scrutiny helped these firms to improve their quality systems. The findings suggest that changes in ICFR scrutiny had the largest impact on firms where the greatest potential for spillovers exists.

*Entropy Balancing*

Our main specification relies on a DiD research design in which non-accelerated filers are used as a benchmark group against which we can compare the changes experienced by the size-restricted group of accelerated filers when they encounter the changes in scrutiny. 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. This quasi-matching approach allows us to weight individual observations in a way that ensures the distributional properties (i.e., mean and standard deviation) 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*

When we construct our sample, we use the SRO list to determine 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. This seems unlikely given that the FDA's mission is to protect public health; therefore, its decisions are unlikely to move in lockstep with those of responsible for regulating the 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. We document a complementary relationship between ICFR scrutiny and operating control outcomes. A concern that emerges when two samples are used is that the sample composition could change, such that one group of firms is driving the relatively stronger AS2 result, while a different set of firms are driving the relatively weaker AS5/SOX 404(a) result. To address this alternative explanation, 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. Once again, our results continue to hold, which reinforces our conjecture that the regulatory changes are driving our results, not changes in sample composition.

*Oster Tests*

Finally, 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, this technique indicates that unobservables would need to have an impact equal to -3.00 times[4] (2.83 times) the impact of the observables included in our AS2 (AS5/SOX 404(a)) specifications. As a result, unobservable variables would need to have a substantial effect in order to threaten the internal validity of our findings. We argue that the existence of unobservable factors, with an impact of this magnitude, is unlikely.

[4] 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.

## V. Conclusion

In this study, we examine whether financial reporting and operating controls exhibit a complementary or substitutive relationship. While increased scrutiny 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, as many stakeholders question whether benefits exceed compliance costs. We investigate the possibility of operational and regulatory 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 the literature that assesses benefits of ICFR regulation by showing that more intense scrutiny improves other aspects of the control system, which focus on producing outputs other than financial reports. 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 also 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 Variable: | |
| *FDA_DEFICIENCY* | An indicator variable equal to one if the firm receives a Form 483 during the fiscal year, 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. |
| Other Variables: | |
| *MAT_WEAK* | An indicator variable coded as 1 if the firm discloses a material weakness at some point during the fiscal year, and 0 otherwise. Material weakness disclosures are based on SOX 404(b) opinions, SOX 404(a) management reports, and/or Section 302 disclosures (obtained from Audit Analytics). |
| *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-1assets. |
| *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). |

| Variable | Description |
|---|---|
| *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 Increase Sample (November 15, 2004 to December 31, 2011) |
|---|---|---|
| All available U.S. Compustat annual observations for the respective fiscal periods | 69,892 | 75,665 |
| Less: Observations that do not merge with Audit Analytics database | (29,872) | (33,221) |
| Less: Observations that are not listed on the FDA's Significantly Regulated Organizations list | (33,754) | (34,630) |
| Less: Observations with missing values for the remaining control variables necessary to run the multivariate analyses | (713) | (481) |
| Less: Transition year observations after regime change | (1,470) | (1,433) |
| Total available observations for the main multivariate analyses | 4,083 | 5,900 |

**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 Panel B, we provide the means and median values for each variable and separate the statistics by regime period. In Panel C, 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 | 0.30 | 0.29 | 0.24 | 0.23 | 0.25 | 0.19 | 0.21 | 0.21 | 0.23 | 0.24 | 0.22 |
| Non-accelerated Filers | 0.06 | 0.06 | 0.07 | 0.08 | 0.09 | 0.11 | 0.05 | 0.09 | 0.06 | 0.07 | 0.06 |

**Panel B: Means and Medians by Filer Group**

| | Pre-Change in Scrutiny | | | | Large Increase in Scrutiny | | | | Small Increase in Scrutiny | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | AF (n=2151) | | NAF (n=646) | | AF (n=2104) | | NAF (n=652) | | AF (n=2668) | | NAF (n=476) | |
| Variable | Mean | Mdn | Mean | Mdn | Mean | Mdn | Mean | Mdn | Mean | Mdn | Mean | Mdn |
| *FDA_DEFICIENCY* | 0.26 | 0.00 | 0.07 | 0.00 | 0.21* | 0.00# | 0.09 | 0.00 | 0.23 | 0.00 | 0.06* | 0.00# |
| *MAT_WEAK* | 0.04 | 0.00 | 0.03 | 0.00 | 0.22* | 0.00# | 0.14* | 0.00# | 0.22 | 0.00 | 0.22* | 0.00# |
| *BSEG* | 1.17 | 1.39 | 0.97 | 0.69 | 1.18 | 1.39 | 0.95 | 0.69 | 1.13* | 1.39# | 0.92 | 0.69 |
| *FOREIGN* | 0.30 | 0.00 | 0.10 | 0.00 | 0.39* | 0.00# | 0.15* | 0.00# | 0.40 | 0.00 | 0.16 | 0.00 |
| *GROWTH* | 0.23 | 0.10 | 0.10 | 0.01 | 0.15* | 0.06# | 0.31* | 0.07# | 0.11* | 0.05# | 0.17* | 0.01# |
| *ARINV* | 0.27 | 0.26 | 0.32 | 0.26 | 0.26* | 0.25# | 0.31 | 0.29 | 0.26 | 0.24# | 0.31 | 0.30 |
| *MERGER* | 0.42 | 0.00 | 0.19 | 0.00 | 0.29* | 0.00# | 0.20 | 0.00 | 0.19* | 0.00# | 0.15* | 0.00# |
| *RESTRUCTURE* | 0.34 | 0.00 | 0.10 | 0.00 | 0.65* | 1.00# | 0.25* | 0.00# | 0.65 | 1.00 | 0.17* | 0.00# |
| *STD_SALE* | 5.29 | 5.33 | 0.92 | 0.90 | 5.40 | 5.83# | 1.64* | 1.17# | 5.55* | 5.70 | 0.93* | 0.96# |
| *STD_CFO* | 4.09 | 4.01 | 0.29 | 0.38 | 4.09 | 4.30 | 0.99* | 0.49# | 4.54* | 4.63# | 0.57* | 0.55 |
| *OP_CYCLE* | 4.74 | 4.72 | 4.84 | 4.83 | 4.76 | 4.85 | 4.84 | 4.89 | 4.62* | 4.60# | 4.79 | 4.86 |
| *INT_INTENSITY* | 0.79 | 0.04 | 0.89 | 0.03 | 0.83 | 0.05# | 1.39* | 0.04# | 0.55* | 0.04# | 1.09 | 0.06# |
| *NO_INT* | 0.23 | 0.00 | 0.27 | 0.00 | 0.16* | 0.00# | 0.20* | 0.00# | 0.18* | 0.00# | 0.14* | 0.00# |
| *CAP_INTENSITY* | 0.26 | 0.25 | 0.25 | 0.19 | 0.23* | 0.20# | 0.22* | 0.18# | 0.23* | 0.22 | 0.17* | 0.12# |
| *SIZE* | 7.71 | 7.87 | 2.93 | 2.99 | 7.86* | 8.08# | 3.88* | 3.49# | 8.22* | 8.58# | 3.03* | 3.02# |
| *PERC_LOSS* | 0.17 | 0.00 | 0.50 | 0.67 | 0.17 | 0.00 | 0.41* | 0.33# | 0.18 | 0.00# | 0.62* | 0.67# |
| *MBR* | 5.07 | 3.72 | 3.73 | 1.71 | 4.39* | 3.24# | 5.04* | 2.71# | 3.43* | 2.34# | 4.39 | 1.81# |
| *BIGN_AA* | 0.97 | 1.00 | 0.60 | 1.00 | 0.93* | 1.00# | 0.40* | 0.00# | 0.91* | 1.00# | 0.19* | 0.00# |
| *ZMIJ_SHUM* | -3.07 | -2.97 | -2.40 | -2.87 | -3.05 | -3.01 | 2.67* | -3.07# | -3.03 | -2.99 | -2.38* | 2.85# |
| *FEES* | 13.80 | 14.05 | 11.52 | 11.45 | 14.79* | 15.02# | 12.2* | 12.07# | 14.80 | 15.06 | 11.99* | 11.97 |
| *AGE* | 3.18 | 3.47 | 2.68 | 2.64 | 3.26* | 3.40# | 2.84* | 2.83# | 3.38* | 3.5# | 2.82 | 2.83 |

**Panel C: Univariate Difference-in-Differences (DiD)**

| | Difference in Means Large Increase in Scrutiny | | | Difference in Means Small Increase in Scrutiny | | |
|---|---|---|---|---|---|---|
| | AF | NAF | DiD | NAF | AF | DiD |
| *FDA_DEFICIENCY* | -0.05 | 0.02 | -0.07* | -0.03 | 0.02 | -0.05* |

**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-year 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* |
|---|---|---|---|
| | (1) | (2) | (3) |
| *REGCHG_0607* | -0.09*** | | |
| | (-4.08) | | |
| *AF* | | 0.08*** | 0.08** |
| | | (4.16) | (2.45) |
| *REGCHG_0607 × AF* | | -0.08** | -0.17** |
| | | (-2.12) | (-2.07) |
| *MAT_WEAK* | 0.02 | 0.02 | -0.02 |
| | (0.53) | (0.88) | (-0.31) |
| *BSEG* | 0.01 | 0.01 | 0.03 |
| | (0.46) | (0.87) | (1.01) |
| *FOREIGN* | -0.01 | 0.00 | -0.05*** |
| | (-0.41) | (0.23) | (-2.65) |
| *GROWTH* | -0.01 | -0.01* | -0.02 |
| | (-1.21) | (-1.80) | (-1.53) |
| *ARINV* | 0.03 | -0.02 | -0.02 |
| | (0.35) | (-0.45) | (-0.33) |
| *MERGER* | -0.01 | 0.00 | 0.03 |
| | (-0.45) | (-0.28) | (0.98) |
| *RESTRUCTURE* | 0.01 | 0.03** | 0.07** |
| | (0.67) | (1.99) | (2.07) |
| *STD_SALE* | -0.01 | -0.01 | -0.01 |
| | (-0.46) | (-0.74) | (-1.63) |
| *STD_CFO* | -0.02** | -0.01 | -0.02* |
| | (-2.16) | (-1.55) | (-1.96) |
| *OP_CYCLE* | 0.02*** | 0.02*** | 0.01 |
| | (2.74) | (3.19) | (0.96) |
| *INT_INTENSITY* | -0.00*** | -0.00** | 0.00 |
| | (-3.62) | (-2.18) | (-1.26) |
| *NO_INT* | 0.01 | 0.00 | -0.06** |
| | (0.39) | (0.21) | (-2.35) |
| *CAP_INTENSITY* | 0.25*** | 0.19*** | 0.04 |
| | (3.94) | (4.75) | (0.85) |

**TABLE 3 (CONTINUNED)**

| | | | |
|---|---|---|---|
| *SIZE* | 0.03* | 0.03*** | 0.04*** |
| | (1.84) | (3.59) | (3.54) |
| *PERC_LOSS* | -0.13*** | -0.10*** | -0.08** |
| | (-2.97) | (-4.10) | (-2.47) |
| *MBR* | 0.00 | 0.00* | 0.00 |
| | (1.55) | (1.90) | (0.55) |
| *BIGN_AA* | -0.01 | -0.05*** | -0.08*** |
| | (-0.27) | (-2.75) | (-3.77) |
| *ZMIJ_SHUM* | -0.01** | -0.01 | 0.00 |
| | (-2.27) | (-1.64) | (0.55) |
| *FEES* | 0.01 | 0.01 | 0.03* |
| | (0.91) | (1.18) | (1.98) |
| *AGE* | 0.01 | 0.01 | 0.02 |
| | (0.94) | (1.12) | (0.80) |
| *CONSTANT* | -0.28* | -0.28*** | -0.37* |
| | (-1.87) | (-2.66) | (-1.80) |
| Sample | AF=1 | DiD, ALL | DiD, MVE<150 \| AF=0 |
| Industry FE | Y | Y | Y |
| Year FE | N | Y | Y |
| Observations | 3221 | 4083 | 1153 |
| Adjusted $R^2$ | 0.10 | 0.12 | 0.09 |

**TABLE 4**
**Small Increase in Scrutiny for Non-Accelerated Filers and Differences in FDA Deficiencies**

This table documents the impact of a small change in scrutiny on FDA deficiencies. We estimate Equation 1 and present the results of using different samples. In Column (1), we use a sample restricted to non-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-year 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* |
|---|---|---|---|
| | (1) | (2) | (3) |
| *REGCHG_0911* | -0.02 | | |
| | (-1.41) | | |
| *NAF* | | -0.01 | 0.02 |
| | | (-0.41) | (0.80) |
| *REGCHG_0911 × NAF* | | -0.05 | -0.10*** |
| | | (-1.26) | (-2.70) |
| *MAT_WEAK* | -0.03* | 0.02 | -0.05** |
| | (-1.89) | (1.25) | (-2.29) |
| *BSEG* | 0.04** | 0.00 | 0.03* |
| | (2.18) | (0.37) | (1.75) |
| *FOREIGN* | -0.05*** | 0.01 | -0.04*** |
| | (-3.25) | (0.48) | (-2.71) |
| *GROWTH* | -0.01 | 0.00 | -0.01** |
| | (-1.13) | (-0.29) | (-2.28) |
| *ARINV* | 0.07 | 0.00 | 0.08 |
| | (1.47) | (0.03) | (1.41) |
| *MERGER* | 0.00 | 0.03** | -0.01 |
| | (-0.11) | (2.05) | (-0.33) |
| *RESTRUCTURE* | -0.02 | 0.02 | 0.00 |
| | (-0.58) | (1.48) | (-0.18) |
| *STD_SALE* | -0.01 | 0.01 | 0.00 |
| | (-0.84) | (0.91) | (-0.70) |
| *STD_CFO* | -0.01 | -0.02** | -0.03** |
| | (-0.99) | (-2.54) | (-2.50) |
| *OP_CYCLE* | 0.00 | 0.02*** | 0.00 |
| | (0.26) | (3.08) | (-0.00) |
| *INT_INTENSITY* | 0.00 | -0.00*** | -0.00* |
| | (-0.55) | (-2.74) | (-1.93) |
| *NO_INT* | -0.05* | -0.05*** | -0.07*** |
| | (-1.87) | (-2.61) | (-3.52) |
| *CAP_INTENSITY* | 0.05 | 0.18*** | 0.05 |
| | (0.86) | (4.22) | (0.91) |
| *SIZE* | 0.02 | 0.02** | 0.04*** |
| | (1.65) | (2.56) | (4.28) |

**TABLE 4 CONTINUED**

| | | | |
|---|---|---|---|
| *PERC_LOSS* | 0.03 | -0.06*** | 0.02 |
| | (0.76) | (-3.27) | (0.79) |
| *MBR* | 0.00 | 0.00*** | 0.00 |
| | (1.08) | (2.91) | (0.51) |
| *BIGN_AA* | -0.07*** | -0.04*** | -0.07*** |
| | (-3.92) | (-2.87) | (-4.25) |
| *ZMIJ_SHUM* | -0.01 | -0.01*** | 0.00 |
| | (-1.62) | (-2.91) | (-0.43) |
| *FEES* | 0.03** | 0.01 | 0.01 |
| | (2.56) | (1.28) | (1.31) |
| *AGE* | 0.02 | 0.03*** | 0.01 |
| | (1.21) | (2.87) | (0.63) |
| *CONSTANT* | -0.49*** | -0.39*** | -0.24* |
| | (-3.13) | (-2.93) | (-1.80) |
| Sample | NAF=1 | DiD, ALL | DiD, MVE<150 \| AF=0 |
| Industry FE | Y | Y | Y |
| Year FE | N | Y | Y |
| Observations | 1126 | 5900 | 1407 |
| Adjusted $R^2$ | 0.06 | 0.11 | 0.07 |

**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) and (2), we focus on the time period surrounding the "large increase" in external scrutiny. In Columns (3) and (4), we focus on the time period surrounding the "small increase" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry-year 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* | -0.01 | 0.08** | | |
| | (-0.08) | (2.45) | | |
| *REGCHG_0607 × AF* | 0.72*** | -0.21*** | | |
| | (5.05) | (-2.77) | | |
| *REGCHG_0607 × AF × AGE* | -0.31*** | | | |
| | (-5.68) | | | |
| *REGCHG_0607 × AF × CASHFLOW* | | -0.32*** | | |
| | | (-4.66) | | |
| *NAF* | | | -0.27 | 0.03 |
| | | | (-1.31) | (1.21) |
| *REGCHG_0911 × NAF* | | | -0.01 | -0.14*** |
| | | | (-0.05) | (-2.86) |
| *REGCHG_0911 × NAF × AGE* | | | -0.04 | |
| | | | (-0.45) | |
| *REGCHG_0911 × NAF × CASHFLOW* | | | | -0.20* |
| | | | | (-1.81) |
| 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 | 1153 | 1153 | 1407 | 1407 |
| Adjusted $R^2$ | 0.10 | 0.09 | 0.07 | 0.07 |

**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) and (2), we focus on the time period surrounding the "large increase" in external scrutiny. In Columns (3) and (4), we focus on the time period surrounding the "small increase" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry-year 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* | 0.09** | 0.12** | | |
| | (2.47) | (2.40) | | |
| *REGCHG_0607 × AF* | -0.20** | -0.32*** | | |
| | (-2.23) | (-3.67) | | |
| *REGCHG_0607 × AF × DISTRESS* | 0.29*** | | | |
| | (3.12) | | | |
| *REGCHG_0607 × AF × PERC_LOSS* | | 0.34*** | | |
| | | (4.07) | | |
| *NAF* | | | 0.03 | 0.04 |
| | | | (1.20) | (0.69) |
| *REGCHG_0911 × NAF* | | | -0.12*** | -0.18* |
| | | | (-2.87) | (-1.85) |
| *REGCHG_0911 × NAF × DISTRESS* | | | 0.23*** | |
| | | | (2.76) | |
| *REGCHG_0911 × NAF × PERC_LOSS* | | | | 0.11 |
| | | | | (0.86) |
| 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 | 1153 | 1153 | 1407 | 1407 |
| Adjusted $R^2$ | 0.08 | 0.09 | 0.07 | 0.07 |

**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 increase" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry-year 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* |
|---|---|---|
| | (1) | (2) |
| *AF* | 0.05 | |
| | (0.84) | |
| *REGCHG_0607* × *AF* | -0.02 | |
| | (-0.29) | |
| *REGCHG_0607* × *AF* × *BIGN_AA* | -0.16** | |
| | (-2.01) | |
| *NAF* | | -0.03 |
| | | (-0.83) |
| *REGCHG_0911* × *NAF* | | 0.02 |
| | | (0.33) |
| *REGCHG_0911* × *NAF* × *BIGN_AA* | | -0.19*** |
| | | (-3.01) |
| Sample | DiD, MVE<150 \| AF=0 | DiD, MVE<150 \| AF=0 |
| Controls | Y | Y |
| Industry FE | Y | Y |
| Year FE | Y | Y |
| Observations | 1153 | 1407 |
| Adjusted $R^2$ | 0.09 | 0.07 |

**TABLE 8**
**Investments and Differences in FDA Deficiencies**

This table documents the effect of financial tangible and intangible investments 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) and (2), we focus on the time period surrounding the "large increase" in external scrutiny. In Columns (3) and (4), we focus on the time period surrounding the "small increase" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry-year 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* |
|---|---|---|---|---|
| | (1) | (2) | (3) | (4) |
| *AF* | 0.09** | 0.09** | | |
| | (2.28) | (2.33) | | |
| *REGCHG_0607* × *AF* | -0.10 | -0.22*** | | |
| | (-1.35) | (-2.81) | | |
| *REGCHG_0607* × *AF* × *CAP_INTENSITY* | -0.46** | | | |
| | (-2.24) | | | |
| *REGCHG_0607* × *AF* × *INT_INTENSITY* | | 0.03*** | | |
| | | (5.88) | | |
| *NAF* | | | 0.00 | 0.02 |
| | | | (0.15) | (0.86) |
| *REGCHG_0911* × *NAF* | | | -0.04 | -0.12*** |
| | | | (-1.08) | (-2.67) |
| *REGCHG_0911* × *NAF* × *CAP_INTENSITY* | | | -0.42* | |
| | | | (-1.75) | |
| *REGCHG_0911* × *NAF* × *INT_INTENSITY* | | | | 0.00 |
| | | | | (0.98) |
| 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 | 1153 | 1153 | 1407 | 1407 |
| Adjusted $R^2$ | 0.09 | 0.09 | 0.07 | 0.07 |

**TABLE 9**
**ICFR/FDA Scrutiny Overlap and Differences in FDA Deficiencies**

This table documents impact of overlap between ICFR and FDA scrutiny 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 increase" in external scrutiny. The t-statistics reported in parentheses are based on standard errors clustered at the industry-year 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* |
|---|---|---|
| | (1) | (2) |
| *AF* | 0.05** | |
| | (2.03) | |
| *REGCHG_0607* × *AF* | -0.10 | |
| | (-0.91) | |
| *REGCHG_0607* × *AF* × *MEDICAL DEVICES* | -0.39** | |
| | (-2.00) | |
| *NAF* | | 0.02 |
| | | (0.57) |
| *REGCHG_0911* × *NAF* | | -0.03 |
| | | (-0.69) |
| *REGCHG_0911* × *NAF* × *MEDICAL DEVICES* | | -0.39*** |
| | | (-2.99) |
| Sample | DiD, MVE<150 \| AF=0 | DiD, MVE<150 \| AF=0 |
| Controls | Y | Y |
| Industry FE | Y | Y |
| Year FE | Y | Y |
| Observations | 1153 | 1407 |
| Adjusted $R^2$ | 0.15 | 0.13 |

**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 distributional properties (i.e., the first two moments) of the AF observations match those of the NAF observations. In Column (2), we perform entropy balancing to ensure that the distributional properties (i.e., the first two moments) 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. The t-statistics reported in parentheses are based on standard errors clustered at the industry-year 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) |
|---|---|---|---|---|---|---|
| *AF* | 0.07** | | 0.18 | | 0.10** | |
| | (2.14) | | (1.15) | | (2.22) | |
| *REGCHG_0607 × AF* | -0.18*** | | -0.39** | | -0.21** | |
| | (-3.67) | | (-2.12) | | (-2.05) | |
| *NAF* | | 0.03** | | 0.18* | | 0.02 |
| | | (2.10) | | (1.97) | | (0.62) |
| *REGCHG_0911 × NAF* | | -0.10*** | | -0.38*** | | -0.11** |
| | | (-3.07) | | (-2.91) | | (-2.33) |
| 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 | 1153 | 1407 | 288 | 332 | 901 | 983 |
| Adjusted $R^2$ | 0.16 | 0.10 | 0.20 | 0.15 | 0.10 | 0.09 |