Information Disclosure and Peer Innovation: Evidence from Mandatory Reporting of Clinical Trials

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Abstract

We document significant increases in the suspension of ongoing drug projects following the passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which mandates that pharmaceutical companies publicly disclose detailed clinical study results. Our results suggest a causal interpretation through difference-in-differences analyses that exploit variations in pre-FDAAA information environments. We also show evidence that fewer new projects are initiated after the FDAAA. Drug developers' learning from peer failures is the primary mechanism, further amplified by financial constraints. We also examine the consequences of enhanced information disclosure, including changes in firm investment efficiency, drug quality, and disease morbidity.

Keywords: Innovation, New Drug Development, Mandatory Information Disclosure, Information Diffusion, Peer Effects, Divestment, Investment Efficiency, Welfare Consequences

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I. Introduction

Pharmaceutical firms, compared to those in other industries, exert significant influence on the economy, public health, and social welfare. Motivated by the need to meet evolving healthcare demands, navigate intense market competition, and comply with strict regulatory standards, these companies prioritize the development of innovative products, leading to substantially more investment in research and development (R&D) compared to others. According to the Congressional Budget Office, the U.S. pharmaceutical industry alone dedicated $83 billion to R&D expenditures in 2019. Also, in that year, pharmaceutical companies allocated approximately one-quarter of their revenues to R&D expenses on average, a larger share than observed in other knowledge-intensive industries such as semiconductors, technology hardware, and software (Congressional Budget Office (2021)). Consequently, the determinants of pharmaceutical firms' R&D investment have gained particular attention in the finance literature, spawning an emerging area of research.[1]

Information externalities are pivotal considerations for pharmaceutical firms when making investment decisions, due to the significantly lower cost of replicating an innovation compared to the substantial expenses involved in the initial experimentation and development processes. Thus, pharmaceutical firms have strong incentives not to publicly disclose any experimental details of drug development because of the immense value placed on proprietary information. However, the information landscape changed with the enactment of the Food and Drug Administration

[1] See, for example, Krieger, Li, and Papanikolaou (2022a), Aghamolla and Thakor (2022), Thakor and Lo (2022), and Mace (2022). Lo and Thakor (2022) also provide an excellent review of this strand of finance research.

Amendments Act (FDAAA) in 2007. Section 801 of this Act heightened information disclosure requirements regarding new drug development by mandating the disclosure of "experimental details" (i.e., detailed designs and outcomes of clinical trials). This led to substantially enhanced information disclosures following the FDAAA, as confirmed by studies such as Gill (2012) and Dos Santos and Atallah (2015). Moreover, the FDAAA requires the disclosure of experimental details of both successful and *unsuccessful* clinical trials, creating information externalities among peers that are free from firms' self-selection and strategic disclosure practices (see Appendix A for further institutional details).[2]

In this paper, we analyze how the passage of the FDAAA, as a quasi-natural shock that mandates the disclosure of experimental details, influences pharmaceutical firms' innovation decisions. The specificity of the FDAAA in disclosing experimental details—the fundamental information signal that is crucial for making investment decisions—offers us a unique and ideal setting to explore the learning channel in corporate innovation.[3] The detailed disclosures influence a pharmaceutical firm's incentive to either continue or discontinue the clinical trial of a

[2]It is worth noting that while drug developers in the pre-FDAAA era may have been aware of the existence of all relevant ongoing projects in the market due to Institutional Review Boards (IRBs) approval requirements, they lacked comprehensive information about the clinical trial designs and experimental outcomes of such projects. Therefore, the FDAAA transformed the type of available information from a mere binary format of initiations and terminations to detailed clinical trial outcomes of ongoing projects.

[3]While prior studies in the finance literature have examined the effects of peer learning, they have focused on broader and indirect information signals such as stock prices (Foucault and Fresard (2014)) and financial statements (Badertscher, Shroff, and White (2013), Leary and Roberts (2014), Bernard, Blackburne, and Thornock (2020), and Bustamante and Frésard (2021)).

new drug project because its expected profits from that project hinge upon observable experimental outcomes of its peers (i.e., other drug developers conducting clinical trials in the same indication as the firm).[4]

Once the focal firm learns from the experimental details of its peers' clinical trials, it revises the prospects for its own project, one which tackles similar experimental challenges, and subsequently aligns its investment decisions *consistent* with the experimental outcomes of its peers (Krieger (2021)). In other words, the firm is more likely to suspend its projects if it observes failed clinical trial details among its peers.

Moreover, we expect that the learning effect of the FDAAA is amplified in the presence of financial constraints because more financially constrained firms typically face higher investment hurdle rates (Bolton, Wang, and Yang (2014) and Bolton, Wang, and Yang (2019)) and have a greater need to gauge the probability of success due to their limited resources and lack of risk diversification. Consequently, financially constrained firms are more inclined to rely on peers' experimental details to adjust their projects' success probability accordingly.

We use the BioMedTracker (BMT) database that covers the progress of a broad scope of clinical trials both before and after the FDAAA. This database gathers information from multiple sources including medical conferences, proprietary or public databases, press releases, company websites, earnings conference calls, and the ClinicalTrials.gov database. In particular, we focus on industry-sponsored clinical trials for new drugs (referred to as "projects") for the ten-year

[4] An indication refers to a medical condition that requires the use of the drug as a treatment (e.g., diabetes is an indication for insulin).

period from 2002 to 2012 surrounding the FDAAA enactment in 2007.[5] We use the suspension of a project as a proxy for *divestment*, distinguishing it from other investment or innovation measures in the prior literature, since project suspension signifies the discontinuation of ongoing projects. We find that the project suspension likelihood increases by approximately 5% following the enactment of the FDAAA. We further support our findings by examining the number of new project initiations, which serves as an additional proxy for investment.

We argue that an aggregate pattern of reductions in drug development activities after the FDAAA aligns more with learning rather than with the competitive effect for the following reasons. The FDAAA requires comprehensive disclosures on both successful and unsuccessful experimental outcomes. For successful outcomes, their *announcements* may initially prompt competitors to abandon their investments due to potentially diminished expected payoffs; however, their *details* could be learned and extended by subsequent innovators, leading to more efficient investments and more project initiations. For unsuccessful outcomes, their announcements may motivate competitors to continue their projects for first-mover advantages; however, their details can deter further pharmaceutical investments by illuminating challenges within specific areas of research. In the end, the aggregate impact of the FDAAA on pharmaceutical investment is contingent upon the relative prevalence of actual clinical trial failures vs. successes. Given the notably high failure rate of clinical trials (reported as 96%, for

[5]Non-industry-sponsored (henceforth, academic or academic-sponsored) clinical trials are projects with principal investigators from non-profit organizations such as universities and hospitals supported by federal agencies (e.g., NIH), states, and non-profit foundations. Since academic-sponsored clinical trials may have different incentives and funding constraints, our analyses focus solely on industry-sponsored clinical trials.

example, in Hingorani, Kuan, Finan, Kruger, Gaulton, Chopade, Sofat, MacAllister, Overington, Hemingway et al. (2019)), the prevalence of clinical trial failures far exceeds that of successes, providing more opportunities for drug developers to learn from the details of these failures after the FDAAA. Furthermore, considering that the FDA typically grants drug developers exclusive rights for a minimum of five years after approval, the benefits of learning from other firms' success details are inherently limited.

To establish a causal interpretation of our result, we employ a difference-in-differences (DID) test by exploiting a difference in the timing of compliance with mandatory disclosure requirements between industry-sponsored and academic-sponsored clinical trials. In September 2004, approximately three years before the FDAAA enactment, the joint editorial of the International Committee of Medical Journal Editors (ICMJE) issued a new policy that requires journal submitters to register their projects in a comprehensive, publicly available database prior to submission (DeAngelis, Drazen, Frizelle, Haug, Hoey, Horton, Kotzin, Laine, Marusic, Overbeke et al. (2005a), DeAngelis, Drazen, Frizelle, Haug, Hoey, Horton, Kotzin, Laine, Marusic, Overbeke et al. (2005b)).[6] Given academics' strong incentive to publish papers based on clinical trials, irrespective of the trial outcomes being successful or failed, we expect that experimental details of a substantial number of academic-sponsored projects have been disclosed under the ICMJE policy. This policy has resulted in a wealth of peer information available to

[6]The policy aims to promote the disclosure of clinical study details conducted by academic investigators and explicitly mandates journal submitters to register their clinical trial details beyond phase 1 in a comprehensive and publicly available database (such as ClinicalTrials.gov) before submission. For a list of journals that follow the ICMJE recommendations, refer to http://www.icmje.org/.

companies developing projects since 2004, in indications with a substantial number of academic-sponsored projects compared to those with fewer academic-sponsored projects. As a result, the FDAAA in 2007 would have significantly more influence on the level of information derived from peers' disclosures for the firms in indications with more industry-sponsored projects (i.e., fewer academic-sponsored projects, or higher industry-sponsored project ratio).

Our DID tests show a significant increase in the suspension rate of industry-sponsored projects in indications with a higher industry-sponsored project ratio after the FDAAA. An additional DID test also shows a significant reduction in project initiations in indications with a higher industry-sponsored project ratio after the FDAAA. We ensure that our findings regarding project suspensions are not driven by the 2008-2009 financial crisis or by either variations in external financing opportunities or innovation capabilities among firms in indications with different industry-sponsored project ratios. We also conduct dynamic DID analyses to further isolate the effects of the FDAAA from other regulatory changes or economic conditions. Our DID results robustly confirm that informational externalities facilitated by the FDAAA significantly contribute to drug developers' divestment decisions.

We recognize a potential self-selection concern in that firms opting to develop new drugs in indications with a lower industry-sponsored project ratio may fundamentally differ from those targeting indications with a higher industry-sponsored project ratio. Hence, we reinforce the causal interpretation of our findings by additionally implementing a *within*-indication DID test that considers within-indication heterogeneity in firms' sensitivity to enhanced disclosures.[7] We find that firms that are more likely to be sensitive to peers' enhanced disclosures (i.e., those new

[7]We hypothesize that, among all firms within the same indication group, those with less experience (i.e., new to a

to a certain indication and phase) tend to suspend their projects more after the FDAAA than other firms within the same indication group.

Further analyses support that the effect of the FDAAA is driven by peer learning rather than competition. In the pre-FDAAA period, we observe a decrease in a project's suspension likelihood with an increase in peer project suspensions, a pattern consistent with the competition mechanism but not the learning mechanism. This suggests that peer learning and information spillover among peers are likely limited before the FDAAA due to the binary nature of information on peer events (i.e., occurrences), which lacks detailed study designs or outcomes. However, the passage of the FDAAA has led to an overall increase in the project's suspension likelihood, especially driven by the disclosures of detailed study designs or outcomes of failed peer projects, indicative of learning. In addition, we show that the positive association between a focal firm's project suspensions and peer suspensions after the FDAAA is concentrated in low-quality focal firms and is also stronger with the information from high-quality peers. These results reaffirm the learning mechanism.

We then examine how the effect of the FDAAA on increased suspension is amplified by financial constraints. We find that, following the FDAAA, the suspension likelihood of financially constrained firms with projects in indications with a higher industry-sponsored project ratio increases relatively more than financially unconstrained firms. This finding underscores the significance of the learning mechanism, as financially constrained firms, facing higher investment hurdle rates (Bolton et al. (2014), Bolton et al. (2019)) and being characterized by both limited

certain indication and phase) are affected by the FDAAA to a greater extent because they are more dependent on information disseminated by peer firms.

resources and a lack of risk diversification, are more likely to rely on peers' experimental details to adjust their investment decisions.

In our last set of empirical tests, we explore possible economic and public health consequences of enhanced disclosures of clinical trials after the FDAAA. First, we find that investment efficiency, measured by the sensitivity of firm investments to Tobin's Q, significantly improves after the FDAAA for firms with projects in indications with a higher industry-sponsored project ratio. This result suggests that firms can make more informed decisions with respect to drug development by leveraging insights from peer investments (both private and public ones) in enhanced information environments, which echoes Hegde, Herkenhoff, and Zhu (2023).

Second, we find that the frequency of serious adverse patient events associated with a drug decreases significantly after the FDAAA for firms with projects in indications with a higher industry-sponsored project ratio. On the other hand, we find a substantial decline in the annual growth rate of active projects post-FDAAA, which can be attributed to firms' learning of peers' failures and reduced first-mover advantage due to mandatory disclosure.[8]

Third, we assess the public health implications of the FDAAA by comparing Disability-Adjusted Life Years (DALYs, the number of years lost due to a given disease) from the World Health Organization (WHO) between two indication groups experiencing contrasting levels of growth in terms of (i) active projects and (ii) serious adverse patient outcomes around

[8]Furthermore, the increased dissemination of information regarding the challenges associated with ongoing new drug development may prompt firms to abandon certain projects sooner and more readily (Garfinkel, Hammoudeh, Irlbeck, and Lie (2022)). While such a decision can be optimal from the perspective of individual firms, it may not necessarily be optimal for overall social welfare (Hall and Lerner (2010) and Budish, Roin, and Williams (2015)).

the FDAAA. Our analysis suggests that if the low-growth group in active projects were to receive an equivalent level of firm investment as the high-growth group, the DALYs of the low-growth group would have also decreased by a similar magnitude (8.27%), resulting in 7.6 million life years saved. On the other hand, the low-growth group in the number of adverse patient outcomes related to the FDAAA exhibits a reduction in health loss by 8.76% due to improved drug quality.

Our paper contributes to the literature in several ways. First, we add to a relatively new strand of the finance literature on drug development (e.g., Krieger et al. (2022a), Aghamolla and Thakor (2022), Thakor and Lo (2022), and Mace (2022)) by examining the impact of the FDAAA and subsequent changes in information environments on drug development. We also highlight the role of financial constraints in drug development and innovation externalities, offering insights into the important finance-innovation nexus.

Second, we use a regulatory change to highlight the role of peer learning in corporate investment decisions with a particular focus on the information content in clinical trial outcomes.[9] Our paper is also related to the emerging literature on pharmaceutical firms' reactions to public disclosure (Krieger (2021) and Krieger, Li, and Thakor (2022b)) and the broader literature on enhanced information disclosure of corporate innovation.[10] Previous empirical evidence for the

[9]This approach differs from, but complements, prior finance studies that have explored the informational role of peer stock prices (e.g., Foucault and Fresard (2014)), financial policies (e.g., Leary and Roberts (2014)), IPO decisions (Aghamolla and Thakor (2022)), and investments (Badertscher et al. (2013), Bernard et al. (2020), and Bustamante and Frésard (2021)).

[10]When firms are required to disclose their innovative activities, they often reduce their investment due to the potential loss of proprietary knowledge and rents from imitation and learning by competitors (Scotchmer and Green (1990), Anton and Yao (1994), Fetter, Steck, Timmins, and Wrenn (2018), and Kim and Valentine (2021)). However,

effects of innovation disclosure is mainly based on the patent system, which covers technical details of successful innovations selectively chosen by firms,[11] and little is known about the effects of disclosure on ongoing and unsuccessful innovation.

Moreover, we quantify the consequences of the FDAAA by utilizing the 2004 ICMJE policy changes to construct an effective control group for more robust causal inferences. Lastly, our analyses focus more on aggregate innovation and public health, which differ from prior studies that primarily focus on how the FDAAA alters individual firms' information environments and decisions.[12]

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the literature also emphasizes the importance of disclosing innovative activities to raise external funding and mitigate information asymmetries (Leland and Pyle (1977), Bhattacharya and Ritter (1983), García-Meca, Parra, Larrán, and Martínez (2005), and Ferreira, Manso, and Silva (2014)). Some studies discuss firms' voluntary disclosure of their patenting activities for strategic purposes (Anton and Yao (2004), Guo, Lev, and Zhou (2004), Gill (2008), and James (2011)).

[11] See, for example, Williams (2013), Hegde and Luo (2018), Furman, Nagler, and Watzinger (2018), Kim and Valentine (2021), and Hegde et al. (2023).

[12] A few recent studies show that additional disclosure from the FDAAA is followed by reduced information asymmetry (Capkun, Lou, and Wang (2019)), increased forecast accuracy (Hao, Forgione, Guo, and Zhang (2017)), and an increased propensity of going public (Aghamolla and Thakor (2019)).

II. Data and Variable Construction

A. Data sources and sample selection

We use the BMT database to obtain our primary sample. The BMT database covers project-level drug development progress for all publicly and privately held firms in the drug industry sector. The database catalogs drug development events since the 1950s, drawing from multiple sources that include the FDA approval database, company filings with the Securities Exchange Commission (SEC), conference calls, press releases, news articles, medical conferences, expert industry analysts, direct communication with companies, and the ClinicalTrials.gov database.[13] Unlike the FDA approval database, the BMT contains information on all current projects under development including the specific development status for each project's trial phase. However, information from the BMT is limited to the occurrence of events in a binary form without detailed study designs and outcomes, and mainly covers industry-sponsored clinical trials, as the purpose of the BMT is to identify biotech and pharmaceutical investment opportunities. From the BMT, we obtain the suspension variable as well as variables for phase advances, partnerships, indications, and peer projects in the same indication.

Our final full sample encompasses 24,608 industry-sponsored project-year observations covered by the BMT during the sample period from 2002 to 2012 with 7,580 pre-FDAAA project years and 17,028 post-FDAAA project years. Our sample has 1,056 unique pharmaceutical firms

[13]The ClinicalTrials.gov database, one of the sources from which the BMT collects data, provides superb information on detailed study designs and outcomes of registered clinical trials; however, complete coverage is only available after the FDAAA.

with 6,537 unique new-drug projects. The relevant SIC codes for these firms are 2834 and 2836. We exclude the following from our sample: (i) clinical trials for generic drugs, which have low uncertainty and follow different FDA requirements, (ii) clinical trials that are not sponsored by industry (i.e., academic-sponsored projects), and (iii) clinical trials in phase 1, which are not subject to the FDAAA.[14]

It is worth noting that, in the pre-FDAAA period, information about the existence (not the experimental details) of ongoing drug projects was available because any research involving human subjects must be approved by Institutional Review Boards (IRBs). However, comprehensive information about the clinical trial designs and experimental outcomes of those projects was not available. Therefore, the FDAAA transforms the type of information from mere binary formats of initiations and terminations to detailed clinical trial designs and outcomes of all successful and unsuccessful projects.

In our DID analyses, to measure the potential enhancement in information environments after the FDAAA, we utilize a continuous treatment variable, Industry Project Ratio, which is the proportion of industry-sponsored projects (vs. academic-sponsored projects) within each indication during the sample period. It is important to note that our sample consists of drug

[14]We do not restrict our sample to "applicable clinical trials" (ACT) of the FDAAA, because the medical literature has found that the definition of ACT, developed when the FDAAA was initially introduced in 2007, was unclear; thus, selecting ACT samples relies on discretion and conjecture. Instead, we apply the clear rule that exempts phase 1 clinical trials and clinical trials for foreign-produced and foreign-marketed drugs from ACT to our sample selection procedure. The FDAAA Final Rule was issued in 2016 to clearly specify which clinical trials are subject to mandatory reporting on ClinicalTrials.gov (ACT). For more details, see Zarin, Tse, Williams, and Carr (2016).

projects from *only* pharmaceutical companies (i.e., industry-sponsored projects), although we consider academic-sponsored projects in the calculation of the continuous treatment variable.

Figure 1 illustrates the time trends of the number of clinical trial projects, disclosure intensities of progress reports, and the fraction of reports with detailed study results. Figure 1(a) shows that the total number of clinical trials has increased over time, but that this increase has slowed down after the FDAAA. Figure 1(b) shows that the average number of progress reports per project has significantly increased in the more recent period after the FDAAA. These two figures suggest that after the FDAAA, the increasing trend in the number of projects has significantly abated while the disclosure frequency per project has increased. Figure 1(c) presents the time trend of the fraction of progress updates that accompany detailed study results. The data on the submitted reports of study results for both industry- and academic-sponsored projects are from the ClinicalTrials.gov database. We find that the average submission rate of detailed study reports has dramatically increased and reached approximately 70% after the FDAAA. The moderate increase in the submission rate from 2004 until the FDAAA coincides with the ICMJE in 2004.

The essence of our empirical design is the change in accessibility of detailed study reports from peers after the FDAAA. Figure 1(c) suggests that the FDAAA coincides with increased disclosures of clinical trial details and the changes in the type of information available to pharmaceutical firms.[15]

[Insert Figure 1 approximately here]

[15]There could be a concern that our sample period spans multiple years and thus may include other important structural changes (e.g., changes in presidency, administrative changes, changes in related regulations). In Section 1 of the Internet Appendix, we present the lists of major legislative and regulatory changes related to new drugs and

B. Variable construction

Our main dependent variable, Suspension, is a proxy for divestment defined as an indicator that equals one if an announcement of suspension is made for a project in a given year or no progress update is made for a duration longer than a specified threshold, and zero otherwise.[16] The latter condition is particularly important to mitigate the concern that drug developers might hide unsuccessful clinical trial outcomes from the public before the FDAAA. Given that FDA regulation requires IRB approval for any research involving human subjects and that the initiation of a clinical trial is thus known, a project with no progress update for a long time is considered suspended under this condition. In Figure 2, we illustrate the time-series trend of the average suspension rate for projects in each clinical trial phase in our sample. The average suspension rate for each phase is calculated as the total number of suspended projects in a given year divided by the total number of projects in that year. We find in Figure 2 that suspension rates are overall stable in all phases before the FDAAA and increase significantly after the FDAAA, especially for phase 2. We observe a slight upward trend in the average suspension rate for phase

clinical trials separately and discuss whether those changes are relevant and significant to the explanation of our findings.

[16] We use the 90th percentile of the sample duration for each phase as the threshold. The 90th percentile duration is 5 years for phase 2 and 3 projects and 4 years for post-phase 3 projects. To ensure robustness, we also consider Disclosed Suspension, an indicator variable that equals one only if a suspension announcement is made for a project in a given year, and zero otherwise. We find qualitatively similar results when using Disclosed Suspension instead of Suspension.

2 projects since 2004, which we attribute to the effect of the ICMJE in 2004. We discuss and address the potential bias arising from this trend in Section A.

[Insert Figure 2 approximately here]

The main independent variable in our regression analyses is Post, which is one after the passage of the FDAAA in 2007 and zero otherwise. We are particularly interested in whether the passage of the FDAAA changes information environments for pharmaceutical firms' drug development. As discussed earlier, the FDAAA requires drug developers to disclose experimental details of clinical trials to the public, including competitors. Appendix B provides an example of the detailed study report for a drug in clinical trial phase 2 from ClinicalTrials.gov.

Panel A of Table 1 presents summary statistics of the variables used in our analyses. Suspension has a mean value of 0.11, indicating that 11% of clinical trials are suspended per year in the middle of the development process. The average number of newly initiated projects per year by a firm within an indication (Number of Initiated Projects (All Phases)) is 0.24. On average, 50% of the projects in our sample have partners (Project with Partner), and a firm carries 48% of its projects with partners (Percent of Projects with Partner). The average of Log(1+Number of Projects) is 2.96, equivalent to 18 projects.[17] The average of Log(1+Project Age) is 1.02, equivalent to 1.77 years of project age.

[Insert Table 1 approximately here]

[17]The mean and median numbers of total projects per firm for a given year are 5.96 and 2, respectively. The numbers in Table 1, calculated at the project-year level (except for Number of Initiated Projects), are greater than those calculated at the firm-year level due to greater weights on firms with a larger number of projects.

We also include the following control variables in our regressions (with detailed definitions provided in Appendix C). The diversification index of a firm's project portfolio has a mean of 0.52 (Project Diversification). Also, 8% of the projects in a firm's project portfolio are matured (i.e., in post-clinical trial phases, denoted by Percent of Matured Projects). The average number of entities in each indication group in a given year is 20.12 (Log(1+Number of Competitors) = 3.05). Competing entities include both private and public pharmaceutical firms, as well as academic drug developers. The average percentage of matured projects in an indication in a year is 12% (Percent of Indication Matured Projects).

In our analyses that explore possible mechanisms for our results, we consider the measures of peer suspensions and peer phase advances. Peer Suspension is the log one plus the total number of peer projects in the same indication and phase that are suspended in a year. Peer Advance is the log one plus the total number of peer projects in the same indication and phase that advance to the next phase in a year. Both the peer suspension and peer advance measures are lagged by one year in our regression analyses.

In Panel B of Table 1, we compare the variables used in our analyses between the pre- and post-FDAAA periods. The suspension rate is significantly higher by 9 percentage points in the post-FDAAA period, indicating that firms are more likely to suspend their ongoing projects after the FDAAA. Firms, on average, have a larger number of total projects, a smaller percentage of matured projects, fewer projects with partners, a larger number of competitors, less diversified projects, an older clinical-trial project age, and fewer matured projects in an indication during the post-FDAAA period. We control for the effects of these variables in our regression analyses.

III. Enhanced Disclosure and Drug Development

A. Project suspensions

In Table 2, we analyze the effects of enhanced disclosure of clinical study details through the FDAAA on drug project suspensions. Our sample consists of a project-year panel. The dependent variable is Suspension, which equals one if the project has been suspended in a given year, and zero otherwise.[18] We present results from estimating baseline linear probability models in Columns 1 and 2 and difference-in-differences (DID) models with the continuous treatment variable (Industry Project Ratio) in Columns 3 and 4.

[Insert Table 2 approximately here]

In Column 1, we regress Suspension on Post, denoting the post-FDAAA period starting in 2008, without controlling for any other variables except firm, indication, and trial-phase fixed effects.[19] The significantly positive coefficient on Post in Column 1 implies that the passage of the FDAAA is associated with a significant increase in the likelihood of suspension. In Column 2, we show that the positive association is robust when we control for characteristics of drug developers and indications as well as characteristics of the project itself (e.g., project age and whether the project has partners). The increase in project suspension likelihood following the FDAAA is economically significant at 12.6 and 4.7 percentage points in Columns 1 and 2, respectively.

[18] When a project is suspended or finally approved by the FDA in year t, it is dropped from our regression sample from year t+1.

[19] It is worth noting that we cannot include project fixed effects in our regressions because projects that have never been suspended or have been approved will be dropped from our estimations.

We next perform DID analyses for causal interpretations of the increased suspensions after the FDAAA in Columns 3 and 4. In our primary DID test, we compare the differential effects of the FDAAA on project suspensions for indications with a high vs. low industry-sponsored project ratio (compared to academic-sponsored projects). The main variable of interest is Industry Project Ratio, which is the proportion of industry-sponsored projects within each indication during the sample period.[20] For the sole purpose of generating this continuous treatment variable, we supplement our sample with data on academic-sponsored projects from ClinicalTrials.gov. We present the distribution of Industry Project Ratio in Figure 3. Figure 3(a) displays the distribution of Industry Project Ratio at the unique indication level across a total of 547 indications. Figure 3(b) displays the distribution of Industry Project Ratio in our sample. Both panels show that the majority of indications only have industry-sponsored projects.

[Insert Figure 3 approximately here]

Projects in the indications with a high industry-sponsored project ratio serve as suitable treatment observations for assessing changes in information environments resulting from the FDAAA. We expect that these changes will be less pronounced in indications with a higher proportion of academic-sponsored projects compared to those with a higher proportion of industry-sponsored projects because the details of academic-sponsored clinical trials have been disclosed to the public to a greater extent before the FDAAA, in compliance with the ICMJE

[20]In Internet Appendix Table IA.1, we provide a list of indications in which over 50% of projects are academic-sponsored projects during our sample period. We choose to report them, given the large number of all indications (N=547) and the prevalence of indications in which over 50% of projects are industry-sponsored projects (N=470).

issued in 2004. Consequently, the FDAAA, implemented three years later, may not significantly affect the disclosure practices of academic-sponsored projects as much as those of industry-sponsored projects. Therefore, we expect that industry-sponsored projects in indications with a low Industry Project Ratio will experience less significant changes in information environments than those in indications with a high Industry Project Ratio at the time of the FDAAA enactment. As such, we exclusively focus on industry-sponsored projects in our sample and analyze the treatment effect based on Industry Project Ratio of each project's corresponding indication.

In Column 3, we regress Suspension on the interaction term between Post and Industry Project Ratio, along with other control variables. This DID specification focusing on the interaction term allows us to include year fixed effects in addition to firm, phase, and indication fixed effects, substantially mitigating the concern that year-specific economic conditions (e.g., financial crisis) drive our results. We note that standalone Post and Industry Project Ratio are both subsumed in our regression as we include year and indication fixed effects. We find that the coefficient on the interaction term between Post and Industry Project Ratio is significantly positive at the 1% level. This indicates that the FDAAA-suspension relation is stronger in the indication group with a higher proportion of industry-sponsored projects. The economic interpretation of

this coefficient is that a one-standard-deviation increase in within-group Industry Project Ratio (0.20)[21] is associated with an increase in suspension of 4.9% from the unconditional mean.[22]

Column 4 presents the dynamic DID analyses of the FDAAA, which aim at examining whether the changes in suspension occur immediately after the FDAAA and are indeed tied to the FDAAA. Year t is the indicator for the FDAAA enactment, and Year t-1 serves as the base year. We find insignificant coefficients on the interaction terms of Industry Project Ratio with Year t-5 to Year t. The result confirms that there is no pre-trend before the passage of the FDAAA and supports the parallel trend assumption underlying the DID test. In addition, the coefficients on the interaction terms of Industry Project Ratio with Year t+1, Year t+2, and Year t+4 are significantly positive. These results indicate that the change of suspension decisions starts after the enactment of the FDAAA and intensifies with Industry Project Ratios. The magnitude of the effects is, for example, a 7.1% increase in suspension with a one-standard-deviation increase in within-group Industry Project Ratio for Year t+1. The results from this dynamic DID analysis strongly indicate that the suspension pattern we discover is tightly linked to the FDAAA rather than attributable to other factors.

As discussed earlier, we acknowledge that we cannot completely rule out the concerns

[21]Recent work by Liu and Winegar (2023) recommends using the within-group standard deviation when discussing economic magnitudes in regression specifications with fixed effects. Following their method for a high-dimensional fixed effects model, we compute the within-group standard deviation of the Industry Project Ratio by regressing the variable on our set of fixed effects (excluding indication fixed effects, as the Industry Project Ratio is an indication-level variable) and calculating the standard deviation of the residuals.

[22]This 4.9% increase is calculated as $0.20 \times 0.027/0.11$ in which 0.11 is the unconditional mean for Suspension.

regarding a potential pre-trend in suspensions, which may be associated with the ICMJE in 2004. In Figure 4, we explore the possibility of such a trend and its implications for our estimated effect of the FDAAA. In Figure 4(a), we replace Post in Column (2) of Table 2 with year dummy variables and estimate the year effects. We find that the coefficients for the years 2004, 2005, and 2006 exhibit an increasing trend over time, yet these coefficients are notably negative and significant. We note that this pre-period increasing trend actually works against the discovery of a positive DID effect when we compare pre-FDAAA and post-FDAAA suspensions. Nevertheless, possible pre-trends are concerning due to their potential to violate the parallel trend assumption in a DID analysis. To address this concern, we conduct further analysis using the "Honest DID" approach proposed by Rambachan and Roth (2023). This method allows for robust inference in DID designs by examining various levels of parallel-trend violations, rather than assuming perfect parallel trends.[23] Figure 4(b) presents results from this sensitivity test and shows that all 95% confidence intervals for the increase in suspensions following the FDAAA remain above zero, indicating the robustness of our results under the considered parallel-trend violations. Despite the moderate levels of considered parallel-trend violations in this analysis, this evidence strengthens our conclusion even in the presence of potential pre-trends.

[Insert Figure 4 approximately here]

Next, we consider the analogous tests to Table 2 using Probit models in Table IA.2.[24]

[23] In the Honest DID approach, we cannot use a continuous treatment variable like Industry Project Ratio as in Table 2. For this analysis, we replace Industry Project Ratio with an indicator for indications that have only industry-sponsored projects.

[24] We do not use the Probit or Logit model as our primary regression specification because (i) they face issues of

Across all columns, we present marginal effects estimated from the Probit models to facilitate interpretation. We find that the increase in the suspension likelihood after the FDAAA is statistically significant in Columns 1 and 2. Column 3 shows that projects with a higher Industry Project Ratio experience statistically significant increases in the suspension likelihood after the FDAAA. Column 4 confirms that the increase in the suspension likelihood is immediately after the FDAAA with no pre-trend.

Overall, our DID analyses alleviate concerns that the increase in suspensions after the FDAAA is driven by any commingled factors unrelated to enhanced information disclosure by the FDAAA. We find that projects in indications with a higher proportion of industry-sponsored projects, which are presumably more affected by the FDAAA, significantly differ in their suspension rates after the FDAAA from projects in indications with a lower proportion of industry-sponsored projects. These findings support a causal interpretation that changes in information environments following the FDAAA significantly influence the investment decisions of pharmaceutical companies.

B. Project suspensions: Heterogeneity within indication

In our DID analyses in Section A, we use a treatment variable based on indication characteristics, which is particularly suitable for our purpose, as we examine the effects of enhanced information for firms that mutually influence each other in the same information

inconsistency due to the incidental parameter problem in scenarios of short panels with large cross-sections, as noted by Wooldridge (2010) and Arellano, Hahn et al. (2013), and (ii) they do not always converge in estimations with many fixed effects.

environment (i.e., indication). However, there is a separate concern that indications are fundamentally different in their original environments with respect to information, investment, and financing. To reinforce a causal interpretation of our findings, we perform an additional DID test by considering treated and control groups divided by firm heterogeneity *within* indication, focusing on the asymmetry of learning needs across firms. In Internet Appendix Section 2, we discuss the results using this alternative DID test. This alternative DID test not only addresses concerns about fundamental differences across indication groups but also supports the conclusion that the FDA has a disproportionately greater impact on investment decisions for firms that need more information disseminated from peers.

C. Project suspensions: Robustness

In this section, we summarize the results of our robustness checks but leave all detailed discussions to Section 3 of the Internet Appendix and Tables IA.4 to IA.7. First, we find consistent results using an alternative definition of project suspension or alternative samples. Second, we address the concern that the enactment of the FDAAA in 2007 is adjacent to the 2008-2009 financial crisis and that our results may be driven by financial distress during this crisis period or by different external financing opportunities across firms with different industry-sponsored project ratios. Third, we address the concern that the proportions of industry-sponsored projects are correlated with overall firm capabilities across indications, leading to different suspension rates following the FDAAA. Lastly, we only consider public firms and additionally control for a comprehensive set of firm financial characteristics and find consistent results.

D. Project initiations

We additionally explore the possibility that the effects of the FDAAA manifest in project initiation decisions.[25] We replace the dependent variable in Table 2 with a measure of project initiation and report the results in Table 3. Different from the project-level suspension variable in Table 2, the dependent variable for project initiation is, at best, a firm-indication level variable. Thus, we consider all indications in which each firm has ever had projects in the past three years and construct a firm-indication-year panel for this test. We first consider the initiations of phase 2 and 3 projects, which are directly affected by the FDAAA in Columns 1 and 2. We then include pre-clinical and phase 1 trials in Columns 3 and 4, as the FDAAA could potentially affect

[25]Law and consulting firms have suggested to their clients that they infer the reaction of pharmaceutical companies to the FDAAA. These are quotes we collected: "One of the main questions raised by the recently enacted FDA Amendments Act of 2007 (FDAAA) is whether all the many new requirements for assessing drug safety and investigating risks will make manufacturers hesitate to develop any test therapy that exhibits adverse events or formulation problems." (https://www.pharmtech.com/view/fda-amendments-act-raises-confidence-and-questions), "The growing momentum towards broader access to investigational drugs is likely to continue placing a heavy burden on drug companies." (https://news.bloomberglaw.com/pharma-and-life-sciences/insight-the-right-to-try-act-and-its-implications-for-pharmaceutical-manufacturers), and "Companies should prepare to make publicly available, through the NIH clinical trials database, all clinical trials (other than Phase I studies) they are conducting, keeping in mind that more comprehensive study information will now be required. Companies should also watch for FDA's rule-making process regarding posting requirements for the expanded clinical trial registry and results databank." (https://www.wilmerhale.com/insights/publications/the-food-and-drug-administration-amendments-act-of-2007-september-27-2007).

initiation decisions across all phases. For these tests, we estimate Poisson regressions using the number of new projects initiated as the dependent variable.[26]

[Insert Table 3 approximately here]

In Columns 1 and 3, we find that the coefficient estimates for the interaction term between Industry Project Ratio and Post are negative and statistically significant at the 1% level. For example, the coefficient estimate in Column 1 implies a 6.5% decrease in the number of newly initiated projects with a one-standard-deviation increase in within-group Industry Project Ratio.[27] Columns 2 and 4 present results from the dynamic DID analyses. We find insignificant coefficients on the interaction terms of Industry Project Ratio with Year t-5 to Year t, while most coefficients on the interaction terms of Industry Project Ratio with Year t+1 to Year t+5 are significantly negative. These results support a causal interpretation of the impact of the FDAAA on the decrease in new project initiations. Notably, firms cut back their investments significantly by not only suspending existing projects but also refraining from initiating new projects after the FDAAA. Our evidence of the decrease in new project initiations following the FDAAA is also consistent with recent work by Oostrom (2021).

[26]The number of new projects initiated for each indication each year is zero for 79%, one for 19%, and two or more for 2% of all observations.

[27]This 6.5% decrease is calculated as $exp(0.20 \times -0.335) - 1$ with 0.20 as a one-standard-deviation in the within-fixed-effect-group Industry Project Ratio.

IV. Mechanisms

A. Learning vs. competition

In this section, we further contrast the two mechanisms: learning vs. competition. At the aggregate level, the FDAAA leads to an increase in project suspensions and a decrease in project initiations in drug development. The underlying mechanisms for this pattern can be analyzed by separately examining successful and unsuccessful experimental outcomes. Announcements of successful outcomes in clinical trials may discourage competitors' investment due to reduced expected payoffs, yet the details of peers' success can also stimulate more informed—and thus efficient—investment endeavors through learning. On the other hand, while announcements of failed outcomes may incentivize competitors to persevere with their projects for potential first-mover advantages, the specific details of these failures can curb pharmaceutical investments by revealing the challenges inherent in certain development procedures.

The aggregate impact of the FDAAA, which mandates the disclosure of *experimental details*, on pharmaceutical investment is thus contingent upon the relative prevalence of actual clinical trial failures vs. successes. Given the notably high failure rate of clinical trials, the prevalence of failure details far exceeds that of success details, providing more opportunities for drug developers to learn from the failure details of their peers. In such a situation, for the competition mechanism to explain the increase in project suspensions after the FDAAA, there should be a surge of clinical trial successes immediately after the FDAAA. This contradicts what we observe in the data. Conversely, the learning mechanism better accounts for the observed

increase in suspensions, as an abundance of details regarding failed experiments are disclosed after the FDAAA.

We further consider heterogeneous effects by examining firms' reactions to peer news. Before the FDAAA, firms only had binary information regarding peer firms' project initiations and terminations. After the passage of the FDAAA, firms could now make more informed investment decisions by learning from detailed clinical trial reports of peers' suspensions (bad news) and peers' phase advances (good news). As a result, the suspension likelihood should be associated with a trade-off between competition and learning, and differently so for good vs. bad news.

These predictions motivate us to examine focal firms' responses to peer firm suspensions or advances and compare those responses before and after the FDAAA using the post-FDAAA period indicator (Post). We measure peer suspensions (Peer Suspension) based on the number of suspended peer projects within the same indication and phase in a given year. Analogously, we measure peer phase advances (Peer Advance) based on the number of advanced peer projects within the same indication and phase in a given year. These variables are transformed into the log form and lagged by one year to allow sufficient time for focal firms to process and learn from the information. We present the results in Table 4.

[Insert Table 4 approximately here]

In Column 1, we interact Peer Suspension and Peer Advance each with Post and estimate the regression using the full sample. We find that the coefficient on Peer Suspension is negative and significant, whereas the coefficient on Peer Suspension $\times$ Post is positive and significant. These results indicate that the peer learning effect dominates the competition effect only after the

FDAAA, while the competition effect holds in the pre-FDAAA period. More comprehensive reports on experimental details mandated by the FDAAA enable firms to learn from their peers' experiences and make informed investments in the same direction. Notably, neither the competition effect nor the learning effect is manifested for peer successes, as indicated by the insignificant coefficients on Peer Advance and also on Peer Advance $\times$ Post. The lack of significance is primarily attributed to the infrequency of clinical trial successes, reported as only 4% in Hingorani et al. (2019). Also, the insignificant learning effect from peer successes following the FDAAA in particular is likely associated with the exclusive rights granted by the FDA to drug developers for a minimum of five years following approval, thereby limiting the benefits that firms can derive from learning from peer successes.

We further consider firm-specific information environments for learning in Columns 2 and 3 of Table 4. We split the sample into low-quality and high-quality firm groups based on drug development progress and then examine the differential learning effects between the two groups. We define high-quality firms as those with the total number of phase advances in the past three years above the sample median; the remaining firms are classified as low-quality firms. In Column 2, for low-quality firms, the coefficient estimate for Peer Suspension $\times$ Post is significantly positive and roughly twice as large as the corresponding result in Column 1, whereas it is no longer significant for high-quality firms in Column 3. These results suggest that suspensions increase only for low-quality firms in response to their peers' suspension events. On the other hand, high-quality firms are less likely to respond to information revealed from peer suspensions, possibly because they already have sufficient progress or information regarding their own

projects' prospects.[28] This finding also supports that, even if the competition effect is strengthened by the FDAAA, it is still dominated by the learning effect; otherwise, we should observe the coefficient on Peer Suspension $\times$ Post to be significantly negative for high-quality firms.

We also note that the quality of peers (information providers) can differently affect focal firms' learning and subsequent suspension decisions. We test for this prediction and present the results in Table 5. We now consider Peer Suspension and Peer Advance variables from high-quality and low-quality peers separately, labeled as High Quality Peer Suspension/Advance and Low Quality Peer Suspension/Advance. In Column 1, we examine the effects of peer suspensions and advances together in one regression, while Columns 2 and 3 consider them separately. In Columns 1 and 2, we find that the coefficient estimates for High Quality Peer Suspension × Post are significantly positive, whereas the coefficient estimates for Low Quality Peer Suspension × Post are only one-third in magnitude and statistically insignificant. This indicates that peer learning is concentrated on information disseminated from high-quality peers' suspensions.

[Insert Table 5 approximately here]

Interestingly, in Columns 1 and 3, we also find that focal firms are more likely to suspend projects when low-quality peers advance to the next phase only after the FDAAA. This seems to

[28] In Internet Appendix Table IA.8, we show the results from analogous tests based on the triple interaction terms with the indicator for low-quality firms. We focus on only peer suspensions in the table due to space constraints. Column 1 first confirms that suspensions, overall, increase with peer suspensions after the FDAAA. The coefficient estimates for Peer Suspension $\times$ Year t to Year t+5 are all positive, significantly so for Year t+4 in Column 2. In Column 3, the coefficient estimates for the triple interaction terms of Peer Suspension $\times$ Year t to Year t+5 $\times$ Low Quality are all significantly positive, reinforcing the findings in Table 4.

be consistent with a strengthened competition effect after the FDAAA specifically regarding low-quality peers' successes. Our interpretation of the result is that low-quality peers' successes are very rare in general and thus are less likely to draw attention and responses from focal firms before the FDAAA.

Collectively, the results in Tables 4 and 5 provide strong evidence that the FDAAA introduced important interactions between competition and learning in pharmaceutical firms' investment decision-making processes and that the peer learning mechanism plays an important role in explaining the significant increase in project suspensions after the FDAAA.

B. Financial constraints

Given that drug development is a costly investment and takes a long time to deliver (if it ever succeeds), pharmaceutical companies consistently raise capital to sustain ongoing funding for their drug development expenses. When firms are financially constrained and thus face difficulty or greater costs in raising capital, their investment hurdle rate is likely higher. Consequently, they are more likely to suspend their ongoing projects earlier and more readily in response to a decreased probability of success. This behavior aligns with the optimal timing to abandon investment in the real-option framework (Bolton et al. (2014) and Bolton et al. (2019)).[29] Mace (2022) and Krieger et al. (2022a) also show the significant role that financial constraints

[29]Bolton et al. (2014) stated that "Typically, the firm's decision of whether to abandon the project or not is influenced not only by its fundamentals (e.g., earning) but also by its financial considerations including the prospect of having to incur external financing costs in the future." Based on these arguments, we expect the learning effect of the FDAAA to intensify with financial constraints. In a similar vein, Leary and Roberts (2014) have shown that

play for pharmaceutical companies. Hence, we propose that our main finding of increased suspension after the FDAAA may be further amplified by financial constraints. These constraints heighten firms' sensitivity to the decreased likelihood of success, prompting them to be more proactive in suspending projects to mitigate potential losses.

To test this proposition, we rerun our main DID analysis in Column 3 of Table 2 with the triple interaction term of Industry Project Ratio $\times$ Post $\times$ financial constraints. Before that, we first examine the effect of financial constraints on suspension decisions around the FDAAA with the double interaction term of financial constraints $\times$ Post. For financial constraint measures, we consider both the HM index (Hoberg and Maksimovic (2015)) and the SA index (Hadlock and Pierce (2010)). We select the HM index as our financial constraint measure because it has demonstrated superior performance in predicting investment reductions following adverse shocks, as evidenced by Hoberg and Maksimovic (2015), and the SA index because it represents an enhanced financial constraint measure compared to alternatives such as the KZ index (Kaplan and Zingales (1997)) or the WW index (Whited and Wu (2006)). The sample is limited to public firms, as financial statement information is needed to construct these financial constraint measures. Table 6 presents the results. Columns 1 to 3 report results using the HM index and Columns 4 to 6 report results using the SA index. Columns 1 and 4 focus on the double interaction terms, while Columns 2 and 5 focus on the triple interaction terms. Lastly, in Columns 3 and 6, we add additional control variables including Size, Leverage, Profitability, R&D and R&D Growth, Cash Holdings, and Paying Dividends that are available for public firms.

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financially constrained firms are more likely to follow their peers' capital structures, suggesting that those firms have "the greatest learning motive."

[Insert Table 6 approximately here]

In Columns 1 and 4 of Table 6, we find that only the SA index on its own is associated with a greater suspension likelihood although this effect does not significantly change following the FDAAA. Across all other columns, we further find that financial constraints affect firm suspension decisions primarily through the interaction of Industry Project Ratio $\times$ Post as shown with significantly positive coefficients on the triple interaction term of Industry Project Ratio $\times$ Post $\times$ financial constraints. These findings confirm our prediction that the FDAAA's impact on the increase in project suspensions, driven by firms learning from peer failures, is further amplified by the financial constraints of focal firms. We also note the persistently positive and significant coefficient estimates for Industry Project Ratio $\times$ Post throughout all columns, reinforcing that firms with a higher Industry Project Ratio suspend their ongoing projects significantly more following the FDAAA, consistent with Table 2.

C. Disciplining effect

We also consider the FDAAA's disciplining effect as another possible interpretation of our results. The enhanced information environments created by the FDAAA could lead to more effective monitoring by the FDA and also by the public. Thus, any previous fraudulent attempts to fabricate data or manipulate clinical trial outcomes would be significantly reduced after the FDAAA. To examine the extent to which our results can be explained by this effect, we refine our sample into a subset of firms that are expected to be less fraudulent. We then run our DID analysis only using each of these subsets of firms that are predicted to be less fraudulent. In Section 4 of

the Internet Appendix, we show that the effects of the FDAAA are still strongly present in each subset of less fraudulent firms. These suggest that our results cannot be substantially explained by the disciplining effect, even though we cannot completely rule it out.

D. Related legislative and regulatory changes

We also examine if our results may be driven by other legislative or regulatory changes. We have constructed a comprehensive list of legislative and regulatory changes related to new drugs and clinical trials (and their implications) around our sample period in Section 1 of the Internet Appendix. We discuss their implications and argue that they either are unrelated to the mandatory disclosure or cannot explain our DID results.

V. Analyses of Consequences

In this section, we explore the consequences of the enhanced information environments by the FDAAA. We first examine the change in investment efficiency on the firm side and then the change in overall drug quality and quantity from the public health standpoint. However, we do not analyze price effects due to the absence of individual drug price data. Although it is difficult to draw definitive conclusions about social welfare implications without accounting for price effects, our analyses of the quality and quantity of drug development offer valuable new evidence and insights for public health policies.

A. Investment efficiency

Regarding firm investment efficiency, we investigate whether the sensitivity of firm investments to Tobin's Q improves in response to enhanced information environments following the FDAAA. We adopt the approach of Chen, Goldstein, and Jiang (2007) and consider regression models of firm investment on Tobin's Q, Industry Project Ratio, Post, and their interaction terms. We first use a standard measure of Tobin's Q as defined in Eisfeldt and Rampini (2006) and also consider two alternative proxies for Tobin's Q, including one by Peters and Taylor (2017). The sample for this analysis is limited to public firms due to the availability of firm investment data. For these public firms, we additionally include firm-level control variables including Size, Leverage, Profitability, Cash Holdings, and Paying Dividends. For investment measures, we consider R&D expenses (R&D), capital expenditures (CAPX), and selling, general, and administrative (SG&A) expenses, all scaled by the same denominator for the Q measure. Specifically, we use R&D, intangible investment (R&D plus 30% of SG&A, Peters and Taylor (2017)), R&D + CAPEX, and R&D + CAPEX + 30% of SG&A, separately. Given that any proxies for Tobin's Q as a measure of investment opportunities are likely subject to errors-in-variables problems, we implement the two-step GMM estimation of the errors-in-variables model using cumulants of residuals as proposed by Erickson, Jiang, and Whited (2014) to address this issue. Table 7 presents the results from these cumulant estimations.

[Insert Table 7 approximately here]

Across all columns, we consistently find that the coefficient estimates for Q $\times$ Industry Project Ratio $\times$ Post are positive and significant, indicating a substantial improvement in

investment efficiency following the FDAAA for firms with projects in indications with a higher proportion of industry-sponsored projects. These results suggest that the availability of detailed information on peer experimental outcomes, and thus the overall enhancement of information environments through the FDAAA, indeed enable firms to make more informed investment decisions.

In Internet Appendix Table IA.10, we present results from the robustness tests using alternative proxies for Q to show that our findings are not dependent on the specific Q measure used. In Panel A, we use Peters and Taylor (2017)'s Q measure (Q_{tot}), which considers both physical and intangible investment opportunities. In Panel B, we use the simplest form of a Q proxy (Q_{alt}), defined as the market value of equity to the book value of assets. The results are consistent with those in Table 7, confirming that our findings on investment efficiency are largely robust to the use of alternative Q measures.

B. Drug quality

We expect that the combination of enhanced information environments and improved firm investment efficiency through the FDAAA may ultimately result in improved drug quality. To investigate changes in drug quality after the FDAAA, we use the FDA Adverse Event Reporting System (AERS) data and analyze the number of adverse event reports (AER) of each FDA-approved drug. To do so, we merge the AER data with the approved and marketed drugs in our sample by matching their names.

The FDA launched the AERS to monitor adverse events and medication errors of all

approved and marketed drugs as part of its own post-marketing safety surveillance program. The FDA receives reports of such events from healthcare professionals (e.g., physicians, pharmacists, nurses) and consumers (e.g., patients, family members, lawyers).[30] Appendix D provides examples of adverse event reports for a drug. We use the number of serious adverse event reports (AER) as a proxy for drug quality. We classify reports as serious if the patient outcome is one of the following conditions: death, life-threatening illness, hospitalization, disability, congenital anomaly, or intervention required to prevent permanent impairment or damage.[31]

We expect drug safety to improve after the FDAAA because firms can make more informed decisions to discontinue projects with less promising outcomes that could send negative signals to the market and also to continue and improve projects with more promising outcomes. Table 8 examines this prediction based on annual observations of serious AER for approved drugs. Because the AERS starts in 2004, the sample in Table 8 covers the period from 2004 to

[30]Clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) evaluate reports in AERS to monitor the safety of approved products. If reviewers identify a safety concern, the FDA may take regulatory actions that include updating the drug's labeling information, restricting the use of the drug, communicating new safety information to the public, or removing the product from the market.

[31]We note that our analysis is on the safety side of drug quality but not on the efficacy side of drug quality due to the lack of drug effectiveness data.

2017.[32] The variable of interest is Project Initiation After FDAAA that equals one if the drug project is initiated after the FDAAA and zero otherwise.

[Insert Table 8 approximately here]

In Table 8, we estimate Poisson regression models using the total number of serious AER in a given year as an inverse measure of drug quality. Columns 1 and 2 present results from the baseline models based on Project Initiation After FDAAA. Columns 3 and 4 present results from the DID analysis considering the continuous treatment variable of Industry Project Ratio. The specifications in Columns 1 and 3 control for Years from Approval in addition to firm, indication, and year fixed effects. The specifications in Columns 2 and 4 include additional characteristics of drug projects, drug developers, and indications as control variables. Log(1+Project Age) is not included as a control variable because this analysis is at the approved drug level, not at the project phase level.

We find in Columns 1 and 2 that the coefficient estimates of Project Initiation After FDAAA are significantly negative, consistent with our prediction. For example, in Column 2, the effect translates into approximately a 49% decrease in the number of serious AER if the clinical trial of a drug project is initiated after the passage of the FDAAA.[33] Considering that the average number of serious AER per year is 181.51, this 49% decrease is equivalent to receiving 89 fewer total serious AER per drug per year. It is worth noting that including Years from Approval and

[32] As the AERS data are from 2004, we restrict our sample to FDA-approved industry-sponsored drugs that are initiated and approved in and after 1990. Our results are robust to the use of all FDA-approved industry-sponsored drugs since 1947, the starting year of the FDA approval database.

[33] The coefficient estimate of -0.670 is equivalent to exp(-0.670)-1 = -0.488.

year fixed effects in our regressions alleviates the concern that older drugs could be widely used and are thus more likely to receive a larger number of AER than newer drugs in a year, or conversely that older drugs are safer and thus likely to receive fewer AER. This finding also holds for the DID analysis in Columns 3 and 4, suggesting a causal relationship between the reduced number of AER and the FDAAA.

Overall, the results in Table 8 suggest that drugs developed under enhanced information environments due to the FDAAA have a lower frequency of serious adverse outcomes on the intensive margin. These results are consistent with our prediction that firms discontinue projects with less promising outcomes, given their better knowledge about ongoing projects and the higher costs of bad outcomes under more transparent information environments.

C. Burden of Disease

We now examine how public health varies with the FDAAA based on the Disability-Adjusted Life Year (DALY) metric from the WHO Health statistics. DALY is used to measure the Burden of Disease.[34] DALY can be considered lost years of "healthy" life with a greater value of DALY indicating greater mortality and morbidity. DALY for a specific disease is calculated as the sum of Years of Life Lost (YLL) due to premature mortality in the population and Years Lost due to Disability (YLD) for people living with a condition or its consequences.

[34]The Burden of Disease is the impact of a health problem as measured by financial costs, mortality, morbidity, or other indicators, and is often quantified with Disability-Adjusted Life Years (DALY), which represents the number of years lost in disability or death due to a given disease.

We use two data points—DALYs for the years 2000 and 2016—for the top 20 leading causes of DALY worldwide.[35] These two points are the closest available data to the FDAAA legislation.

We analyze whether the FDAAA has any implication on the Burden of Disease is through the following two channels: 1) changes in the number of active projects and 2) changes in drug quality. First, evidence in Sections III and IV indicates that enhanced disclosures from the FDAAA lead to more suspensions of active projects, mainly through the peer learning mechanism. Also, the FDAAA is associated with a decrease in new project initiations. Society may lose potential remedies for critical diseases if firms give up their projects earlier or more often, or if they avoid taking risks in initiating new projects. Therefore, we expect that such a decrease in drug development activities can result in a greater Burden of Disease. To check this conjecture, we calculate the annual growth rate of active projects (i.e., the number of total projects minus the number of suspended projects) for each indication as the number of active projects in a given year divided by the number of active projects in the previous year, minus one. Figure 5 displays the average number and growth rate of active projects over time. We observe that the average number of active projects continuously increases in the pre-FDAAA period, but this increase suddenly stops around the enactment of the FDAAA. The trend in growth rates also confirms that the FDAAA might be associated with a substantial slowdown in project growth. The pre-FDAAA growth rate is approximately 25%, but this growth collapses to almost zero after the

[35]The DALY data are available for 2000, 2010, 2015, and 2016 at `https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html`. However, the indication-level DALYs are only available for 2000 and 2016.

FDAAA. Together with prior results, Figure 5 points to a significant slowdown of the growth in drug development activities after the FDAAA.

[Insert Figure 5 approximately here]

We then focus on indications targeting the top 20 leading causes (diseases) of the globally measured DALY. To quantify the social welfare loss in DALY due to the slowdown in drug development activities for these critical conditions, we compare the reductions in DALY between high-growth and low-growth indication groups and take the difference to quantify the slowdown. Using the difference between average growth rates before and after the FDAAA (Post - Pre), we split indications into two groups: (a) the low project growth indication group if the difference is less than the sample median and (b) the high project growth indication group, which comprises all others. Panel A of Table 9 shows the average differences in project growth, suspension rate, number of newly initiated projects, and the burden of disease based on DALY between pre- and post-FDAAA periods for the two groups.

[Insert Table 9 approximately here]

We observe a clear difference between the two groups in active project growth rates in Row 1 because the division of groups is based on this variable. In the low-growth group, the average growth rate of active projects decreases by 46% after the FDAAA, while that in the high-growth group increases by 5%. Row 2 shows that in the low-growth group, the increase in suspension rates is 7.0%, which is 3.8 percentage points higher than that in the high-growth group (3.1%). Row 3 further shows that the average number of new project initiations also decreases significantly more for the low-growth group at approximately 3 fewer projects per year than the high-growth group.

We then use DALY to quantify the public health loss associated with the decrease in the number of active projects. In Rows 4 and 5, we first show the DALY statistics for the two groups for the pre-FDAAA period. As previously discussed, the detailed indication-level DALYs are only available from the WHO for two years: 2000 and 2016. We, therefore, use the former for statistics representing the pre-FDAAA period and the latter for the post-FDAAA period. In Row 4, we find that the DALY for low- and high-growth groups are 91.900 and 100.542 million years, respectively, in 2000; the difference between the two groups is not statistically significant. Our findings hold for another measure of DALY that uses % in Row 5. DALY (%) represents the fraction of DALY attributable to a given disease in the entire DALY. Next, in Rows 6 and 7, we show the difference between 2000 and 2016 for the same statistics. We find that the decrease in DALY from 2000 to 2016 is significantly greater for the high-growth group compared to the low-growth group with both measures. The difference is 18.68 million years in Row 6.

In sum, as shown in Row 8, the average percentage changes in DALY from 2000 to 2016 are -8.27% for the high-growth group and +4.21% for the low-growth group. These final statistics suggest that if the low-growth group had received the same level of aggregate investment as the high-growth group, then the DALY of the corresponding indications would have dropped by the same magnitude (8.27%, or 7.6 million years).[36] This finding, together with our previous findings, suggests that enhanced information environments lead to more frequent suspensions of active projects and fewer initiations of new projects and, in turn, a possible increase in the Burden of

[36]The potential decline in DALY is estimated at 7.6 million years based on the mean DALY for the low-growth group of 91.9 million years in 2000.

Disease for public health. These results reflect the potential unintended consequences of the FDAAA.

However, it is also possible that the positive changes in drug quality measured by AER have positive consequences for the Burden of Disease. Therefore, we explore this prediction in a similar way. We first calculate the average growth rates of serious AER for each indication and take the difference between the serious AER growth rates before and after the FDAAA (Post - Pre). We then split indications into two groups: (a) the low serious AER growth group if the difference is less than the sample median and (b) the high serious AER growth group for all others. Panel B of Table 9 shows our results. Row 1 shows a clear difference in serious AER growth rates between the two groups because the division of groups is based on this variable. In the low serious AER growth group, the average serious AER growth rate significantly decreased, while it still increased in the high serious AER growth group.

In Rows 2 and 3, we do not observe statistical differences between the two groups for two DALY measures in the pre-FDAAA period. However, in Rows 4 and 5, we find that the decrease in DALY from 2000 to 2016 is significantly greater for the low serious AER growth group than for the high serious AER growth group with both measures. The difference is 19.47 million years in Row 4. Lastly, as shown in Row 6, the average percentage changes in DALY from 2000 to 2016 are -8.76% for the low serious AER growth group and +5.85% for the high serious AER growth group. These final statistics show that improved drug quality is associated with an 8.76% reduction in DALY, which is equivalent to 10.2 million years.[37]

[37]The potential decline in DALY is estimated at 10.2 million years based on the mean DALY for the low AER growth group of 116.88 million years in 2000.

In this section, we attempt to estimate the potential loss of public health from decreased drug quantity and the potential gain of public health from improved drug quality. Our results imply that the FDAAA has counterbalancing effects on public health, thus leaving welfare implications of the FDAAA to future research.

VI. Conclusion

To better understand the effects of information disclosure in highly innovative industries, we use a unique policy change, the enactment of Section 801 of the Food and Drug Administration Amendments Act in 2007 (FDAAA), to examine how mandatory disclosure of pharmaceutical firms' clinical trial details affects peer innovation investments, as captured by suspensions of ongoing projects and initiations of new projects.

We find higher suspension rates of ongoing projects after the FDAAA, suggesting that increased information disclosure reduces the continuation of pharmaceutical firms' innovative investments. This relation has a causal interpretation based on difference-in-differences analyses showing that projects are suspended more often after the FDAAA when there are increases in information transparency or higher demand for peer information. As supplementary evidence, we also find fewer new project initiations after the FDAAA. Our mechanism tests suggest that the learning effect dominates the competition effect overall after the FDAAA. This relation is more pronounced for low-quality firms that are highly dependent on information disseminated by peer firms and also for information disseminated by high-quality peer firms. Further analysis indicates that the FDAAA effect is amplified by firm financial constraints. This finding is intuitive:

constrained firms have fewer resources to continue their projects and thus their learning can result in a stronger effect on suspension decisions.

We also quantitatively analyze the change in pharmaceutical firms' investment efficiency as well as multifaceted consequences of the FDAAA. After the FDAAA, firms' investments become more efficient. In addition, the original goal of the FDAAA–to enhance transparency and safety of drugs–has been achieved, as we find fewer serious adverse patient outcomes after the passage of the FDAAA. On the other hand, as unintended consequences of enhanced information disclosure, pharmaceutical firms become less motivated to initiate risky projects and more likely to cut risky ongoing projects.

Appendix A. Institutional Background of the FDAAA

The Food and Drug Administration Modernization Act (FDAMA Section 113) that was enacted in 1997 established the ClinicalTrials.gov database, a website that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately funded clinical trials.[38] The website established the protocols for recording clinical trials to disclose design, methods, objectives, relevant scientific background, and statistical information and is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). FDAMA Section 113 requires summary information about clinical trials of investigational new drugs only for serious or life-threatening diseases and conditions (Tse and Zarin (2009)). Voluntary reports from uncovered trials are also accepted.

The most significant change in the disclosure of drug development is Section 801 of the FDAAA, which was enacted in 2007 (Tse and Zarin (2009) and Tse, Williams, and Zarin (2009)).[39] This act is regarded as an advancement in information disclosure for all drug developers, following the FDAMA, the ICMJE joint editorial, the Joint Position on the Disclosure of Clinical Trial Information issued by four pharmaceutical industry associations worldwide, and other relevant U.S. and international policies (Tse and Zarin (2009), Zarin et al. (2016), Lassman, Shopshear, Jazic, Ulrich, and Francer (2017)). The FDAAA amends the Public Health Service

[38]The history and evolution of the ClinicalTrials.gov database are available at `https://clinicaltrials.gov/ct2/about-site`.

[39]The details of Section 801 can be found at `https://www.congress.gov/bill/110th-congress/house-bill/3580`.

(PHS) Act to require the FDA (i) to mandate the expanded scope and additional information of an "applicable clinical trial" (ACT)[40] to be registered in the ClinicalTrials.gov database within 21 days of enrollment of the first patient; in addition, summary results are required to be filed within a year of a clinical trial's completion date,[41] (ii) to make the database publicly available, and (iii) to establish civil penalties for failure to submit required clinical trial information or for the submission of false or misleading information to the database (Tse and Zarin (2009) and Tse et al. (2009)). The FDAAA requires sponsors, sponsor-investigators, or sponsor-designated principal investigators of clinical trials to submit information about a clinical study to ClinicalTrials.gov and update that information accordingly. The penalties for noncompliance include the withholding of NIH grant funding and civil monetary penalties of up to $10,000.

Overall, the literature suggests that the FDAAA significantly enhanced the information disclosure of clinical trials. Dos Santos and Atallah (2015) find that the rate of ClinicalTrials.gov

[40]Registration is required for studies that meet the definition of an "applicable clinical trial" (ACT) and either were initiated after September 27, 2007 or were initiated on or before that date and were still ongoing as of December 26, 2007. ACTs, as defined in section 402(j) of the PHS Act, include (i) controlled clinical investigations (other than phase 1 investigations) of any FDA-regulated drug or biological product for any disease or condition, and (ii) certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric postmarket surveillances of a device product. For a more detailed definition of applicable clinical trials, see `https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf`.

[41]The completion date is the date of the last clinical trial visit of the last patient enrolled in the clinical trial. This deadline, however, can be extended up to 2 years under certain circumstances related to the market's approval of novel products. See `http://www.atlantclinical.com/compliance-with-fdaaa801`.

registration increases from 13.6% before the FDAAA to 70.2% for trials subject to the mandatory reporting under the FDAAA (and 35.6% of trials that are not subject to the FDAAA).[42] Gill (2012) confirms a substantial increase in the number of registered trials in ClinicalTrials.gov since 2007. Some studies suggest that the database may not be updated in a timely manner; however, such criticism is denied by the FDA (Hawkes (2012), Lassman et al. (2017)).[43] All these studies collectively indicate a substantial albeit imperfect coverage of the results of industry-sponsored clinical trials after the enactment of the FDAAA. In fact, all discussions (including criticisms) on the efficacy and consequence of the FDAAA suggest that its impact on information disclosure was well-perceived and widely discussed among participants.

The FDAAA was refined in 2016 with the issuance of 42 CFR Part 11 for Clinical Trials Registration and Results Information Submission (i.e., the "Final Rule"). The Final Rule aims to

[42]The fact that the registration rate of industry-sponsored trials is not close to 100% can be attributed to several reasons (Miller, Korn, and Ross (2015), Lassman et al. (2017)). First, collaboration among different institutes and the occurrences of mergers and acquisitions make it difficult for the FDA to hold any one party responsible for the registration. Second, the coverage of applicable clinical trials of the FDAAA is not well-defined, and some descriptions about the registration obligation and deadlines are ambiguous. Third, the delay penalty has not been imposed.

[43]Prayle, Hurley, and Smyth (2012) find that only 126 (40%) of 317 industry-sponsored trials had submitted their results to ClinicalTrials.gov on time. The FDA has disagreed with the results reported by Prayle et al. (2012) and pointed out methodological flaws in that study (e.g., including trials not covered by the FDAAA, only tracking the on-time registrations) (Hawkes (2012)). In response to this dispute, the NIH implemented an unofficial analysis and reported that 52% of industry-sponsored trials had filed the results on time. Reexamining the data of Miller et al. (2015), Lassman et al. (2017) find that almost all of the 15 novel drugs that were sponsored by big firms and approved in 2012 fully complied with the FDAAA.

clarify the requirements for regulated parties, interpret ambiguous statutory provisions, and make decisions about additional necessary reporting requirements (Zarin et al. (2016)). In sum, the FDAAA essentially requires all clinical trials of new drugs that are under the FDA jurisdiction to be registered on ClinicaTrials.gov within 21 days of enrolling the first patient and also requires summary results (including adverse events) to be reported within a year of clinical trial completion dates (Fassbender (2018)).

Appendix B. An Example of Study Details from ClinicalTrials.gov

This appendix presents an example of the detailed study report for a suspended clinical trial of a drug named Lumicitabine, a drug used to treat Respiratory Syncytial Viruses. We only present the Table of Contents of the study report to conserve space and show how detailed the report is. The entire report is available at `https://clinicaltrials.gov/ProvidedDocs/73/NCT02935673/Prot_000.pdf`.

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Appendix C. Variable Definitions (in Alphabetical Order)

- Cash Holdings: The total amount of cash scaled by the total assets of the firm in a given year from Compustat.
- Debt Issuance: The log of one plus the total amount of debt issuances for public firms, including public debt from SDC and bank loans from Dealscan.
- Disability-Adjusted-Life-Years (DALY) (years): Sum of the years lived with disability and the years of life lost due to that disease.
- Disability-Adjusted-Life-Years (DALY) (%): The fraction of DALY (years) attributable to a given disease in DALY (years) for any diseases.
- Disclosed Suspension: An indicator that is one if a suspension announcement is made for the project in a given year, and zero otherwise.
- Equity Issuance: The log one plus the total amount of equity issuances for the full sample, including both initial and seasoned public equity offerings from SDC.
- Firm Success Rates: A firm's total number of phase advances minus its total number of suspensions scaled by the total number of projects.
- High Quality: An indicator that is one if the total number of phase advances in the past three years for a firm is above the sample median.
- HM index: The Hoberg and Maksimovic 10-K text-based financial constraint measure from Hoberg and Maksimovic (2015).
- Industry Project Ratio: The proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period.
- Indication Average Initiation: The average number of new projects in each indication initiated in a given year.
- Leverage: The debt to assets ratio, calculated as the total debt divided by the total assets.

- Log(1+Number of Competitors): The log of one plus the total number of drug developers in each indication in a given year. The entire industry-sponsored (both public and private) and academic-sponsored projects from the preclinical stage to the final FDA approval stage are considered for the variable construction.
- Log(1+Project Age): The log of the difference between a given year and the drug project's initial year.
- Log(1+Number of Projects): The log of the total number of drug projects for the firm in a given year.
- Low Quality: An indicator that is one if the total number of phase advances in the past three years for a firm is equal to or below the sample median.
- No Experience: An indicator that is one if the project is the first one for the firm in a certain indication for a certain phase and zero otherwise.
- Number of Serious AER: The total number of serious AER in which the patient outcome is a serious condition (death, life-threatening, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment and damage).
- Number of Initiated Projects (All Phases): The total number of new projects in any phase in each indication initiated by the firm in a given year.
- Number of Initiated Projects (Phases 2 & 3): The total number of new phases 2 & 3 projects in each indication initiated by the firm in a given year.
- Paying Dividends: An indicator that is one if a firm pays dividends in a given year and zero otherwise from Compustat.
- Peer Advance (Lagged): The log one plus the total number of phase-advanced peer projects in the same indication as that of a given project in the prior year.
- Peer Suspension (Lagged): The log one plus the total number of suspended peer projects in the same indication as that of a given project in the prior year.
- Percent of Indication Matured Projects: The percentage of matured projects (post-phase 3) in an indication.

- Percent of Matured Projects: The percentage of matured projects (post-phase 3) in the firm's pipeline in a given year.
- Percent of Projects with Partner: The percentage of projects in the firm's pipeline that have partners in a given year.
- Phase Advances: A firm's total number of phase advances during the previous three years.
- Post: An indicator that is one after the passage of the FDAAA in 2007, and zero otherwise.
- Profitability: The operating income before depreciation and amortization scaled by the total assets of the firm in a given year from Compustat.
- Project Diversification: The firm-year level diversification index, calculated as one minus the sum of the squared project shares of the disease groups in the firm's pipeline in a given year.
- Project Initiation After FDAAA: An indicator that is one if the project is initiated after the passage of the FDAAA in 2007, and zero otherwise.
- Project with Partner: An indicator that is one if the project has partners in a given year, and zero otherwise.
- Q: The market-to-book ratio following Eisfeldt and Rampini (2006). The market value of assets is the book value of assets (at) plus the market value of the common stock (prcc_c$\times$csho) less the sum of the book value of the common stock (ceq) and balance sheet deferred taxes (txdb, with txdb=0 if missing).
- Q_{alt}: The market value of equity (prcc_c$\times$csho) to the book value of assets (at).
- Q_{tot}: Peters and Taylor (2017)'s Q measure. The market value of a firm divided by the replacement costs of physical capital and intangible capital.
- R&D: R&D expenses scaled by the sales of a firm in a given year from Compustat.
- R&D Growth: The annual percentage of R&D expense growth calculated as ((R&D expense this year - R&D expense last year)/R&D expense last year) * 100.

- SA Index: The size-age index calculated as (-0.737 * Size) + (0.043 * Size^2) - (0.040 * Age), in which Size equals the log of inflation-adjusted book assets, and Age is the number of years the firm is listed with a non-missing stock price on Compustat, as in Hadlock and Pierce (2010). Size is winsorized at (the log of) $4.5 billion, and Age is winsorized at thirty-seven years.
- Size: The log of the total assets of a firm in a given year from Compustat.
- Suspension: An indicator that is one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration with the same phase, and zero otherwise.
- VC Funding: The log of one plus the total amount of venture capital financing for private firms from VentureXpert.
- Years from Approval: The difference between a given year and the FDA approval year of a drug.

Appendix D. Examples of FDA Adverse Event Reports

This appendix presents examples of the FDA adverse event reports for Androgel, a testosterone supplement. The field, Outcomes, in the table indicates whether the reported outcome is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A report can state multiple outcomes. If the field is missing, the report is classified as non-serious. In the four adverse event reports shown, the number of serious AER for Andgogel is three.

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2010	7271740	EXPEDITED (15-DAY)	Y	DE	US-SOLVAY-00310000680		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	ANDROGEL	S	TRANSDERMAL	Daily dose: unknown	1 YR	
Off label use	UNKNOWN DIABETIC MEDS	C	ORAL	Daily dose: unknown		
	ZOCOR	C	ORAL	Daily dose: unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2010	7271758	EXPEDITED (15-DAY)	N	OT	US-SOLVAY-00210000660	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Prostate cancer	ANDROGEL	S	TRANSDERMAL	Daily dose: 5 gram(s)		
Cataract	METOPROLOL TARTRATE	C	ORAL	Daily dose: unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7195451	EXPEDITED (15-DAY)	N		US-SOLVAY-00209007046	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hirsutism	ANDROGEL	S	TRANSDERMAL	Daily dose: 2.5 gram(s)	19 MTH	
	VIVELLE DOT	C	OTHER	Daily dose: unknown, As used: 0.075 milligram, frequency: Twice a week, route: transdermal		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2010	7252209	EXPEDITED (15-DAY)	Y	DE	US-SOLVAY-00210000159		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	ANDROGEL	S	TRANSDERMAL	Daily dose: 5 gram(s)	16 MTH	
	ZOCOR	C	ORAL	Daily dose: unknown		
	UNKNOWN DIABETIC MEDS	C	ORAL	Daily dose: unknown		

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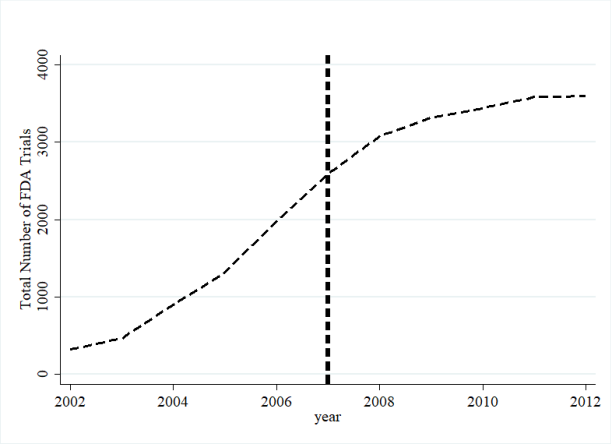
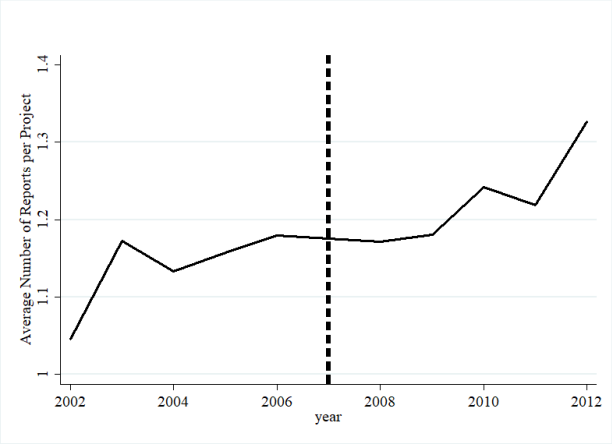
FIGURE 1

Pre- and Post-FDAAA Trends of Clinical Trials and Disclosures

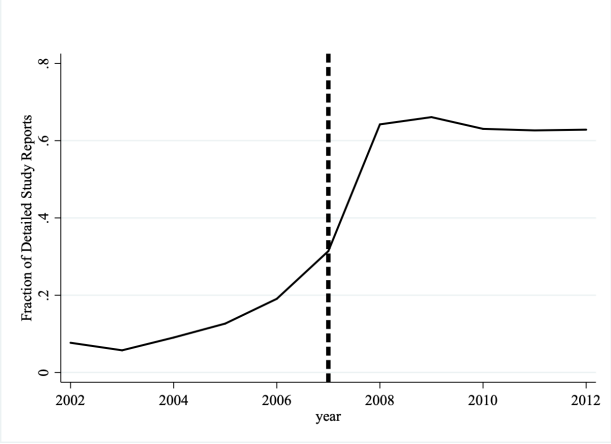
The figures present the time trends of clinical trials from 2002 to 2012. Figure (a) shows the total number of clinical trials. The number of clinical trials includes all ongoing projects that are not suspended. A suspended project is a project that is publicly disclosed as suspended or that has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase. Figure (b) shows the average number of progress reports (e.g., trial initiation, progress update, trial progressing, and updated results) per project. Figure (c) shows the average fraction of progress updates with a detailed study result report for both industry- and academic-sponsored projects. We use the ClinicalTrials.gov data for submitted study results after we exclude clinical trials in phase 1 that are not subject to the FDAAA.



(a) The number of clinical trials



(b) The average number of progress reports



(c) The fraction of projects with detailed study reports

FIGURE 2

Pre- and Post-FDAAA Trends of Project Suspension

The figure presents the time trends of clinical trial suspensions from 2002 to 2012 for the project initiated before the FDAAA in 2007. Each line shows the average suspension rate (i.e., the total number of suspended projects divided by the total number of projects in a given year) for each phase. The FDAAA covers all clinical trials other than phase 1 investigations of any U.S. FDA-regulated drug.

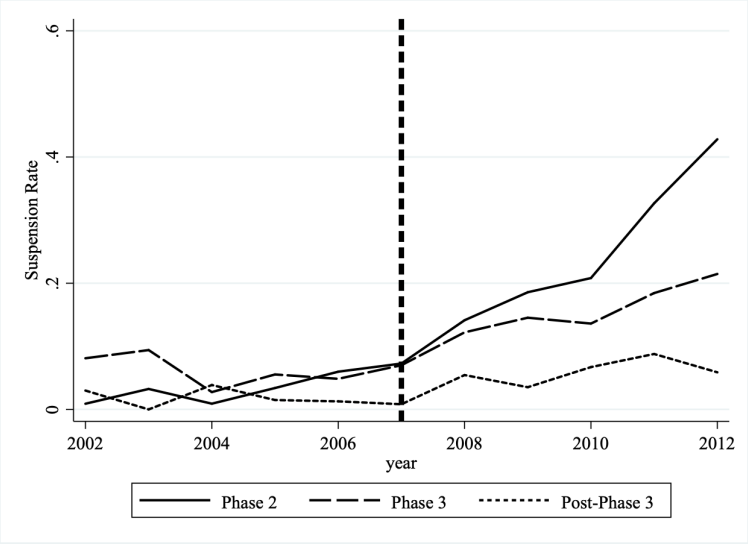
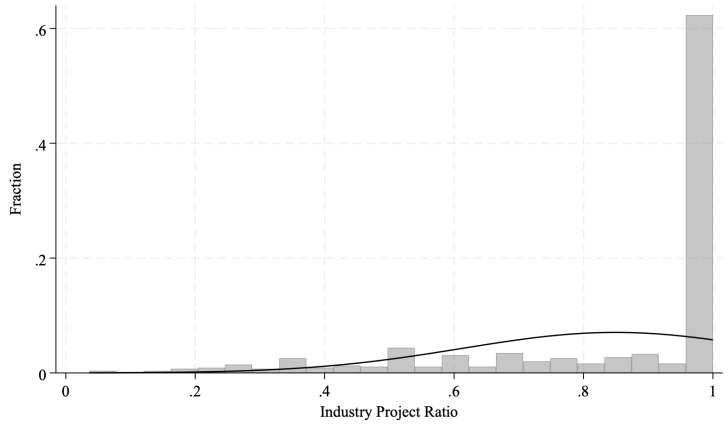


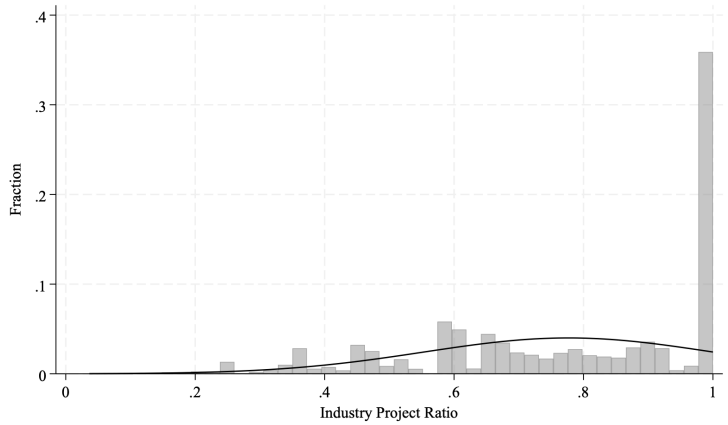
FIGURE 3

Distribution of Industry Project Ratio (Treatment Variable)

The figures present the distribution of our treatment variable, Industry Project Ratio, for difference-in-differences analyses. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. Figure (a) shows the distribution of Industry Project Ratio at the unique indication level among 547 indications in total. Figure (b) shows the distribution of Industry Project Ratio in our sample.



(a) Distribution across unique indications

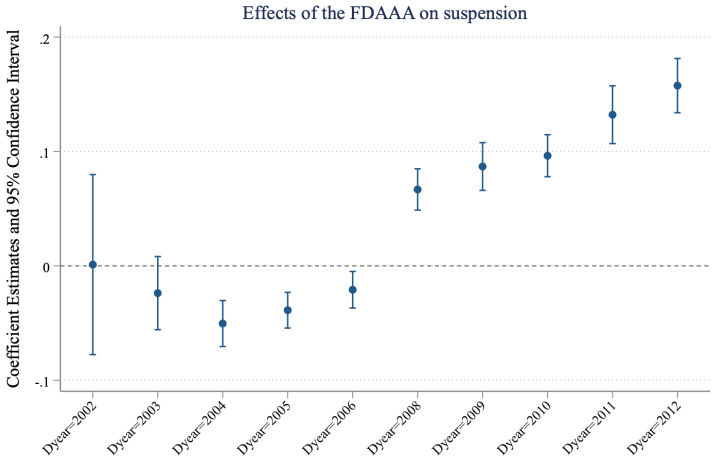


(b) Distribution in our sample

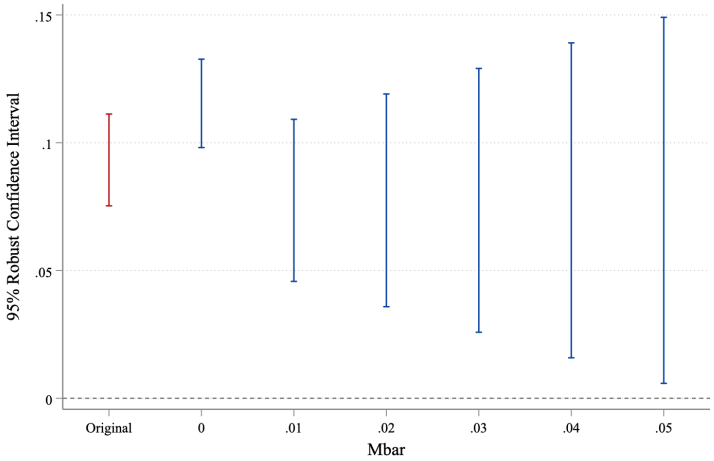
FIGURE 4

The FDAAA and Pre-trend in Suspensions

The figures present a potential pre-trend in suspensions and the results from our analysis assessing robustness to this potential pre-trend. Figure (a) shows the dynamic analysis of suspensions over our sample period. We replace Post in Column (2) of Table 2 with year dummy variables. The FDAAA was enacted in 2007, and we use the year 2007 as the reference year for the plot. Figure (b) plots the sensitivity of the estimated Difference-in-Differences (DID) effect. The red bar represents the 95% confidence interval of our original DID effect without imposing any further restrictions. The blue bars represent the robustness of the DID effect with the 95% confidence interval under various degrees (Mbar) of parallel trend assumption violations.



(a) Suspensions around the FDAAA in 2007



(b) Sensitivity analyses imposing pre-trends with Honest DID

FIGURE 5

Pre- and Post-FDAAA Number and Growth of Active Projects

The figure presents the time trends of the average number and growth rate of active projects within indication from 2002 to 2012. The number of active projects is the total number of projects including new project initiations minus the number of suspended projects in a given year for a given indication. The active project growth rate is the percentage growth in the number of active projects for a given indication, which is the number of active projects in a given year divided by the number of active projects in the prior year, minus one.

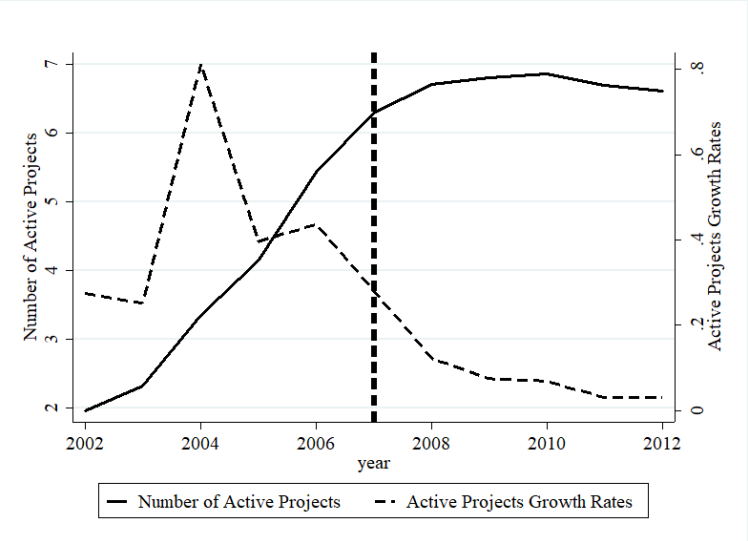


TABLE 1

Descriptive Statistics

The table presents summary statistics for our sample in Panel A and compares the variables used in the regressions between the pre- and post-FDAAA periods in Panel B. The sample consists of 24,068 project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. We exclude the following clinical trials from our sample: (i) clinical trials for generic drugs; (ii) clinical trials that are not sponsored by industry (i.e., academic-sponsored drugs); and (iii) phase 1 trials that are not subject to the FDAAA. Suspension, our main dependent variable, is one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Detailed descriptions of all other variables are available in Appendix C.

Panel A. Summary Statistics

	Mean	SD	Min	Median	Max	Obs.
Suspension	0.11	0.31	0.00	0.00	1.00	24,608
Number of Initiated Projects (All Phases)*	0.24	0.51	0.00	0.00	11.00	24,706
Number of Initiated Projects (Phases 2 & 3)*	0.21	0.44	0.00	0.00	9.00	20,455
Industry Project Ratio	0.78	0.22	0.04	0.83	1.00	24,568
Project with Partner	0.50	0.50	0.00	1.00	1.00	24,608
Log(Number of Projects)	2.96	1.49	0.69	2.77	5.61	24,608
Project Diversification	0.52	0.31	0.00	0.62	0.90	24,608
Percent of Matured Projects	0.08	0.15	0.00	0.03	1.00	24,608
Percent of Projects with Partner	0.48	0.31	0.00	0.48	1.00	24,608
Log(1+Number of Competitors)	3.05	1.12	0.69	3.18	5.19	24,608
Percent of Indication Matured Projects	0.12	0.17	0.00	0.06	1.00	24,608
Log(1+Project Age)	1.02	0.66	0.00	1.10	3.22	24,608

Panel B. Univariate Analysis

	Pre-FDAAA			Post-FDAAA			
	Mean	Median	Obs.	Mean	Median	Obs.	Diff
Suspension	0.05	0.00	7,580	0.14	0.00	17,028	-0.09***
Project with Partner	0.55	1.00	7,580	0.48	0.00	17,028	0.07***
Log(Number of Projects)	2.73	2.64	7,580	3.06	2.83	17,028	-0.33***
Project Diversification	0.53	0.64	7,580	0.51	0.62	17,028	0.01**
Percent of Matured Projects	0.13	0.09	7,580	0.06	0.03	17,028	0.08***
Percent of Projects with Partner	0.54	0.54	7,580	0.45	0.46	17,028	0.09***
Log(1+Number of Competitors)	2.51	2.56	7,580	3.29	3.40	17,028	-0.78***
Percent of Indication Matured Projects	0.14	0.05	7,580	0.10	0.06	17,028	0.03***
Log(1+Project Age)	0.71	0.69	7,580	1.17	1.39	17,028	-0.36***

*Firm-Indication-Year level observations

TABLE 2

Project Suspension Before and After the FDAAA

The table presents regression results from the linear probability models that examine the effect of the FDAAA on suspension decisions. The sample consists of project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. Columns 1 and 2 report results from the baseline regression analyses. Columns 3 and 4 report the results from difference-in-differences (DID) analyses based on Industry Project Ratio. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For the dynamic DID analysis in Column 4, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension			
	1	2	3	4
Post	0.126***	0.047***		
	(0.005)	(0.006)		
Industry Project Ratio × Post			0.027***	
			(0.009)	
Industry Project Ratio × Year$_{t-5}$				0.049
				(0.043)
Industry Project Ratio × Year$_{t-4}$				-0.030
				(0.031)
Industry Project Ratio × Year$_{t-3}$				0.026
				(0.025)
Industry Project Ratio × Year$_{t-2}$				0.005
				(0.015)
Industry Project Ratio × Year$_{t}$				0.003
				(0.018)
Industry Project Ratio × Year$_{t+1}$				0.039**
				(0.018)
Industry Project Ratio × Year$_{t+2}$				0.032***
				(0.011)
Industry Project Ratio × Year$_{t+3}$				0.026
				(0.020)
Industry Project Ratio × Year$_{t+4}$				0.029**
				(0.012)
Industry Project Ratio × Year$_{t+5}$				0.030
				(0.019)
Project with Partner		-0.040***	-0.040***	-0.040***
		(0.008)	(0.008)	(0.008)
Log(Number of Projects)		-0.020***	-0.004	-0.004
		(0.005)	(0.006)	(0.006)
Project Diversification		0.065***	0.072***	0.073***
		(0.019)	(0.018)	(0.018)
Percent of Matured Projects		-0.020	-0.034	-0.034
		(0.021)	(0.024)	(0.024)
Percent of Projects with Partner		0.026	0.037*	0.037*
		(0.022)	(0.019)	(0.019)
Log(1+Number of Competitors)		0.026***	0.030***	0.029***
		(0.005)	(0.006)	(0.006)
Percent of Indication Matured Projects		0.040	0.011	0.011
		(0.029)	(0.026)	(0.027)
Log(1+Project Age)		0.108***	0.105***	0.105***
		(0.004)	(0.003)	(0.004)
Year Fixed Effects	No	No	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Observations	24,501	24,501	24,465	24,465
R-squared	0.093	0.133	0.135	0.135
Adjusted R-squared	0.035	0.076	0.078	0.078

TABLE 3

New Project Initiation Before and After the FDAAA

The table presents results from the Poisson regressions that examine the effects of the FDAAA on new project initiations. The sample consists of firm-indication-year observations for the sample period from 2002 to 2012. The dependent variable is the number of new projects in each indication initiated by the firm in a given year. Columns 1 and 2 count initiations of phases 2 and 3 projects, which are directly affected by the FDAAA. Columns 3 and 4 count all phase initiations including pre-clinical (phase 0) and phase 1 projects. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. All columns report the results from difference-in-differences (DID) analyses based on Industry Project Ratio. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For the dynamic DID analyses in Columns 2 and 4, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Number of Initiated Projects			
	1	2	3	4
	Phases 2 & 3		All Phases	
Industry Project Ratio × Post	-0.335***		-0.418***	
	(0.084)		(0.089)	
Industry Project Ratio × $Year_{t-5}$		0.192		-0.207
		(0.705)		(0.394)
Industry Project Ratio × $Year_{t-4}$		0.042		-0.195
		(0.212)		(0.308)
Industry Project Ratio × $Year_{t-3}$		0.084		-0.000
		(0.164)		(0.234)
Industry Project Ratio × $Year_{t-2}$		0.197		0.200
		(0.133)		(0.151)
Industry Project Ratio × $Year_{t}$		-0.309		-0.134
		(0.188)		(0.234)
Industry Project Ratio × $Year_{t+1}$		-0.298**		-0.264***
		(0.151)		(0.097)
Industry Project Ratio × $Year_{t+2}$		-0.312		-0.152
		(0.223)		(0.143)
Industry Project Ratio × $Year_{t+3}$		-0.494***		-0.731***
		(0.153)		(0.188)
Industry Project Ratio × $Year_{t+4}$		-0.516***		-0.579**
		(0.196)		(0.231)
Industry Project Ratio × $Year_{t+5}$		-0.265		-0.603***
		(0.170)		(0.172)
Project with Partner	0.144	0.152	0.205	0.200
	(0.404)	(0.405)	(0.317)	(0.323)
Log(1+Number of Projects)	-0.719***	-0.722***	-0.462***	-0.461***
	(0.045)	(0.044)	(0.063)	(0.063)
Project Diversification	-1.024***	-1.027***	-1.141***	-1.142***
	(0.099)	(0.101)	(0.114)	(0.116)
Percent of Matured Projects	-0.417	-0.415	-0.395	-0.393
	(0.258)	(0.257)	(0.241)	(0.245)
Percent of Projects with Partner	-0.367	-0.375	-0.462*	-0.455*
	(0.382)	(0.378)	(0.247)	(0.247)
Log(1+Number of Competitors)	-0.571***	-0.578***	-0.298***	-0.313***
	(0.064)	(0.064)	(0.052)	(0.054)
Percent of Indication Matured Projects	0.385***	0.386***	0.179**	0.178*
	(0.123)	(0.122)	(0.090)	(0.093)
Log(1+Project Age)	0.022	0.024	-0.103	-0.105
	(0.061)	(0.065)	(0.071)	(0.072)
Indication Average Initiation	4.721***	4.694***	5.045***	5.034***
	(0.236)	(0.242)	(0.219)	(0.217)
Year Fixed Effects	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Observations	16,596	16,596	20,521	20,521
Pseudo R-squared	0.147	0.148	0.178	0.179

TABLE 4

Suspension Responses to Peer Suspensions

The table presents results from the regressions that examine the effects of peer suspensions and peer advances on focal firms' suspension decisions after the FDAAA. The sample consists of project-year observations for the sample period from 2002 to 2012. Column 1 for the full sample. Columns 2 and 3 are for the subsample of low-quality and high-quality firms, respectively. The dependent variable is Suspension that is one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. Peer Suspension (Lagged) is the log one plus the total number of suspended peer projects (within the same indication and phase) in the prior year. Peer Advance (Lagged) is the log one plus the total number of phase-advanced peer projects (within the same indication and phase) in the prior year. Low Quality represents firms with the total number of phase advances in the past three years that are equal to or below the sample median. High Quality represents firms with the total number of phase advances in the past three years above the sample median. Indication-year level control variables, Log(1+Number of Competitors) and Percent of Indication Matured Projects, are subsumed by the indication-year fixed effects. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and indication-year. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension		
	1	2	3
	Full Sample	Low Quality	High Quality
Peer Suspension (Lagged)	-0.034**	-0.077**	-0.009
	(0.017)	(0.032)	(0.022)
Peer Advance (Lagged)	0.015	0.014	0.014
	(0.021)	(0.034)	(0.030)
Peer Suspension (Lagged) × Post	0.042**	0.099***	0.003
	(0.018)	(0.033)	(0.025)
Peer Advance (Lagged) × Post	0.020	-0.002	0.032
	(0.022)	(0.038)	(0.031)
Project with Partner	-0.053***	-0.022	-0.069***
	(0.010)	(0.016)	(0.013)
Log(1+Number of Projects)	0.029	0.048*	0.074
	(0.020)	(0.027)	(0.052)
Project Diversification	0.166***	0.118**	0.365**
	(0.043)	(0.052)	(0.143)
Percent of Matured Projects	-0.060	-0.062	-0.353**
	(0.040)	(0.050)	(0.154)
Percent of Projects with Partner	0.040	0.006	0.078
	(0.039)	(0.052)	(0.106)
Log(1+Project Age)	0.150***	0.174***	0.135***
	(0.010)	(0.014)	(0.013)
Firm Fixed Effects	Yes	Yes	Yes
Indication-Year Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Observations	16,179	7,701	7,686
Adjusted R-squared	0.069	0.073	0.075

TABLE 5

Quality of Peers and Focal Firm's Decisions

The table presents results from the regressions that examine the effects of peer suspensions and advances on focal firms' suspension decisions after the FDAAA, based on the quality of peers. The sample consists of project-year observations for the sample period from 2002 to 2012. The dependent variable is Suspension that is one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. High/Low Quality Peer Suspension is the log of one plus the total number of suspended peer projects (within the same indication and the same phase) from high/low quality peers in the prior year. High/Low Peer Advance is the log of one plus the total number of phase-advanced peer projects (within the same indication and the same phase) from high/low quality peers in the prior year. High/Low Quality represents firms with the total number of phase advances in the past three years that are larger/smaller than the sample median. Indication-year level control variables, Log(1+Number of Competitors) and Percent of Indication Matured Projects, are subsumed by the indication-year fixed effects. Standard errors reported in parentheses are robust and clustered by firm and indication-year ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension		
	1	2	3
High Quality Peer Suspension	-0.040**	-0.032	
	(0.019)	(0.020)	
Low Quality Peer Suspension	-0.004	-0.007	
	(0.032)	(0.031)	
High Quality Peer Advance	0.032*		0.023
	(0.019)		(0.021)
Low Quality Peer Advance	-0.024		-0.020
	(0.026)		(0.023)
High Quality Peer Suspension × Post	0.045**	0.045**	
	(0.022)	(0.022)	
Low Quality Peer Suspension × Post	0.010	0.016	
	(0.035)	(0.033)	
High Quality Peer Advance × Post	-0.007		0.004
	(0.020)		(0.022)
Low Quality Peer Advance × Post	0.060**		0.059**
	(0.029)		(0.025)
Project with Partner	-0.053***	-0.053***	-0.053***
	(0.011)	(0.011)	(0.011)
Log(1+Number of Projects)	0.029	0.029	0.029
	(0.028)	(0.028)	(0.028)
Project Diversification	0.168***	0.168***	0.169***
	(0.044)	(0.045)	(0.045)
Percent of Matured Projects	-0.060	-0.061*	-0.059
	(0.036)	(0.036)	(0.036)
Percent of Projects with Partner	0.041	0.041	0.041
	(0.029)	(0.029)	(0.029)
Log(1+Project Age)	0.151***	0.150***	0.150***
	(0.019)	(0.019)	(0.019)
Firm Fixed Effects	Yes	Yes	Yes
Indication-Year Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Observations	16,179	16,179	16,179
Adjusted R-squared	0.069	0.068	0.069

TABLE 6

The FDAAA and Financial Constraints

The table presents results from the regressions that examine how drug developers' financial constraints affect suspension decisions after the FDAAA. The sample consists of project-year observations of public firms with Compustat data for the sample period from 2002 to 2012. The dependent variable is Suspension as defined in prior tables. For measures of financial constraints, we use the HM index from Hoberg and Maksimovic (2015) and the SA index from Hadlock and Pierce (2010). Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. All columns report the results from difference-in-differences tests based on Industry Project Ratio. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For this public firm analysis, we include additional control variables including Size, Leverage, Profitability, R&D, R&D Growth, Cash Holdings, and Paying Dividends from the Compustat data in Columns 3 and 6. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension					
	1	2	3	4	5	6
Industry Project Ratio × Post	0.054*	0.058**	0.057**	0.048**	0.050**	0.050*
	(0.028)	(0.025)	(0.025)	(0.021)	(0.023)	(0.025)
HM Index	-0.033	0.417***	0.418***			
	(0.105)	(0.109)	(0.118)			
HM Index × Post	-0.017	-0.584***	-0.622***			
	(0.033)	(0.103)	(0.110)			
Industry Project Ratio × HM Index		-0.581***	-0.601***			
		(0.061)	(0.082)			
Industry Project Ratio × Post × HM Index		0.732***	0.775***			
		(0.175)	(0.174)			
SA Index				0.050**	0.061**	0.061*
				(0.023)	(0.026)	(0.032)
SA Index × Post				0.007	-0.036**	-0.035*
				(0.006)	(0.017)	(0.017)
Industry Project Ratio × SA Index					-0.014	-0.014
					(0.013)	(0.014)
Industry Project Ratio × Post × SA Index					0.056***	0.056**
					(0.019)	(0.020)
Size			0.001			0.005
			(0.017)			(0.016)
Leverage			-0.002***			-0.002***
			(0.000)			(0.000)
Profitability			-0.023			-0.012
			(0.030)			(0.029)
R&D			-0.049*			-0.024
			(0.025)			(0.019)
R&D Growth			0.021**			0.007
			(0.007)			(0.010)
Cash Holdings			-0.002			-0.023
			(0.023)			(0.022)
Paying Dividends			0.026			0.018
			(0.015)			(0.015)
Previous Controls	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	6,816	6,816	6,780	8,466	8,466	8,424
Adjusted R^2	0.079	0.079	0.080	0.079	0.080	0.080

TABLE 7

Effects of the FDAAA on Investment Efficiency

The table presents results from the regressions that examine the effects of the FDAAA on firm investment efficiency. Following the idea of Chen et al. (2007), we use the sensitivity of firm investments to Tobin's Q as a measure of investment efficiency. We use a standard measure of Tobin's Q as defined in Eisfeldt and Rampini (2006). We implement the two-step GMM estimation of the errors-in-variables model using cumulants of residuals as proposed by Erickson et al. (2014). Our sample consists of firm-year observations of public firms with Compustat data for the sample period from 2002 to 2012 that have no missing values for both Q and investment measures. The dependent variable is a measure of firm investment that includes R&D, CAPEX, and SG&A expenses normalized by the same denominator for a Q measure. Post is one for firm years in the post-FDAAA period and zero for the pre-FDAAA period. For this public-firm analysis, we include additional control variables including Size, Leverage, Profitability, Cash Holding, and Paying Dividends from the Compustat data. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	R&D	R&D + 0.3×SG&A	R&D + CAPX	R&D + CAPX + 0.3×SG&A
	1	2	3	4
Q	-0.018***	0.021***	-0.019***	0.020***
	(0.005)	(0.003)	(0.005)	(0.003)
Industry Project Ratio	-0.010	-0.016	-0.002	-0.019
	(0.093)	(0.088)	(0.095)	(0.088)
Post	-0.154***	-0.152**	-0.162***	-0.160***
	(0.053)	(0.059)	(0.054)	(0.060)
Q × Industry Project Ratio	0.031**	0.044***	0.035**	0.040***
	(0.015)	(0.011)	(0.016)	(0.010)
Q × Post	0.034***	-0.010*	0.034***	-0.002
	(0.005)	(0.006)	(0.005)	(0.006)
Industry Project Ratio × Post	-0.149	-0.033	-0.173	-0.068
	(0.205)	(0.213)	(0.212)	(0.216)
Q × Industry Project Ratio × Post	0.240***	0.063***	0.253***	0.048**
	(0.039)	(0.024)	(0.038)	(0.022)
Size	-0.101***	-0.104***	-0.100***	-0.104***
	(0.019)	(0.026)	(0.019)	(0.027)
Leverage	-0.097**	-0.080	-0.116**	-0.094
	(0.048)	(0.057)	(0.048)	(0.058)
Profitability	-0.179***	-0.189***	-0.180***	-0.190***
	(0.053)	(0.069)	(0.053)	(0.069)
Cash/Assets	0.005	-0.044	-0.017	-0.067
	(0.072)	(0.103)	(0.074)	(0.106)
Paying Dividends	0.064*	0.099**	0.062*	0.096**
	(0.035)	(0.044)	(0.036)	(0.045)
Previous Controls	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	1,129	1,129	1,129	1,129

TABLE 8

Effects of the FDAAA on Drug Quality: Adverse Event Reports (AER)

The table presents results from the Poisson regressions that examine the effects of the FDAAA on drug quality. To measure drug quality, we use adverse event reports (AER) from the FDA Adverse Event Reporting System (AERS) data for drugs in the sample period from 2004 to 2017. The AERS data start in 2004. We restrict our sample to marketed drugs that are approved by the FDA in and after 1990 (1,303 unique drugs), and our sample consists of drug-year observations. The dependent variable is the total number of serious AER in a given year. We classify reports as serious if the patient outcome is one of the following conditions: death, life-threatening illness, hospitalization, disability, congenital anomaly, or intervention required to prevent permanent impairment or damage. Project Initiation After FDAAA is an indicator variable that is one if the project is initiated after the passage of the FDAAA, and zero otherwise. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. Log(1+Project Age) is not included as a control variable because this analysis is at the approved drug level, not at the project phase level. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Number of Serious AER			
	1	2	3	4
Project Initiation After FDAAA	-0.527*	-0.670**	0.473	0.232
	(0.278)	(0.282)	(0.377)	(0.266)
Project Initiation After FDAAA × Industry Project Ratio			-1.327***	-1.191**
			(0.500)	(0.468)
Years from Approval	-0.012	-0.071	-0.012	-0.076
	(0.046)	(0.060)	(0.046)	(0.061)
Project with Partner		-0.046		-0.055
		(0.151)		(0.164)
Log(1+Number of Projects)		-0.628*		-0.623*
		(0.331)		(0.335)
Project Diversification		-1.136**		-1.147**
		(0.562)		(0.559)
Percent of Matured Projects		-2.692***		-2.676***
		(0.998)		(0.996)
Percent of Projects with Partner		1.210***		1.197***
		(0.418)		(0.416)
Log(1+Number of Competitors)		-0.099		-0.123
		(0.195)		(0.203)
Percent of Indication Matured Projects		0.537		0.518
		(0.618)		(0.622)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	7,430	7,430	7,373	7,373
Pseudo R-squared	0.723	0.735	0.723	0.734

TABLE 9

Effects of the FDAAA on Public Health

The table examines how the changes in drug quantity and quality after the FDAAA are associated with changes in public health. We use the Disability-Adjusted Life Year (DALY) metric from the WHO Health statistics to measure public health. DALY is used to measure the Burden of Disease, which is the number of years lost in disability or death due to a given disease. We use the two points DALY data from the WHO for 2000 and 2016 to represent public health before and after the FDAAA. In Panel A, we split indications into two groups with (a) low and (b) high project growth before and after the FDAAA. The significance in the Difference (a)-(b) column is based on the t-tests for the equality of means in both groups. Rows 1 to 3 show the differences in active project growth rates, suspension rates, and initiated projects between the pre- and the post-FDAAA periods for the two groups. Suspension rate is defined as the mean of Suspension in a given indication. Initiated projects are defined as the number of new projects initiated by firms in a given indication. In Rows 4 to 8, we quantify the indication-level changes in DALY for the two groups. DALY (million years) represents the years lived with disability and the years of life lost due to that disease in millions. DALY (%) represents the fraction of the DALY (years) attributable to a given disease in the entire DALY (years) for any disease. In Panel B, we split indications into two groups with (a) low and (b) high growth in serious AER before and after the FDAAA. Row 1 shows the difference in average serious AER growth rates between the pre- and the post-FDAAA periods for the two groups. In Rows 2 to 6, we quantify indication-level changes in DALY for the two groups as in Panel A. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A. Changes in Project Growth Rates and the Burden of Disease

	(a) Indications with low project growth	(b) Indications with high project growth	Difference (a) - (b)	Difference t-statistics
Difference, Post – Pre:				
(1) Active projects growth rates	-0.462	0.049	-0.511***	-11.74
(2) Suspension rates	0.070	0.031	0.038**	2.39
(3) Initiated projects	-3.637	-0.585	-3.052***	-3.53
Pre-FDAAA period, 2000:				
(4) DALY (million years)	91.900	100.542	-8.643	-0.76
(5) DALY (%)	3.26%	3.57%	-0.31%	-0.76
Difference, 2016 – 2000:				
(6) DALY (million years)	-2.800	-21.483	18.683**	2.60
(7) DALY (%)	0.08%	-0.59%	0.67%***	2.63
Percentage Change:				
(8) (2016 DALY – 2000 DALY) / 2000 DALY	4.21%	-8.27%	12.48%**	2.08
Observations	69	66		

Panel B. Changes in Adverse Event Reports and the Burden of Disease

	(a) Indications with low AER growth	(b) Indications with high AER growth	Difference (a) - (b)	Difference t-statistics
Difference, Post – Pre:				
(1) AER growth rates	-1.442	0.193	-1.635***	-6.00
Pre-FDAAA period, 2000:				
(2) DALY (million years)	116.880	90.848	26.032	1.65
(3) DALY (%)	4.15%	3.22%	0.93%	1.65
Difference, 2016 – 2000:				
(4) DALY (million years)	-23.317	-3.847	-19.470*	-1.85
(5) DALY (%)	-0.64%	-0.05%	-0.69%*	-1.83
Percentage Change:				
(6) (2016 DALY – 2000 DALY) / 2000 DALY	-8.76%	5.85%	-14.61%*	-1.82
Observations	40	41		

Information Disclosure and Peer Innovation: Evidence from Mandatory Reporting of Clinical Trials

Internet Appendix

The Internet Appendix includes our discussions on (i) related legislative and regulatory changes, (ii) DID tests based on heterogeneity within indication, (iii) robustness tests that are referenced in the paper, and (iv) tests for the disciplining effect.

1. Related legislative and regulatory changes

We examine if our results may be driven by other legislative or regulatory changes. We first provide a comprehensive list of legislative and regulatory changes related to new drugs and clinical trials (and their implications) around our sample period in the following table. Among these events, we organize events that are relevant to our research design as follows. The first group is specific to disclosure and includes the launch of the ClinicalTrials.gov website in 2000, its winning of the Innovations in American Government Award in 2004, and the initiative of the World Health Organization (WHO) to standardize the registrations of clinical trials internationally in 2006. Thus, as the ClinicalTrials.gov website has been well-known and publicly available at least since 2004, we do not expect its accessibility to affect our identification. While the WHO's initiative provides an international platform for the clinical trial registry, the registration is voluntary while the disclosure requirements of the FDAAA are mandatory under U.S. laws.

Second, there are several laws and initiatives to encourage drug development or facilitate drug reviews including the Project BioShield Act in 2004, the Critical Path Initiative (CPI) in 2004, the Priority Review Voucher program in 2007, and the FDASIA in 2012. However, these events do not explain the aggregate pattern of increased suspensions that we document. We acknowledge that some laws and initiatives aim to facilitate drug development in specific areas, such as the Priority Review Voucher program that encourages the development of drugs for neglected diseases. It is worth noting that most of the active updates/introductions of expedited

drug approval programs are outside of our sample period.[1] However, even if these programs are associated with firms with larger treatment effect (i.e., higher Industry Project Ratio) suspending their projects more in our main DID setting, they cannot explain our other DID test based on firm heterogeneity within indication, which focuses on the asymmetry for learning needs across firms.

Third, there are three laws and initiatives to ensure drug quality and public safety: the FDA's current good manufacturing practice (cGMP) in 2002, the Drug Safety Board in 2005, and the Safety and Innovation Act (FDASIA) in 2012. While these events may affect overall drug quality and explain the aggregate pattern of reduced drug development, they apply to all indications and all drug developers and thus cannot explain our DID results.

Fourth, it is well-known that Medicare Part D in 2003 and the Affordable Care Act (ACA) in 2010 increased public insurance coverage and reduced discrimination in health insurance. While their effects on drug prices and pharmaceutical firms' profits are unclear,[2] they cannot explain our DID results based on firms' information environments, especially in short event windows.

Major legislative and regulatory changes related to new drugs from 2000 to 2012

2000	The Information Quality Act (IQA), sometimes referred to as the Data Quality Act, was enacted in December 2000. The act required the Office of Management and Budget (OMB) to issue guidance to federal agencies designed to ensure the quality, objectivity, utility, and integrity of information disseminated to the public (Bakst (2020)). The NIH releases the ClinicalTrials.gov website.
2001	President Bush is elected.
2002	The Public Health Security and Bioterrorism Preparedness and Response Act is enacted. It is designed to improve the country's ability to prevent and respond to public health emergencies, and provisions include a requirement for the FDA to issue regulations to enhance controls over imported and domestically produced commodities that it regulates (`https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions`).

[1] See `https://www.pfizer.com/news/articles/speeding_up_the_drug_approval_process_and_what_that_means_for_patients`

[2] See, for example, https://www.bu.edu/questrom/2020/02/27/the-acas-effect-on-the-prescription-drug-market-and-what-might-come-next/ and https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01432

	The current good manufacturing practice (cGMP) initiative is launched by the FDA. This initiative focuses on the greatest risks to public health in manufacturing procedures and ensures that process and product quality standards do not impede innovation (https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps). The Best Pharmaceuticals for Children Act is enacted. This Act provides an incentive of additional marketing exclusivity to sponsors who voluntarily complete pediatric clinical studies (https://www.fda.gov/drugs/development-resources/best-pharmaceuticals-children-act-bpca).
2003	Medicare Part D, a government program to subsidize the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries, is passed. Prior studies suggest that Medicare Part D is associated with increased prescription use and reductions in out-of-pocket prescription expenditures (Diebold (2018)).
2004	The Project BioShield Act authorized the FDA to expedite its review procedures to enable rapid distribution of treatments as countermeasures to chemical, biological, and nuclear agents that may be used in a terrorist attack against the U. S., among other provisions (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#bioshield). The FDA launched the Critical Path Initiative (CPI) and published a landmark report "Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products," which analyzed the reasons for the widening gap between scientific discoveries with the potential to prevent and cure some of today's prevailing diseases and illnesses and translate discoveries into innovative medical treatments. The report concludes that collective action is needed to modernize scientific and technical tools as well as harness information technology to evaluate and predict the safety, effectiveness, and manufacturability of medical products (https://www.fda.gov/science-research/science-and-research-special-topics/critical-path-initiative).
2005	The Drug Safety Board is formed and consists of the FDA staff and representatives from the National Institutes of Health and the Veterans Administration. The board will advise the Director, the Center for Drug Evaluation and Research, and the FDA, on drug safety issues and work with the agency in communicating safety information to health professionals and patients (https://www.fda.gov/files/drugs/published/A-History-of-the-FDA-and-Drug-Regulation-in-the-United-States.pdf). The International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials (https://www.icmje.org/news-and-editorials/update_2005.html).
2006	The World Health Organization (WHO) stated that all clinical trials should be registered, and identified a minimum trial registration standard. The WHO also launched the International Clinical Trials Registry Platform (ICTRP), which includes a search portal providing a single point of access to studies registered in various international registries (https://apps.who.int/iris/bitstream/handle/10665/274994/9789241514743-eng.pdf).
2007	The Food and Drug Administration Amendments Act of 2007 (FDAAA) is enacted. Section 801 of the FDAAA required more types of trials to be registered, additional trial registration information, and the submission of summary results (including adverse events) for certain trials. The law also included penalties for noncompliance, such as the withholding of NIH grant funding and civil monetary penalties of up to $10,000 a day. The U.S. Congress created the Priority Review Voucher program in 2007 to encourage the development of drugs for neglected diseases, and later expanded the program in 2012 to include rare pediatric diseases (Ridley (2017)).
2008	ClinicalTrials.gov begins allowing sponsors and principal investigators to submit the results of clinical studies. The submission of adverse event information was optional when the results database was released but became mandatory beginning in September 2009.
2009	President Obama is elected.
2010	The Affordable Care Act (ACA), colloquially known as Obamacare, is signed into law (https://www.hhs.gov/healthcare/about-the-aca/index.html). The Act is found to increase insurance access, to reduce discrimination in health insurance, and to enhance public health (https://www.hhs.gov/about/news/2022/03/18/fact-sheet-celebrating-affordable-care-act.html) (Courtemanche et al.(2018); Rapfogel et al.(2020)).
2012	The Food and Drug Administration Safety and Innovation Act (FDASIA) is enacted and permits FDA authorities to collect fees from the industry to fund reviews of innovative drugs, to promote innovation to speed patient access to safe and effective products, to increase stakeholder involvement in FDA processes, and to enhance the safety of the drug supply chain (https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-safety-and-innovation-act-fdasia).

Major legislative and regulatory changes related to clinical trials from 1997 to 2023

1997	Congress passes law (FDAMA) requiring trial registration.
2000	NIH releases clinicalTrials.gov website.
2000–2004	FDA issues guidance for industry documents, which provides recommendations for researchers submitting information to clinicalTrials.gov.
2004	ClinicalTrials.gov wins the Innovations in American Government Award.
2005	International Committee of Medical Journal Editors requires trial registration. State of Maine passes Clinical Studies Registration Law (Repealed in 2011).
2006	World Health Organization establishes trial registration policy.
2007	Congress passes law (FDAAA) expanding clinicalTrials.gov submission requirements.
2008	ClinicalTrials.gov releases results database. Declaration of Helsinki Revision Promotes Trial Registration and Results Dissemination.

2009	Public meeting held at the National Institutes of Health.
2013	European Medicines Agency expands clinical trial database to include summary results.
2014	Notice of Proposed Rulemaking (NPRM) for FDAAA 801 issued for public comment.
	NIH Draft Policy on Registration and Results Submission of NIH-Funded Clinical Trials issued for public comment.
2015	National Cancer Institute issues Clinical Trial Access Policy.
2016	Final rule for FDAAA 801 issued.
	Final NIH policy on the Dissemination of NIH-Funded Clinical Trial Information issued.
2017	Revised Common Rule (45 CFR 46) issued.
2020	Federal court decision in Seife et al. v. HHS et al., 18-cv-11462 (NRB) (S.D.N.Y. Feb. 24, 2020).
2023	NIH releases Good Cause Extension Request Process and Criteria.

See `https://clinicaltrials.gov/ct2/about-site/history`.

2. Project suspensions: Heterogeneity within indication

In our DID analyses in Section A, we use a treatment variable based on indication characteristics, which is particularly suitable for our purpose, as we examine the effects of enhanced information for firms that mutually influence each other in the same information environment (i.e., indication). However, there is a separate concern that indications are fundamentally different in their original environments for information, investment, and financing. To reinforce a causal interpretation of our findings, we perform an additional DID test by considering treated and control groups divided by firm heterogeneity *within* indication, focusing on the asymmetry of learning needs across firms.

We divide firms in our sample into two groups based on whether a project is from a firm that has any previous projects in the same indication for the specific phase. This differentiation is made because inexperienced firms in drug development for a particular disease are presumed to be more dependent on external information. The variable of interest for this test is No Experience which takes the value of one if the project is the first one for the firm in a certain indication for a certain phase and zero otherwise. The results for this test are reported in Table IA.3.

We find in Column 1 that the coefficient estimates for the interaction term between No

Experience and Post is positive and significant at the 1% level. This result indicates that a project in a certain indication and phase in which a firm has no previous experience is more likely to be suspended after the FDAAA. The magnitude of the effect is a 6.8 percentage-point increase in the suspension likelihood. The dynamic DID test in Column 2 shows that the effect starts from the year of the FDAAA enactment and thus there is no pre-trend. The results imply that even firms within one narrow indication can have significantly different learning needs. This alternative DID test not only addresses concerns about fundamental differences across indication groups but also supports the conclusion that the FDAAA has a disproportionately greater impact on investment decisions for firms that need more dissemination of information from peers.

3. Details of robustness checks

We discuss several robustness tests in this section. First, in Table IA.4, we consider an alternative definition of project suspension and alternative samples. In Columns 1 and 2, we replace Suspension with Disclosed Suspension, which equals one only if a suspension announcement is made for a project in a given year, and zero otherwise.[3] Our results are robust to this alternative definition of project suspension. Consistent results using both measures of

[3]Previously, Suspension is defined as an indicator that equals one if an announcement of suspension is made for a project in a given year or no progress update is made for a duration longer than a threshold (the duration in the 90th percentile of its distribution), and zero otherwise. Thus, Disclosed Suspension differs from Suspension in the sense that the former only considers firms' announcements.

suspension alleviate the concern that our result can be driven by strategic delays in reporting or by increased duration between progress updates.

We exclude phase 1 projects from our sample because the FDAAA does not require phase 1 information to be disclosed in ClinicalTrials.gov (i.e., not included in ACT) although firms can voluntarily do so. However, the FDAAA could potentially affect divestment decisions of phase 1 projects, as post-phase 1 trial outcomes may be correlated with phase 1 investment. To alleviate these concerns, we expand our sample to include clinical trials in all phases. Columns 3 and 4 of Table IA.4 show our results when we use this expanded sample. These results are consistent with our findings so far, suggesting that our findings are not sensitive to the inclusion or exclusion of specific phases or projects.

Our results could be also driven by M&A waves that possibly coincide with the FDAAA in the pharmaceutical industry. For example, Cunningham, Ederer, and Ma (2021) suggest that pharmaceutical firms have an incentive to acquire industry rivals to terminate targets' projects and capture preemptive advantages in competition. Thus, the increase in project suspensions after the FDAAA can be caused by such "killer acquisitions" rather than by changes in the information environments. To rule out this alternative explanation, we limit our sample to projects of firms that experience no M&A transactions in a given year either as an acquirer or target. Columns 5 and 6 of Table IA.4 present our results.[4] We find that our results remain robust when we use a sample free of M&A transactions. These results indicate that our findings are unlikely to be driven by strategic project terminations involving M&A activities in the pharmaceutical industry.

[4]We consider comprehensive global M&A transactions from the SDC Platinum database in which more than 50% (majority) of equity stakes are acquired.

Importantly, we note that there is a particular concern that the enactment of the FDAAA in 2007 is adjacent to the 2008-2009 financial crisis and that our results may be driven by financial distress during the crisis period. We first address this concern by using a refined sample that completely excludes observations closely related to the financial crisis (i.e., observations from 2007 to 2009). To maintain balance in the number of observations before and after the FDAAA, we extend the sample period for this analysis up to 2014. Columns 1 and 2 of Table IA.5 report the results. We find consistent results in both columns. Although these results suggest that the financial crisis is not the main driver of our results, we further examine firms' financing activities directly. We use the following three variables to measure firms' financing activities: equity issuance and debt issuance for public firms and VC funding for private firms. If our DID results are driven by the possibility that firms with projects in indications with a higher proportion of industry-sponsored projects (i.e., our treatment variable) experience greater financial distress relative to those with projects in indications with a lower proportion of industry-sponsored projects, we expect to find significantly more deteriorated financing activities for firms with a high industry-sponsored project ratio. The results in Columns 3 to 5 of Table IA.5 indicate that there is no significant difference in financing activities among firms with different industry-sponsored project ratios after the FDAAA. Overall, our results suggest that the increase in suspension cannot be simply attributed to financial distress.

One may be concerned that the ratio of industry-sponsored projects is correlated with the overall firm capabilities across indications. To address this concern, we directly examine the correlation between Industry Project Ratio and firm success rates or phase advance frequencies in

the pre-FDAAA period. A firm's success rate is its total number of phase advances minus its total number of phase suspensions scaled by the total number of projects, during the previous three years. A firm's phase advances is its total number of phase advances during the previous three years. In Table IA.6, we find no evidence that Industry Project Ratio is correlated with the pre-FDAAA success rates and phase advance frequencies. This effectively alleviates concerns related to different levels of firm performance and innovation capabilities among firms with projects in indications with a higher vs. lower ratio of industry-sponsored projects.

Lastly, in Table IA.7, we only consider public firms in the sample and control for several firm-specific variables that could plausibly influence the decision to continue the project. Our sample includes both public and private firms. Including private firms offers the benefit of a more representative sample, while a potential drawback is the inability to control for firm-specific variables that are available only for public firms. To ensure robustness, we additionally control for Size, Leverage, Profitability, R&D, R&D growth, Cash Holdings, and Paying Dividends for the sample with public firms only; when we do so, our DID results are intact.

4. Disciplining effect

In this section, we consider the FDAAA's disciplining effect as another possible interpretation of our results. The enhanced information environments created by the FDAAA could lead to more effective monitoring by the FDA and also by the public. Thus, any previous fraudulent attempts to fabricate data or manipulate clinical trial outcomes would be significantly reduced after the FDAAA. Our key finding of the significant increase in suspensions might be

driven by such effective monitoring. To examine the extent to which our results can be explained by this effect, we refine our sample into a subset of firms that are expected to be less fraudulent. Using the legal case and legal parties data from Audit Analytics, we classify a firm as predicted to be less fraudulent if it has no litigation records whatsoever or no litigation records related to health & health care law over the preceding three years. We then run our DID analysis only using each of these subsets of firms that are predicted to be less fraudulent.

Table IA.9 presents the results. We find that the effects of the FDAAA are still strongly present in each subset of less fraudulent firms. For example, the magnitude of the DID effect for less fraudulent firms in Column 1 is estimated at a 5.7 percentage points increase in suspension, which is even larger than the magnitude of the effect for the entire sample in Column 3 of Table 2. Moreover, George and Buyse (2015) show that the percentage of fraudulent clinical trial attempts ranges from 0.01% to 0.40%. These collectively suggest that our results cannot be substantially explained by the disciplining effect, even though we cannot completely rule it out.

TABLE IA.1

List of Academic-Dominated Indications

The table presents the list of 77 indications where over 50% of projects are academic-sponsored projects during our sample period. Among the total of 547 indications, those where industry-sponsored projects comprise over 50% are more prevalent, totaling 470 indications.

Indication	Fraction of Academic -sponsored Projects	Number of Academic -sponsored Projects	Number of Industry -sponsored Projects	Total Number of Projects
Cancer	96%	10	264	274
Transplant Rejection	93%	2	25	27
Metabolic - General	90%	3	27	30
Pancreatitis	88%	1	7	8
Esophageal Cancer	84%	8	42	50
Mild Cognitive Impairment (MCI)	83%	2	10	12
Alcohol Dependence	82%	12	54	66
Acute Promyelocytic Leukemia (APL)	80%	1	4	5
Coronary Artery Disease	80%	14	55	69
End-Stage Renal Disease (ESRD)	78%	5	18	23
Myopic Macular Degeneration (MMD)	78%	2	7	9
Preterm Labor	78%	4	14	18
Respiratory Distress Syndrome (RDS)	77%	3	10	13
Cardiovascular Disease	76%	7	22	29
Aplastic Anemia	75%	1	3	4
Endometrial Hyperplasia	75%	1	3	4
Fever	75%	2	6	8
Panic Disorder	75%	2	6	8
Turner Syndrome	75%	1	3	4
Vitiligo	75%	1	3	4
HIV / AIDS	75%	61	181	242
Traumatic Brain Injury (TBI)	74%	6	17	23
Malaria	70%	13	31	44
Anesthesia	69%	8	18	26
Smoking Cessation	68%	12	26	38
Graft vs. Host Disease (GVHD)	68%	8	17	25
Allergy	67%	2	4	6
Dumping Syndrome	67%	1	2	3
Endometriosis	67%	5	10	15
Familial Adenomatous Polyposis (FAP)	67%	2	4	6
Hemangioma	67%	1	2	3
Psychiatric Disorder or Disease	67%	1	2	3
Spinal Muscular Atrophy	67%	2	4	6
Varicose Veins	67%	1	2	3
Hepatitis B (HBV) Treatment (Antiviral)	66%	19	37	56
Kidney Transplant Rejection	66%	12	23	35
Liver Transplant Rejection	65%	7	13	20
Post-Traumatic Stress Disorder (PTSD)	65%	7	13	20
Dementia	64%	4	7	11
Breast Cancer	63%	184	319	503
Bipolar Disorder	63%	27	45	72

(Table IA.1 continued)

Indication	Fraction of Academic -sponsored Projects	Number of Academic -sponsored Projects	Number of Industry -sponsored Projects	Total Number of Projects
Cervical Cancer	62%	14	23	37
Nasal Polyposis	60%	2	3	5
Urinary Incontinence	60%	2	3	5
Postsurgical Pain	59%	48	69	117
Eating Disorders	57%	3	4	7
Macular Edema from Retinal Vein Occlusion	57%	6	8	14
Seizure Disorders (Epilepsy)	57%	13	17	30
Liver Failure / Cirrhosis	56%	7	9	16
Osteoarthritis	55%	25	31	56
Major Depressive Disorder (MDD)	55%	79	97	176
Generalized Anxiety Disorder (GAD)	55%	20	24	44
Bladder Cancer	54%	32	38	70
Schizophrenia	54%	78	92	170
Chronic Cough	54%	6	7	13
Multiple Myeloma (MM)	53%	75	86	161
Head and Neck Cancer	53%	48	54	102
Sarcoma	52%	39	42	81
Adult Polycystic Kidney Disease	50%	5	5	10
Amyloidosis	50%	2	2	4
Aortic Aneurysm	50%	1	1	2
Chronic Fatigue Syndrome (CFS)	50%	2	2	4
Chronic Pressure Ulcers	50%	2	2	4
Down Syndrome	50%	3	3	6
Glaucoma / Ocular Hypertension	50%	36	36	72
Hidradenitis Suppurativa	50%	2	2	4
Kaposi's Sarcoma	50%	2	2	4
Kawasaki Disease	50%	1	1	2
Leishmaniasis	50%	1	1	2
Malignant Ascites	50%	1	1	2
Neurogenic bladder	50%	1	1	2
Porphyria	50%	1	1	2
Postoperative Ileus	50%	4	4	8
Primary Central Nervous System Lymphoma	50%	1	1	2
Progressive Supranuclear Palsy	50%	2	2	4
Short Bowel Syndrome (SBS)	50%	1	1	2
Tumor lysis syndrome (TLS)	50%	1	1	2

TABLE IA.2

Project Suspension Before and After the FDAAA (Probit)

The table presents regression results that examine the effect of the FDAAA on suspension decisions using probit models. The sample consists of project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. Columns 1 and 2 report results from the baseline regression analyses. Columns 3 and 4 report the results from difference-in-differences (DID) analyses based on Industry Project Ratio. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For the dynamic DID analysis in Column 4, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors are clustered by firm only due to the convergence issue. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension			
	1	2	3	4
Post	0.157***	0.041***		
	(0.007)	(0.008)		
Industry Project Ratio × Post			0.051***	
			(0.014)	
Industry Project Ratio × $Year_{t-5}$				0.147
				(0.094)
Industry Project Ratio × $Year_{t-4}$				-0.095
				(0.071)
Industry Project Ratio × $Year_{t-3}$				0.028
				(0.056)
Industry Project Ratio × $Year_{t-2}$				-0.013
				(0.033)
Industry Project Ratio × $Year_{t}$				0.021
				(0.031)
Industry Project Ratio × $Year_{t+1}$				0.054**
				(0.022)
Industry Project Ratio × $Year_{t+2}$				0.059***
				(0.009)
Industry Project Ratio × $Year_{t+3}$				0.062***
				(0.019)
Industry Project Ratio × $Year_{t+4}$				0.065***
				(0.011)
Industry Project Ratio × $Year_{t+5}$				0.077***
				(0.021)
Project with Partner		-0.044***	-0.044***	-0.044***
		(0.007)	(0.007)	(0.007)
Log(1+Number of Projects)		-0.004	0.021**	0.021**
		(0.014)	(0.010)	(0.010)
Project Diversification		0.117***	0.132***	0.133***
		(0.026)	(0.024)	(0.024)
Percent of Matured Projects		-0.054	-0.073*	-0.074*
		(0.036)	(0.042)	(0.042)
Percent of Projects with Partner		0.036	0.051*	0.052*
		(0.034)	(0.030)	(0.030)
Log(1+Number of Competitors)		0.039***	0.047***	0.050***
		(0.008)	(0.007)	(0.006)
Percent of Indication Matured Projects		-0.075	-0.115*	-0.116*
		(0.077)	(0.067)	(0.066)
Log(1+Project Age)		0.145***	0.141***	0.141***
		(0.004)	(0.004)	(0.004)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	No	No	Yes	Yes
Observations	20,494	20,494	20,488	20,488
Pseudo R-squared	0.104	0.181	0.184	0.185

TABLE IA.3

Project Suspension: Within-Indication Difference-in-Differences

The table presents results from the within-indication DID analyses for suspension decisions. For learning asymmetry across firms within indication, we consider a firm's drug development experience in an indication. No Experience is one if the project is the first one for the firm in a certain indication for a certain phase and zero otherwise. The sample consists of project-year observations for the sample period from 2002 to 2012. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. For the dynamic DID analysis, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension	
	1	2
No Experience × Post	0.068***	
	(0.006)	
No Experience × Year$_{t-5}$		-0.008
		(0.039)
No Experience × Year$_{t-4}$		0.000
		(0.024)
No Experience × Year$_{t-3}$		-0.007
		(0.018)
No Experience × Year$_{t-2}$		0.030
		(0.021)
No Experience × Year$_{t}$		0.045***
		(0.010)
No Experience × Year$_{t+1}$		0.094***
		(0.010)
No Experience × Year$_{t+2}$		0.083***
		(0.011)
No Experience × Year$_{t+3}$		0.070***
		(0.007)
No Experience × Year$_{t+4}$		0.083***
		(0.017)
No Experience × Year$_{t+5}$		0.129***
		(0.011)
No Experience	-0.017**	-0.041***
	(0.006)	(0.008)
Project with Partner (indicator)	-0.039***	-0.039***
	(0.007)	(0.008)
Log(1+Number of Projects)	0.002	0.002
	(0.006)	(0.006)
Project Diversification	0.059***	0.057***
	(0.018)	(0.019)
Percent of Matured Projects	-0.038*	-0.039*
	(0.021)	(0.021)
Percent of Projects with Partner	0.036*	0.035*
	(0.018)	(0.019)
Log(1+Number of Competitors)	0.029***	0.030***
	(0.007)	(0.006)
Percent of Indication Matured Projects	0.008	0.008
	(0.025)	(0.026)
Log(1+Project Age)	0.101***	0.101***
	(0.003)	(0.004)
Year Fixed Effects	Yes	Yes
Firm Fixed Effects	Yes	Yes
Phase Fixed Effects	Yes	Yes
Indication Fixed Effects	Yes	Yes
Observations	24,501	24,501
Adjusted R-squared	0.081	0.081

TABLE IA.4

Project Suspension: Robustness

The table presents results from the regressions that examine the effects of the FDAAA on disclosed project suspension (Columns 1 and 2), using an expanded sample that includes phase 1 projects (Columns 3 and 4), and excluding firm years that experience any M&A transactions either as an acquirer or a target (Columns 5 and 6). The sample consists of project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. The dependent variable in Columns 1 and 2 is Disclosed Suspension and equals one if a suspension announcement is made for the project in a given year and zero otherwise. The dependent variable in Columns 3 to 6 is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For the dynamic DID analyses, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Disclosed Suspension		Suspension		Suspension	
	1	2	3	4	5	6
Industry Project Ratio × Post	0.016*		0.013*		0.041***	
	(0.008)		(0.007)		(0.010)	
Industry Project Ratio × Year_{t-5}		0.015		0.031		0.106
		(0.039)		(0.035)		(0.093)
Industry Project Ratio × Year_{t-4}		-0.011		-0.003		-0.056
		(0.025)		(0.029)		(0.042)
Industry Project Ratio × Year_{t-3}		0.016		0.032		0.042
		(0.022)		(0.030)		(0.029)
Industry Project Ratio × Year_{t-2}		0.005		0.012		0.040
		(0.014)		(0.014)		(0.023)
Industry Project Ratio × Year_{t}		0.006		0.020		-0.012
		(0.019)		(0.015)		(0.029)
Industry Project Ratio × Year_{t+1}		0.032		0.029		0.020
		(0.019)		(0.020)		(0.023)
Industry Project Ratio × Year_{t+2}		0.021		0.024*		0.080***
		(0.013)		(0.013)		(0.026)
Industry Project Ratio × Year_{t+3}		0.017		0.052***		0.024
		(0.016)		(0.010)		(0.041)
Industry Project Ratio × Year_{t+4}		0.003		0.009		0.067**
		(0.009)		(0.013)		(0.026)
Industry Project Ratio × Year_{t+5}		0.023**		0.011		0.059**
		(0.010)		(0.014)		(0.025)
Project with Partner	-0.045***	-0.045***	-0.034***	-0.034***	-0.032***	-0.032***
	(0.007)	(0.007)	(0.005)	(0.005)	(0.008)	(0.008)
Log(1+Number of Projects)	0.026***	0.027***	0.004	0.004	0.004	0.004
	(0.006)	(0.006)	(0.005)	(0.005)	(0.007)	(0.007)
Project Diversification	0.048*	0.048*	0.054***	0.054***	0.023	0.024
	(0.025)	(0.026)	(0.018)	(0.018)	(0.031)	(0.032)
Percent of Matured Projects	-0.021	-0.021	-0.024	-0.024	-0.062***	-0.062***
	(0.017)	(0.017)	(0.024)	(0.025)	(0.018)	(0.018)
Percent of Projects with Partner	0.050**	0.051**	0.025	0.026	0.018	0.018
	(0.024)	(0.024)	(0.018)	(0.018)	(0.020)	(0.020)
Log(1+Number of Competitors)	0.028***	0.027***	0.034***	0.033***	0.025***	0.025***
	(0.007)	(0.007)	(0.004)	(0.003)	(0.009)	(0.009)
Percent of Indication Matured Projects	0.022	0.022	0.014	0.014	0.017	0.018
	(0.016)	(0.016)	(0.024)	(0.024)	(0.022)	(0.022)
Log(1+Project Age)	0.074***	0.074***	0.118***	0.118***	0.101***	0.101***
	(0.005)	(0.005)	(0.005)	(0.005)	(0.006)	(0.006)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	24,465	24,465	33,999	33,999	14,885	14,885
Adjusted R-squared	0.065	0.065	0.087	0.087	0.083	0.082

TABLE IA.5

Financial Crisis and Financing Activities

The table presents results from the regressions that examine the effects of the FDAAA on suspension decisions after excluding the financial crisis period in Columns 1 and 2 and its effects on financing activities in Columns 3 to 5. In Columns 1 and 2, we use a refined sample that excludes observations closely related to the financial crisis (i.e., observations from 2007 to 2009). To maintain balance in the number of observations before and after the FDAAA, we extend the sample period for this analysis up to 2014. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. For the dynamic DID analyses, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. In Columns 3 to 5, we examine financing activities across firms with different levels of Industry Project Ratio. The sample consists of project-year observations for our sample period from 2002 to 2012. The dependent variable in Column 3 is the log of one plus the total amount of equity issuance for the full sample, including both initial and seasoned public equity offerings from SDC. The dependent variable in Column 4 is the log of one plus the total amount of debt issuance for public firms, including public debt from SDC and bank loans from Dealscan. The dependent variable in Column 5 is the log of one plus the total amount of venture capital investment for private firms. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension		Equity Issuance (Full Sample)	Debt Issuance (Public Firms)	VC Funding (Private Firms)
	1	2	3	4	5
Industry Project Ratio × Post	0.038*		-0.003	-0.116	0.058
	(0.021)		(0.060)	(0.160)	(0.061)
Industry Project Ratio × $Year_{t-5}$		0.031			
		(0.032)			
Industry Project Ratio × $Year_{t-4}$		-0.036			
		(0.038)			
Industry Project Ratio × $Year_{t-3}$		0.032			
		(0.021)			
Industry Project Ratio × $Year_{t-2}$		0.008			
		(0.016)			
Industry Project Ratio × $Year_{t+3}$		0.032			
		(0.029)			
Industry Project Ratio × $Year_{t+4}$		0.042*			
		(0.022)			
Industry Project Ratio × $Year_{t+5}$		0.045			
		(0.030)			
Industry Project Ratio × $Year_{t+6}$		0.083**			
		(0.031)			
Industry Project Ratio × $Year_{t+7}$		0.026			
		(0.027)			
Project with Partner (indicator)	-0.039***	-0.039***	-0.012*	-0.035	-0.004
	(0.006)	(0.006)	(0.006)	(0.022)	(0.013)
Log(1+Number of Projects)	0.004	0.004	-0.143**	-1.153*	0.045
	(0.006)	(0.006)	(0.067)	(0.653)	(0.039)
Project Diversification	0.043*	0.044*	0.479***	1.626	0.050
	(0.022)	(0.022)	(0.133)	(1.344)	(0.106)
Percent of Matured Projects	-0.026	-0.026	-0.077	-1.133	0.080
	(0.021)	(0.021)	(0.129)	(1.039)	(0.084)
Percent of Projects with Partner	0.044**	0.044**	0.026	-1.767***	0.053
	(0.016)	(0.016)	(0.115)	(0.552)	(0.039)
Log(1+Number of Competitors)	0.027***	0.028***	0.025	-0.102	0.003
	(0.008)	(0.008)	(0.023)	(0.104)	(0.013)
Percent of Indication Matured Projects	0.012	0.012	0.028	-0.007	-0.112**
	(0.028)	(0.028)	(0.046)	(0.139)	(0.042)
Log(1+Project Age)	0.137***	0.137***	0.013	0.023	0.114***
	(0.005)	(0.006)	(0.009)	(0.022)	(0.023)
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	22,087	22,087	24,465	17,977	6,412
Adjusted R-squared	0.092	0.091	0.439	0.594	0.343

TABLE IA.6

Relation between Treatment and Pre-FDAAA Firm Quality

The table compares overall firm success rates and phase advance frequencies for firms with projects in indications with different levels of Industry Project Ratios during the pre-FDAAA period. The dependent variable is either Firm Success Rates or Phase Advances. Firm Success Rates is a firm's total number of phase advances minus the total number of suspensions scaled by the total number of projects during the previous three years. Phase Advances is a firm's total number of phase advances during the previous three years. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Firm Success Rates	Phase Advances
	1	2
Industry Project Ratio	0.005	0.119
	(0.003)	(0.156)
Project with Partner	-0.002*	-0.133**
	(0.001)	(0.052)
Log(1+Number of Projects)	-0.014	7.960***
	(0.013)	(1.393)
Project Diversification	-0.032	-9.764***
	(0.034)	(3.024)
Percent of Matured Projects	0.068*	-3.701
	(0.034)	(2.341)
Percent of Projects with Partner	-0.019	-1.953
	(0.037)	(2.388)
Log(1+Number of Competitors)	0.001	-0.031
	(0.001)	(0.039)
Percent of Indication Matured Projects	-0.021**	-0.941*
	(0.009)	(0.529)
Log(1+Project Age)	-0.000	0.138
	(0.001)	(0.084)
	(0.032)	(3.498)
Year Fixed Effects	Yes	Yes
Firm Fixed Effects	Yes	Yes
Indication Fixed Effects	No	No
Phase Fixed Effects	Yes	Yes
Observations	6,602	6,602
Adjusted R-squared	0.635	0.865

TABLE IA.7

Robustness with Public Sample and Compustat Controls

The table presents results from the regressions that examine the effects of the FDAAA on suspension decisions using only public firms. We include additional control variables, including Size, Leverage, Profitability, R&D, R&D Growth, Cash Holdings, and Paying Dividends from the Compustat data. The sample consists of project-year observations of public firms for our sample period from 2002 to 2012. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For the dynamic DID analyses, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension	
	1	2
Industry Project Ratio × Post	0.033*	
	(0.018)	
Industry Project Ratio × Year_{t-5}		0.014
		(0.087)
Industry Project Ratio × Year_{t-4}		-0.056
		(0.054)
Industry Project Ratio × Year_{t-3}		0.019
		(0.028)
Industry Project Ratio × Year_{t-2}		0.006
		(0.020)
Industry Project Ratio × Year_{t}		0.039*
		(0.021)
Industry Project Ratio × Year_{t+1}		0.078***
		(0.026)
Industry Project Ratio × Year_{t+2}		0.069**
		(0.030)
Industry Project Ratio × Year_{t+3}		0.045
		(0.027)
Industry Project Ratio × Year_{t+4}		0.025
		(0.017)
Industry Project Ratio × Year_{t+5}		0.002
		(0.016)
Size	-0.006	-0.006
	(0.008)	(0.008)
Leverage	0.017	0.016
	(0.017)	(0.017)
Profitability	-0.010	-0.010
	(0.058)	(0.058)
R&D	-0.046	-0.046
	(0.070)	(0.070)
R&D Growth	-0.001	-0.001
	(0.006)	(0.006)
Cash Holdings	-0.002	-0.004
	(0.016)	(0.017)
Paying Dividends	0.009	0.009
	(0.013)	(0.013)
Previous Controls	Yes	Yes
Year Fixed Effects	Yes	Yes
Firm Fixed Effects	Yes	Yes
Indication Fixed Effects	Yes	Yes
Phase Fixed Effects	Yes	Yes
Observations	13,313	13,313
R-squared	0.125	0.125
Adjusted R-squared	0.077	0.077

TABLE IA.8

Suspension Responses to Peer Suspensions

The table presents results from the regressions that examine the effects of peer suspensions on focal firms' suspension decisions after the FDAAA. The sample consists of project-year observations for the sample period from 2002 to 2012. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. For the dynamic analyses, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Peer Suspension is the log one plus the total number of suspended peer projects (within the same indication and the same phase) in the prior year. Peer Advance is the log one plus the total number of phase-advanced peer projects (within the same indication and the same phase) in the prior year. Low Quality represents firms with the total number of phase advances in the past three years that are equal to or below the sample median. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and indication-year. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension		
	1	2	3
Peer Suspension	-0.036**	-0.048	-0.001
	(0.017)	(0.040)	(0.036)
Peer Advance	0.032***	0.032***	0.031***
	(0.009)	(0.009)	(0.009)
Peer Suspension × Post	0.044**		
	(0.018)		
Peer Suspension × Year_{t-5}		0.000	0.000
		(0.000)	(0.000)
Peer Suspension × Year_{t-4}		0.021	0.090
		(0.101)	(0.107)
Peer Suspension × Year_{t-3}		-0.051	-0.087
		(0.069)	(0.107)
Peer Suspension × Year_{t-2}		0.127	0.183
		(0.114)	(0.127)
Peer Suspension × Year_{t}		0.008	-0.023
		(0.043)	(0.039)
Peer Suspension × Year_{t+1}		0.023	-0.030
		(0.050)	(0.045)
Peer Suspension × Year_{t+2}		0.034	-0.006
		(0.045)	(0.044)
Peer Suspension × Year_{t+3}		0.039	-0.001
		(0.046)	(0.045)
Peer Suspension × Year_{t+4}		0.088**	0.036
		(0.041)	(0.039)
Peer Suspension × Year_{t+5}		0.068	0.015
		(0.043)	(0.040)
Peer Suspension × Year_{t-5} × Low Quality			0.000
			(0.000)
Peer Suspension × Year_{t-4} × Low Quality			0.000
			(0.000)
Peer Suspension × Year_{t-3} × Low Quality			0.077
			(0.109)
Peer Suspension × Year_{t-2} × Low Quality			-0.132
			(0.157)
Peer Suspension × Year_{t} × Low Quality			0.083*
			(0.044)
Peer Suspension × Year_{t+1} × Low Quality			0.117**
			(0.049)
Peer Suspension × Year_{t+2} × Low Quality			0.094*
			(0.048)
Peer Suspension × Year_{t+3} × Low Quality			0.101**
			(0.049)
Peer Suspension × Year_{t+4} × Low Quality			0.101**
			(0.048)
Peer Suspension × Year_{t+5} × Low Quality			0.104**
			(0.048)
Previous Controls	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes
Indication-Year Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Observations	16,179	16,179	16,179
Adjusted R-squared	0.069	0.069	0.071

TABLE IA.9

Project Suspension: Excluding Potentially Fraudulent Firms

The table presents results from the regressions that examine the effects of the FDAAA on suspension decisions after we exclude firm years with previous litigation records. In Columns 1 and 2, we exclude firm years with any litigation record during the preceding three years, and in Columns 3 and 4, we exclude firm years with litigation records related to health & health care law during the preceding three years. The sample consists of project-year observations for our sample period from 2002 to 2012. The dependent variable is Suspension and equals one if the project is suspended in a given year or has no progress update for a duration longer than the 90th percentile of the sample duration for each clinical trial phase, and zero otherwise. Post is one for project years in the post-FDAAA period and zero for the pre-FDAAA period. Industry Project Ratio is the proportion of industry-sponsored projects (vs. academic-sponsored projects that are funded by universities, hospitals, and the NIH) within each indication during the sample period. For the dynamic DID analyses, Year t represents the year of the FDAAA enactment, and Year t-1 is used as the base year. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

	Suspension			
	1	2	3	4
Industry Project Ratio × Post	0.057*		0.043*	
	(0.031)		(0.024)	
Industry Project Ratio × Year_{t-5}		0.099		0.009
		(0.145)		(0.106)
Industry Project Ratio × Year_{t-4}		0.175		-0.017
		(0.126)		(0.045)
Industry Project Ratio × Year_{t-3}		0.105		0.040
		(0.086)		(0.046)
Industry Project Ratio × Year_{t-2}		0.117		0.047
		(0.078)		(0.054)
Industry Project Ratio × Year_{t}		0.123*		0.060
		(0.071)		(0.057)
Industry Project Ratio × Year_{t+1}		0.125*		0.132***
		(0.060)		(0.035)
Industry Project Ratio × Year_{t+2}		0.245***		0.091**
		(0.068)		(0.034)
Industry Project Ratio × Year_{t+3}		0.209**		0.071**
		(0.092)		(0.030)
Industry Project Ratio × Year_{t+4}		0.071		0.037
		(0.050)		(0.035)
Industry Project Ratio × Year_{t+5}		0.006		-0.023
		(0.064)		(0.031)
Previous/Compustat Controls	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Observations	3,282	3,282	7,793	7,793
Adjusted R-squared	0.090	0.090	0.081	0.081

TABLE IA.10

Effects of the FDAAA on Investment Efficiency with Alternative Q Measures

The table presents results from the regressions that examine the effects of the FDAAA on firm investment efficiency. Following the idea of Chen et al. (2007), we use the sensitivity of firm investments to Tobin's Q as a measure of investment efficiency. We use Peters and Taylor (2017)'s new Tobin's Q proxy (Q_{tot}) that accounts for intangible capital in Panel A. We also consider the simplest form of the Q measure (Q_{alt}), computed as market equity value divided by total assets. Our sample consists of firm-year observations of public firms with Compustat data for the sample period from 2002 to 2012 that have no missing values for both Q and investment measures. The dependent variable is a measure of firm investment that includes R&D, CAPEX, and SG&A expenses normalized by the same denominator for a Q measure. Post is one for firm years in the post-FDAAA period and zero for the pre-FDAAA period. For this public-firm analysis, we include additional control variables including Size, Leverage, Profitability, Cash Holding, and Paying Dividends from the Compustat data. Detailed descriptions of all other variables are available in Appendix C. Standard errors reported in parentheses are robust and clustered by firm and industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Using Tobin's Q proxy from Peters and Taylor (2017)

	R&D	R&D + 0.3×SG&A	R&D + CAPX	R&D + CAPX + 0.3×SG&A
	1	2	3	4
Q_{tot}	0.014***	0.012***	0.017***	0.014***
	(0.004)	(0.004)	(0.005)	(0.004)
Industry Project Ratio	-0.040	-0.043	-0.032	-0.038
	(0.079)	(0.086)	(0.080)	(0.087)
Post	-0.120**	-0.155***	-0.123**	-0.159***
	(0.050)	(0.058)	(0.051)	(0.059)
Q_{tot} × Industry Project Ratio	0.045***	0.027**	0.057***	0.033***
	(0.012)	(0.013)	(0.013)	(0.012)
Q_{tot} × Post	0.044***	0.029***	0.047***	0.031***
	(0.006)	(0.007)	(0.007)	(0.007)
Industry Project Ratio × Post	-0.104	-0.016	-0.124	-0.039
	(0.182)	(0.203)	(0.187)	(0.208)
Q_{tot} × Industry Project Ratio × Post	0.090***	0.028	0.118***	0.042**
	(0.017)	(0.021)	(0.018)	(0.021)
Previous Controls	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	1,128	1,128	1,128	1,128

Panel B: Using a simple Q proxy based on market equity

	R&D	R&D + 0.3×SG&A	R&D + CAPX	R&D + CAPX + 0.3×SG&A
	1	2	3	4
Q_{alt}	0.011***	-0.032***	0.013***	-0.034***
	(0.003)	(0.005)	(0.003)	(0.005)
Industry Project Ratio	-0.036	-0.016	-0.029	-0.007
	(0.080)	(0.145)	(0.081)	(0.146)
Post	-0.120**	-0.176**	-0.127**	-0.184**
	(0.049)	(0.072)	(0.051)	(0.073)
Q_{alt} × Industry Project Ratio	0.041***	-0.232***	0.051***	-0.223***
	(0.006)	(0.022)	(0.007)	(0.022)
Q_{alt}× Post	-0.009**	0.099***	-0.005	0.096***
	(0.004)	(0.009)	(0.005)	(0.009)
Industry Project Ratio × Post	-0.103	-0.411	-0.127	-0.431
	(0.194)	(0.326)	(0.199)	(0.329)
Q_{alt} × Industry Project Ratio × Post	0.002	0.499***	0.012	0.512***
	(0.015)	(0.062)	(0.016)	(0.063)
Previous Controls	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	1,129	1,129	1,129	1,129