



## Institutional investors and medical innovation

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### ABSTRACT

In this research paper, we investigate if institutional investors influence corporate innovation in the US pharmaceutical industry. We hand collect unique datasets from the Food and Drug Administration (FDA), including drug patents, drug approvals, medical device approvals, and Phase I-II-III drugs under clinical testing. We find that higher institutional ownership has a positive, causal effect on firm innovation. We document that institutional ownership increases the number of FDA approved products. Then, we examine the innovation quality and find that institutional ownership reduces the likelihood of both drug recalls and market withdrawals. Our results investigate possible underlying mechanisms through which institutional investors provide faster and more frequent innovation outcomes: Institutional holdings act as active monitors by providing insurance for firm executives against innovation failures. Our article sheds new lights on the real effects of institutional investors on pharmaceutical firms' innovation.

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### 1. Introduction

This paper investigates the impact of institutional ownership on firms' innovation outcomes. We focus on institutional investors for two reasons. First, innovation is a long-term investment with a high probability of failure. The previous literature has highlighted an institutional investor's ability to monitor firms and act as an external corporate governance mechanism. Second, institutional investors may provide a "failure tolerant" environment for executives who are reluctant to take risky innovation projects due to career concerns (Manso (2011)). The innovation of new products and services is risky and requires a calculated long-term perspective on behalf of the firm's management and shareholders. Therefore, institutional investors should play a role in increasing corporate innovation performance as measured by innovation quantity and innovation quality.

Innovation is a primary determinant of economic growth (Griliches (1990)) and institutional ownership has been found to have a positive effect on innovation outcomes (Aghion, Van Reenen, and Zingales (2013); Luong et al. (2017)). Over the past 50 years the share of institutional investors in the US has dramatically increased from 20% in the 1960's to more than 60% in 2011 (Celik and

Isaksson (2014)). In competitive industries, such as the pharmaceutical industry, the demand and risk associated with innovation are unique. We contribute to the literature by documenting how institutional investors fuel innovation in the medical industry. In this study, we employ Food and Drug Administration (FDA) approved drugs, medical devices, pre-market approvals, and Phase I-II-III drugs under clinical testing. We hypothesize that external pressure from institutional investors might encourage firms and managers to engage in innovating activities, helping to shape corporate innovation in the medical field.

This study provides evidence regarding the benefits of institutional ownership by testing a) whether institutional ownership increases the number of FDA approved products, b) whether institutional ownership provides a "failure tolerant" working environment for executives engaging in high-risk-high-reward industries, and c) whether institutional investors ultimately increase not only the amount of medical innovation, but also the quality of approved medical products. Our study represents an initial analysis of a new panel dataset of a database of FDA-approved medical discoveries (i.e., drug patents) along with product quality measures (i.e., drug recalls).

Institutional investors may increase innovation outcomes via two channels. The first channel is the "monitoring effect;" institutional investors have the ability and incentive to act as corporate monitors. In addition, active institutional investors may intervene when needed to increase firm value (Burkart, Panunzi, and Shleifer (2003); Shleifer and Vishny (1986)). The second channel is the

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“insurance effect.” Institutional investors hold diversified portfolios, which reduces their exposure to the individual risk associated with medical innovation. Therefore, as a primary shareholder, institutional investors may be more tolerant of early failures during the innovation process. This channel is related to the work of Manso (2011). By eliminating the career concerns of executives, institutional investors can promote a failure-tolerant working environment and influence the managerial decision-making process, which may ultimately provide a lift to a firm’s innovation performance.

First, we study the empirical relationship between institutional ownership and innovation. Our results show that increased institutional ownership is associated with increased innovation outcomes. Next, we investigate the effect of institutional ownership on innovation performance and quality. Our results suggest that firms with high institutional ownership navigate the product approval process faster. We employ additional measures of innovation quality and performance, such as product recalls, market withdrawals, post-market drug, biologic safety evaluations, and patent lawsuits. Our analysis shows that institutional ownership reduces product failures and enhances innovation quality, which is vital to a firm’s ability to generate economic and financial value.

Lastly, we examine several alternative explanations focused around the “insurance effect”. Because medical innovation is a long and tedious process accompanied by a high probability of failure, increased tolerance for failure may promote innovation (Manso, 2011). Increased tolerance may come in the form of reduced executive career concerns (increased job security) or reputation benefits. We find that firms with higher levels of institutional ownership are more likely to retain CEOs following low firm performance. In addition, increased levels of institutional ownership weaken a CEO’s pay-for-performance sensitivity. Our results provide an understanding about how institutional investors provide insurance to managers by reducing their career and reputation concerns.

Our final sample includes 919 unique firms for the years 2000 to 2014, collected from the S&P Capital IQ database. We also hand-collect 24,312 total FDA approvals, including 3202 drug patents, 8566 drug approvals, 5445 pre-market approvals, and 7099 medical device approvals. Our results provide evidence that institutional ownership increases the number of patents, as well as the number of FDA approved medical products. Our results remain robust to both patent counts as well as citation-weighted patent counts. This work contributes to the literature surrounding institutional ownership and firm innovation.

This paper proceeds as follows: In Section 2, we provide a summary of existing literature on lawsuits and firm performance. Section 3 describes our research data. Section 4 presents our hypothesis and methodology. In Section 5, we discuss our findings, and we conclude our work in Section 6.

## 2. Literature review

### 2.1. Innovation in pharmaceutical industry

Medical innovation faces unique challenges as compared to other business sectors. The pharmaceutical industry is a high-risk but high-reward sector, where promising treatments provide a financial boost. The industry commits considerable resources to disease-specific research without the guarantee of success. Measuring the impact of pharmaceutical innovation has many challenges; a simple count of new drugs, for example, gauges quantity not quality.

In innovative industries, such as the pharmaceutical industry, sustaining a high level of innovation can be challenging. On average, it can take up to 12 years for drugs to go from pre-clinical

testing to FDA approval, and approximately seven years for medical devices (Van Norman (2016)). Slow drug approvals and the high-cost of failure pose a challenge to medical innovation. The need for innovation is a major driving force in biotechnology. From the discovery of therapeutic remedies in the 1920s to the blockbuster drugs birthed in the 1990s, pharmaceuticals have always been on a quest for groundbreaking drug development. A PricewaterhouseCoopers survey among pharmaceutical firms highlights the importance of innovation. The study finds a clear correlation between innovation and growth, where the top 20% of innovative pharmaceutical firms grow at a rate 16% higher than the least innovative. Pharmaceutical respondents specifically (86%) indicate that innovation is important to their business, with 58% defining it as a necessity.<sup>1</sup>

U.S. consumers account for about 64 to 78 percent of total pharmaceutical profits. American patients use newer drugs and face higher prices than patients in other countries.<sup>2</sup> Drugs that are used to treat complex, chronic conditions like cancer, rheumatoid arthritis, and multiple sclerosis have very high prices, thus generating greater revenues. Drug patents are important protection for pharmaceutical firms who commit billions of dollars each year to drug development. Pharmaceutical firms apply for patent protection early in the development process, before pre-clinical studies, in order to benefit from exclusive revenues, once the product is released to the market.<sup>3</sup>

Innovation in the pharmaceutical industry can also benefit the economy; investments in manufacturing and R&D create positive socioeconomic values. In 2014, the production value of the industry was \$997 billion (globally), compared to \$345 billion in 2006. In the same year the pharmaceutical industry generated 3.8% of the gross value added.<sup>4</sup> More than 810,000 people work in the biopharmaceutical industry, in occupations such as scientific research, technical support and manufacturing. Directly and indirectly, the industry supported over 3.4 million jobs and added an estimated \$790 billion to the economy in 2014. The pharmaceutical sector is consistently ranked one of the most R&D-intensive industries in the United States, where pharmaceutical firms allocate around 15–20 percent of their revenues to R&D activities and invest over \$50 billion in R&D annually.<sup>5</sup>

### 2.2. Innovation and institutional investors

Scholars document that patents are an important measure of firms’ innovation output (Griliches (1990)). A firm legal environment (Acharya, Baghai, and Subramanian (2013)), financial markets (Hsu, Tian, and Xu (2014)), stock liquidity (Fang, Tian, and Tice (2014)), market conditions and competition (Nanda and Rhodes-Kropf (2013)), quality of financial analysts (He and Tian (2013)), labor unions (Bradley, Kim, and Tian (2016)), venture-capital investors (Chemmanur, Loutskina, and Tian (2014)) or the country’s culture and corporate governance practices (Acharya and Subramanian (2009); Brown, Fazzari, and Petersen (2009); Hsu et al. (2014); Xie, Davidson, and DaDalt (2003)) can determine a firm’s innovation performance. This study investigates the impact of institutional investors on innovation.

<sup>1</sup> <https://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-managing-innovation-pharma.pdf>

<sup>2</sup> <https://www.brookings.edu/research/the-global-burden-of-medical-innovation/>

<sup>3</sup> See EFPIA Figures 2012 Final, European Federation of Pharmaceutical Industry and Association web site. [www.efpia.eu](http://www.efpia.eu).

<sup>4</sup> <https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf>

<sup>5</sup> [https://www.trade.gov/topmarkets/pdf/Pharmaceuticals\\_Executive\\_Summary.pdf](https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf).

The prior literature documents a positive relationship between institutional holdings and innovation output. [Aghion et al. \(2013\)](#) find that a higher share of institutional ownership is associated with a higher level of innovation output. The authors explain that a higher innovation outcome is a function of the monitoring power of institutional investors. Additionally, the authors describe that institutional investors can alleviate career concerns of top managers. [Bena, Ferreira, and Matos \(2014\)](#); [Luong, Moshirian, Nguyen, Tian, and Zhang \(2017\)](#) and [Lee \(2005\)](#) also document a positive effect of institutions on innovation output. In the pharmaceutical industry, the process of developing a new drug can span generations of CEOs, as well as require a significant capital allocation. Institutional investors can act as active monitors, as well as provide insurance against failures, ultimately boosting innovation ([Berger, Stocker, and Zeileis \(2017\)](#); [Rong, Wu, and Boeing \(2017\)](#); [Schain and Stiebale \(2016\)](#)).

Our work is similar to [Aghion et al. \(2013\)](#) and [Luong et al. \(2017\)](#), who analyze the relationship between institutional ownership and firm innovation. Our study provides three unique perspectives. First, we utilize several hand-collected databases related to innovation outcomes, including patents, citations, FDA-approved drugs, medical devices, pre-market approvals, Phase I – II – III drugs under clinical testing, and licensed patents. We measure a firm's innovation performance as well as the overall development of a competitive industry. Second, we analyze how institutional investors influence a firm's product development. Lastly, our study explores not only firm innovation output, but also innovation quality. We measure whether institutional investors promote innovation quality by reducing product failures, in the long run, using a dataset of product recalls, post-market evaluations, and patent lawsuits. Overall, our work complements the study of [Aghion et al. \(2013\)](#) by documenting the positive and significant effect of institutional investors on firms' innovation performance.

### 3. Data

#### 3.1. Firm

Our sample consists of publicly traded pharmaceutical firms in the US, listed in the Capital IQ database. For this study, we define pharmaceutical firms based on the Fama and French 12 industry classification. Under this classification, the 10<sup>th</sup> industry is defined as Healthcare, Medical Equipment, Pharmaceutical Products, and Drugs. We divide our sample into four primary subsectors. "Pharmaceutical firms" produce medicine with a chemical basis; "biotech firms" produce medicines using live organisms, such as bacteria or enzymes; "biopharmaceutical firms" develop medicines from both chemicals and living organisms; and "healthcare equipment firms" develop medical devices. Other common subindustries are life sciences, tools and services, veterinary drugs, microbiology, agricultural biology, home healthcare equipment, and therapeutic devices.

We exclude healthcare providers, since they are also defined under Financial Services and Insurance. Our final sample includes 919 unique firms for the years 2000 to 2014. This includes 603 unique firms from pharmaceuticals, biotech, and biopharmaceuticals. There are 247 unique healthcare equipment firms. The remaining 69 firms are from subindustries such as life sciences and microbiology. More information is provided in Appendix A and summary statistics are presented in [Table 1](#).

#### 3.2. Institutional investors data

To measure institutional holdings, we use the percentage of institutional ownership invested in firm *i* in year *t*. Following

**Table 1**  
Summary Statistics.

Variables	Mean	Std.Dev	Min	Max
<b>Panel A. Total FDA Approvals</b>				
Total Patent	0.42	2.85	0.00	96.00
Total FDA Approval	1.23	8.59	0.00	250.00
Total Medical Device Approval	0.71	6.66	0.00	292.00
Total Pre-Market Approval	0.90	3.07	0.00	45.00
Total Licenced Patent	1.16	12.10	0.00	337.00
Total Phase 1 Drugs	0.15	1.36	0.00	54.00
Total Phase 2 Drugs	0.20	1.15	0.00	24.00
Total Phase 3 Drugs	0.17	1.06	0.00	22.00
<b>Panel B. Innovation Quality</b>				
Total Recall	0.85	7.59	0.00	292.00
Recall%	0.09	0.28	0.00	1.00
Total Post Market Evaluations	1.30	8.50	0.00	129.00
Post Market Evaluations%	0.09	0.28	0.00	1.00
Total Patent Lawsuit	0.08	0.39	0.00	7.00
Lawsuit%	0.06	0.23	0.00	1.00
<b>Panel C. Institutional Ownership</b>				
Inst. Own%	0.65	0.23	0.01	1.00
Max. Inst. Own%	0.11	0.07	0.01	1.00
Top 5 Own	0.45	0.14	0.01	0.90
Top 10 Own	0.33	0.12	0.01	0.94
Top Block Hold.	0.23	0.11	0.05	0.83
Mutual Funds	0.25	0.04	0.01	0.79
Investment	0.19	0.21	0.01	0.91
Banks	0.16	0.23	0.01	0.89
Pension	0.17	0.19	0.01	0.92
Insurance	0.13	0.15	0.01	0.79
Long Term	0.15	0.18	0.01	0.90
Short Term	0.12	0.01	0.00	0.54
Lerner Index	0.01	0.02	0.01	1.00
<b>Panel D. Control Variables</b>				
Log(Asset)	2.73	2.18	0.00	12.27
Tobin's Q	2.60	21.78	0.28	12.94
RnD	0.27	1.00	0.00	27.20
Book Leverage	0.46	9.20	0.00	32.01
Tangibility	0.14	0.14	0.00	1.00
ROA	-0.32	9.70	-12.00	15.45
HHI Index	0.08	0.08	0.04	1.00
Log(Firm Age)	2.58	0.64	0.00	4.17
Free Cash Flow	-0.45	2.98	-14.00	2.96

[Table 1](#) Reports the summary statistics for the variables of interest used in this study. Variable definition and sources are reported in Appendix A.

[Hartzell and Starks \(2003\)](#) and [Aghion et al. \(2013\)](#), we calculate *Insts Own%* as the ratio of total common stocks held by institutional investors and total shares outstanding by examining 13-F filings collected from Edgar.

#### 3.3. Innovation data

We measure a firm's innovation outcome by employing the FDA product submission database. Our final sample is comprised of 24,312 total FDA approvals. This includes 3202 drug patents, 8566 drug approvals, 5445 pre-market approvals, and 7099 medical device approvals. [Table 1](#), Panel A, documents the summary statistics for FDA-approved products. We gather information for drugs under clinical testing drugs which include total licensed patents, as well as Phase I – Phase II – Phase III drugs from the Capital IQ database.

#### 3.4. Innovation quality

To increase the value of our study, we employ several unique measures of innovation quality. We amass data on unsafe recalled pharmaceutical products from the Food and Drug Administration, as well as medical products that fail post-market safety evaluations. In addition, we gather products that are identified in patent lawsuits.

Table 1 documents the summary statistics for the variables used in this study. In Panel A, we document FDA-approved products and descriptive statistics. In Panel B, we exhibit innovation quality by employing product failures and recalls. Panel C documents the summary statistics for institutional ownership variables. Panel D shows the firm-specific control variables in our study.

#### 4. Hypothesis and methodology

We hypothesize that institutional investors increase innovation outcomes via two primary channels; the “monitoring” and “insurance” effects. Researchers suggest that institutional investors are skilled investors who seek long-term gains from their investments (Allen (1993a, 1993b)); Jarrell, Lehn, and Marr (1985)). Aoki (1984) suggests that institutions carefully evaluate alternatives before making investment decisions. Before they invest, they possess superior knowledge about the firm, compared to individual investors (Black (1992)).

In this study, we specifically examine how institutional investors enhance innovation in a highly-competitive industry. We examine firm innovation through FDA approvals, rather than R&D expenditures. It is possible that two biotechnology firms may have the same intensity of R&D spending, yet be different in their FDA-approved products, because resources are not efficiently managed by executives (Hitt, Hoskisson, Ireland, and Harrison (1991)). Therefore, higher R&D does not necessarily correspond to better innovation. Our study contributes to the literature by examining “tangible innovation outcomes”, such as, FDA-approved patents, drugs, medical devices, and other pre-market notifications.

For a better corporate capital-allocation mechanism, we argue that institutional investors are an important factor in corporate governance, due to their distinct voice and superior monitoring ability Aggarwal, Erel, Ferreira, and Matos (2011). Therefore, we expect that intensive monitoring encourages managers to invest in long-term innovative activities. The relationship between institutional holdings and innovation, if positive, indicates that institutional investors support innovation (monitoring effect).

**H1.** All other things being equal, institutional investors are positively associated with firm innovation.

$$\begin{aligned} Innovation_t = & \alpha + \beta_1 Inst. Own\%_{i,t-1} + \beta_2 Log(Asset)_{i,t-1} \\ & + \beta_3 Tobin's Q_{i,t-1} + \beta_4 RnD_{i,t-1} + \beta_5 Leverage_{i,t-1} \\ & + \beta_6 Tangibility_{i,t-1} + \beta_7 ROA_{i,t-1} + \beta_8 HHI Index_{i,t-1} \\ & + \beta_9 Log(FirmAge)_{i,t-1} + \beta_{10} Free Cash FLOW_{i,t-1} \\ & + \theta_{it} + \varphi_{it} + \varepsilon_{it} \end{aligned} \quad (1)$$

We calculate *Inst. Own%* as the sum of shares owned by institutional investors as a percentage of firms' total number of shares outstanding. Our dependent variable, the firm's innovation outcome, is measured by the number of patents granted to pharmaceutical firms. Following the prior literature, we control for firm size measured by the log of total assets. We add Tobin's Q (growth opportunities), RnD, book leverage, tangibility, and free cash flow as additional control variables. We add ROA to proxy for a firm's profitability, Herfindahl Index for market competition, and firm age (Aghion and Tirole (1994); Robinson and Smith (2008)). In addition, we include firm-year fixed effects and cluster standard errors at the firm level.

For the robustness of our results, we estimate innovation by using medical discoveries that are approved by FDA. The medical discoveries include total FDA-approved drugs, medical devices, pre-market approvals, Phase I – II – III drugs under clinical testing,

and licensed patents. First, we investigate the impact of institutional investors on the different stages of the FDA approval process.

Bringing a drug to market is a lengthy and expensive process. The cost of bringing a new drug on average was \$11 billion in 2011 compared to \$4 billion in 1997. The average time can be up to 16 years from research to market, while the clinical trial phase can take up to 8 years. On average, one molecule of 10,000 reach commercialization (Bunnage (2011)); Kaitin (2010). Pharmaceutical formulations can consume a significant amount of time and R&D spending. Innovation in the pharmaceutical industry can be defined as a) a new benefit to a condition where no prior treatment exists, b) an improvement to already existing treatment, c) a safer treatment (e.g., lower adverse effects), d) a lower treatment cost (Aronson, Ferner, and Hughes (2012)). Innovation is challenging, less than 10% of all drug candidates proceed from phase one to final approval. The success from mid-stage phase two trials to large-scale phase three was just 31% between 2006 and 2015. The chance of Phase I drugs eventually making it to market is 21.5%, and approximately \$5.08 billion each year is spent on drugs that will never reach the market. According to Hay, Thomas, Craighead, Economides, and Rosenthal (2014), the overall success rate from Phase I to FDA approval is even lower if the “Pre-Clinical Phase” is included, a stage during which researchers look for potential new compounds to target selected diseases.

Based on FDA guidelines, Phase I trials refer to a new drug or treatment. The length of the Phase I study is several months, with approximately 70% of drugs in that stage moving to the next phase. The main motivation of Phase I clinical testing is to find the highest dose of the new treatment without serious side effects. Safety is one of the main concerns during Phase I.

Phase II clinical trials focus on the safety of the treatment, as well as its side effects. Phase II testing can take 2 years or more and approximately 33% proceed to Phase III. Phase III is the final stage associated with the FDA approval process. Phase III clinical testing lasts between 1–4 years.<sup>6</sup> Medical discoveries that progress to Phase III are extensively tested for their effectiveness in treating a specific condition.<sup>7</sup>

We extend our research to investigate what happens post-FDA-approval to the quality of a firm's innovation. For quality purposes, we employ three metrics. First, we identify FDA-recalled products. When the FDA is informed that a specific drug or medical device under their jurisdiction has significant health or safety concerns, the FDA may issue a public recall of that item. In 2016 alone, the FDA issued 2847 recalls and 14,590 warning letters.<sup>8</sup>

Our second measure of quality is FDA Post-Market Evaluations. The FDA conducts post-market evaluations to determine any new or previously undiscovered health or safety concerns. Lastly, we measure the quality of innovation by observing the patents named in a future infringement lawsuit. Previous literature has shown that defending a patent in court can represent a serious threat to firm value (Bessen, Ford, and Meurer (2011); Bessen and Meurer (2005); Cohen, Gurun, and Kominers, (2014); Paik and Zhu (2016); Raghu, Woo, Mohan, and Rao (2008); Smeets (2014)). We are able to identify whether a pharmaceutical firm is a defendant or a plaintiff. We integrate these innovation quality measures in our primary “monitoring effect” hypothesis. We believe that institutional investors not only increase the quantity of innovation, but also encourage

<sup>6</sup> <https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm>

<sup>7</sup> <https://www.reuters.com/article/us-pharmaceuticals-success-rates-for-experimental-drugs-falls-study-idUSTRE71D2U920110214>

<sup>8</sup> <https://www.fda.gov/downloads/iceci/enforcementactions/ucm540606.pdf>



better quality of innovation as measured by fewer recalled products.

Our second hypothesis investigates whether institutional investors encourage a “failure tolerant working environment. The managerial working environment is important during drug development. A workplace culture that strongly discourages failure has been found to cause managers to under-invest (Ward, Yin, and Zeng (2017)). When job security concerns arise, managers fail to invest a firm’s resources efficiently. For example, investment in projects with a high probability of failure (e.g., clinical testing of drugs) may be diverted to projects with a more certain outcome. In a highly competitive market (e.g., biotechnology), the chances of innovation failures are high. We hypothesize that informed institutional investors are better equipped to evaluate the risk and failure associated with the pharmaceutical industry. Therefore, monitoring by investors plays an important role in mitigating the career concerns of managers when market competition is greater. We define this phenomenon as the “insurance effect”. The insurance hypothesis would suggest that, when institutional ownership is higher, managers have a lower probability of being fired. Following Aghion et al. (2013) and Ward et al. (2017), we test the insurance effect in three distinct ways. First, we test the competition among pharmaceutical firms.

**H2.** All other things being equal, institutional investors alleviate managers’ career concerns.

$$\begin{aligned} Innovation_t = & \alpha + \beta_1 (1 - \text{Lerner Index})_{i,t-1} \\ & + \beta_2 \text{Inst. Own\%}_{i,t-1} \times (1 - \text{Lerner Index})_{i,t-1} \\ & + \beta_3 \text{Inst. Own\%}_{i,t-1} + \beta_4 \text{Log(Asset)}_{i,t-1} + \beta_5 \text{Tobin's } Q_{i,t-1} \\ & + \beta_6 \text{RnD}_{i,t-1} + \beta_7 \text{Leverage}_{i,t-1} + \beta_8 \text{Tangibility}_{i,t-1} \\ & + \beta_9 \text{ROA}_{i,t-1} + \beta_{10} \text{HHI Index}_{i,t-1} + \beta_{11} \text{Log(FirmAge)}_{i,t-1} \\ & + \beta_{12} \text{Free Cash Flow}_{i,t-1} + \theta_{it} + \varphi_{it} + \varepsilon_{it} \end{aligned} \quad (2)$$

Our dependent variable is the total number of FDA approvals. Competition is measured by 1 – Lerner index (Aghion et al. (2013)) and is interacted with institutional holdings. We hypothesize that, when market competition is higher and institutional ownership is present, the number of FDA approvals a firm receives is higher.

Pharmaceutical firms can experience many extremes when going through the FDA approval process. For example, shares in Sage Therapeutics soared 70 percent on December 7th, 2017 after the company announced positive results in testing a major depressive disorder (MDD) treatment. However, news may not always be positive for pharmaceutical firms. Alkermes closed 22% down on April 3rd, 2018 after a market reaction prompted by the FDA Refusal to File letter relating to the New Drug Application (NDA) for a proposed depression treatment. In addition, recalls can also affect the share price of pharmaceutical firms. For example, in 2004, Merck announced the recall of the drug, Vioxx, which accounted for \$2.55 billion of company sales in 2003. Merck’s shares plunged at the opening bell on the New York Stock Exchange by 27%. Overall, these real examples suggest that innovation is a high risk, high award, or high failure process.

Next, we collect CEO turnover announcements from the Nexis Lexis database. CEO turnover is a binary variable equal to one if the CEO leaves the firm during year  $t$ , and zero otherwise. We interact institutional ownership and measure of profitability,  $\Delta ROA$ , to examine whether institutional ownership reduces CEO turnover (Aghion et al. (2013)). If institutional investors do alleviate the career concerns of a manager, we expect CEO turnover sensitivity

to be reduced.

$$\begin{aligned} CEO_{Turnover} = & \alpha + \beta_1 \Delta ROA_{i,t-1} + \beta_2 \text{Inst. Own\%}_{i,t-1} \times \Delta ROA_{i,t-1} \\ & + \beta_3 \text{Inst. Own\%}_{i,t-1} + \beta_4 \text{Log(Asset)}_{i,t-1} + \beta_5 \text{Tobin's } Q_{i,t-1} \\ & + \beta_6 \text{RnD}_{i,t-1} + \beta_7 \text{Leverage}_{i,t-1} + \beta_8 \text{Tangibility}_{i,t-1} + \beta_9 \text{ROA}_{i,t-1} \\ & + \beta_{10} \text{HHI Index}_{i,t-1} + \beta_{11} \text{Log(FirmAge)}_{i,t-1} \\ & + \beta_{12} \text{Free Cash Flow}_{i,t-1} + \theta_{it} + \varphi_{it} + \varepsilon_{it} \end{aligned} \quad (3)$$

$$\begin{aligned} CEO \text{ Cash (or Equity)} = & \alpha + \beta_1 \Delta \text{Wealth}_{i,t-1} \\ & + \beta_2 \text{Inst. Own\%}_{i,t-1} \times \Delta \text{Wealth}_{i,t-1} + \beta_3 \text{Inst. Own\%}_{i,t-1} \\ & + \beta_4 \text{Log(Asset)}_{i,t-1} + \beta_5 \text{Tobin's } Q_{i,t-1} + \beta_6 \text{RnD}_{i,t-1} \\ & + \beta_7 \text{Leverage}_{i,t-1} + \beta_8 \text{Tangibility}_{i,t-1} + \beta_9 \text{ROA}_{i,t-1} \\ & + \beta_{10} \text{HHI Index}_{i,t-1} + \beta_{11} \text{Log(FirmAge)}_{i,t-1} \\ & + \beta_{12} \text{Free Cash Flow}_{i,t-1} + \theta_{it} + \varphi_{it} + \varepsilon_{it} \end{aligned} \quad (4)$$

Our last insurance variable is the CEO pay-for-performance sensitivity of Hartzell and Starks (2003).  $\Delta CEO\_Cash$  is defined as the change in the level of cash and bonus compensation for CEO  $i$  in year  $t$ . We regress the change in CEO pay on the interaction of institutional ownership and  $\Delta \text{Wealth}$ . We calculate  $\Delta \text{Wealth}$  as the change in a firm’s market value between year  $t-1$  and  $t$ . We aim to capture the effect of institutional investors on CEO’s pay-for-performance sensitivity.

## 5. Empirical results

### 5.1. Institutional ownership and innovation output: monitoring effect

In Table 2, we conduct multivariate analysis of institutional investors and innovation performance. Our dependent variable is the total number of FDA approved patents. From column (1) to (3), we use the number of awarded patents in year  $t+1$ . We conduct OLS, Poisson regression, and negative binomial regression respectively. In column (4), we use the number of patents in year  $t+2$ . From column (5) to (7), we measure the relationship between different concentrations of institutional ownership and innovation performance. In column (8), we calculate the decline in institutional ownership as the yearly change in institutional holdings between year  $t$  and  $t+1$ , where positive values are replaced by zero. Similarly, in column (9), our dependent variable is the decline in the number of patents which is calculated as the change in the number of patents between year  $t$  and  $t+1$ , where positive values are replaced by zero.

Column (1) shows that institutional ownership is significantly positively associated with innovation and our results hold across distributional assumptions. Our results indicate that an increase in institutional ownership increases innovation output. These results are similar to the prior literature that highlights the supporting role of institutional investors in innovation. In column (4), we use approved patents as the dependent variable in time  $t+2$ . Consistent with expectations, we document that a greater amount of institutional ownership leads to a higher number of approved patents. In columns (5)–(7), we document that a different concentration of institutional ownership has a positive effect on firm innovation. We show that a decline in institutional ownership between two consecutive years has a negative effect on the innovation outcome in column (8). In the same manner, we document that the decline in institutional ownership moves in the same direction with the

**Table 2**  
Institutional Ownership and Total FDA Approvals.

Panel A.										
Dependent Variable										
Sample	Ln(TotalApproval) <sub>t+1</sub>			Ln(TotalApproval) <sub>t+2</sub>	Ln(TotalApproval) <sub>t+1</sub>				Decline in Approvals	
	OLS (1)	Poisson (2)	Neg. Binominal (3)	OLS (4)	OLS (5)	OLS (6)	OLS (7)	OLS (8)	OLS (9)	
Inst. Own%	0.174 [0.001]***	0.188 [0.001]***	0.473 [0.001]***	0.015 [0.001]***						
Top 5 Own					0.021 [0.001]***					
Top 10 Own						0.287 [0.023]**				
Top Block Hold.							0.011 [0.001]***			
Decline in Ins. Own%								0.805 [0.001]***	0.039 [0.001]***	
Log(Asset)	0.075 [0.001]***	0.126 [0.001]***	0.246 [0.001]***	0.059 [0.001]***	0.244 [0.001]***	0.164 [0.001]***	0.170 [0.001]***	0.224 [0.001]***	0.018 [0.001]***	
Tobin's Q	0.001 [0.181]	0.001 [0.083]*	0.003 [0.054]*	0.003 [0.090]*	0.003 [0.043]**	0.002 [0.057]*	0.002 [0.052]*	0.011 [0.001]***	-0.001 [0.072]8	
RnD	0.006 [0.580]	0.010 [0.392]	-0.021 [0.526]	0.073 [0.026]*	-0.031 [0.367]	-0.066 [0.040]**	-0.064 [0.047]**	-0.033 [0.463]	0.020 [0.050]**	
Book Leverage	-0.004 [0.299]	-0.003 [0.155]	-0.006 [0.167]	0.002 [0.745]	-0.004 [0.259]	-0.004 [0.268]	-0.004 [0.264]	-0.011 [0.292]	0.001 [0.783]	
Tangibility	0.214 [0.112]	0.184 [0.115]	-0.014 [0.945]	-0.063 [0.566]	-0.016 [0.935]	0.070 [0.709]	0.052 [0.782]	0.008 [0.970]	-0.004 [0.926]	
ROA	0.004 [0.189]	-0.002 [0.036]**	-0.007 [0.001]***	-0.001 [0.952]	-0.008 [0.001]***	-0.007 [0.001]***	-0.007 [0.001]***	0.008 [0.708]	0.004 [0.322]	
HHI Index	-0.112 [0.001]***	-0.880 [0.001]***	-2.621 [0.001]***	-0.062 [0.001]***	-2.561 [0.001]***	-2.341 [0.001]***	-2.359 [0.001]***	-2.578 [0.001]***	0.258 [0.001]***	
Log(Firm Age)	0.134 [0.001]***	0.225 [0.001]***	0.264 [0.001]***	0.170 [0.001]***	0.269 [0.001]***	0.214 [0.001]***	0.223 [0.001]***	0.308 [0.001]***	-0.025 [0.001]***	
Free Cash Flow	-0.009 [0.179]	-0.006 [0.120]	-0.026 [0.013]**	0.025 [0.183]	-0.030 [0.001]***	-0.025 [0.001]***	-0.026 [0.001]***	-0.032 [0.001]***	-0.005 [0.334]	
Year/Firm Fixed Effect	YES	NO	NO	YES	YES	YES	YES	YES	YES	
N	6,329	6,329	6,329	6,329	6,329	6,329	6,329	6,329	5,317	
R <sup>2</sup>	20%	26%	28%	21%	23%	24%	23%	25%	16%	

Panel B. Institutional Ownership and Citation

Dependent Variable				
Sample	Number of Cites <sub>t+1</sub> (1)	Citation-Weighted Value <sub>t+1</sub> (2)	Number of Cites <sub>t+1</sub> (1)	Citation-Weighted Value <sub>t+1</sub> (2)
Inst. Own%	1.245 [0.001]***	2.011 [0.001]***	1.088 [0.001]***	0.981 [0.001]***
Log(Asset)	1.067 [0.001]***	1.899 [0.001]***	1.334 [0.001]***	1.309 [0.001]***
Tobin's Q	0.001 [0.611]	0.001 [0.617]	0.002 [0.312]	0.001 [0.356]
RnD	0.008 [0.774]	0.221 [0.733]	0.445 [0.599]	0.988 [0.587]
Book Leverage	0.001 [0.733]	0.002 [0.498]	0.001 [0.733]	0.001 [0.498]
Tangibility	-0.066 [0.190]	-0.617 [0.078]*	-0.389 [0.698]	-0.367 [0.509]
ROA	0.778 [0.001]***	0.078 [0.001]***	0.889 [0.045]**	0.590 [0.067]*
HHI Index	5.285 [0.052]*	4.216 [0.033]**	2.112 [0.001]***	2.198 [0.001]***
Log(Firm Age)	3.084 [0.001]***	3.121 [0.001]***	0.043 [0.001]***	0.031 [0.001]***
Free Cash Flow	-0.019 [0.031]**	-0.023 [0.044]**	0.019 [0.556]	0.023 [0.567]
Year/Firm Fixed Effect	YES	YES	YES	YES
N	6,329	6,329	3063	3063
R <sup>2</sup>	4%	4%	3%	2%

Table 2 (Continued)

Panel C. Institutional Ownership Types and Employee Lawsuits								
Dependent Variable								
Sample	Ln(TotalApproval) <sub>t+1</sub>							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Mutual Funds	0.556 [0.021]**					0.033 [0.044]**		
Investment		-0.511 [0.899]				0.799 [0.403]		
Banks			0.900 [0.599]			-0.553 [0.788]		
Pension				0.883 [0.001]***		0.455 [0.073]*		
Insurance					-0.003 [0.781]	-0.290 [0.677]		
Long Term							0.442 [0.039]**	
Short Term								0.033 [0.132]
CONTROLS	YES	YES	YES	YES	YES	YES	YES	YES
Year/Industry48	YES	YES	YES	YES	YES	YES	YES	YES
N	6,329	6,329	6,329	6,329	6,329	6,329	6,329	6,329
R <sup>2</sup>	4%	3%	3%	4%	4%	6%	5%	4%

Table 2 Shows the impact of institutional ownership on innovation output in the pharmaceutical industry using Poisson, negative binomial, and OLS regression. In Panel A, from column (1) to (8), our dependent variable is log transformation of total FDA approvals. In column (9), our dependent variable is decline in approvals, where we calculate the change in approvals between year t and t-1, then replace positive values with zero. In Panel B, we use number of cites and citation weighted values as dependent variables. In Panel C, we measure the relationship between institutional ownership and FDA approvals for different types of holders. Standard errors are clustered at the firm level. We run firm and year fixed effects but omit the coefficients. P-values are presented in brackets represents \* <0.10, \*\* <0.05, \*\*\* <0.0, significance levels.

decline in innovation performance in column (9). Each regression includes firm-year fixed effects which suggest that our baseline finding is not driven by time-invariant, unobservable firm characteristics. Our control variables, (Log(Asset)) and (Log(Age)), are positive and significant, which indicates that larger and older firms are also positively associated with firm innovation.

A simple count of approved FDA products (patents, drugs, or medical devices) may fail to identify remarkable innovations from supplementary medical discoveries. Following the innovation literature, we employ two additional measures of innovation activity; total citations and citation-weighted patent counts. Previous literature indicates that citation-weighted patents are a more meaningful measure of innovation quality (Hall, Jaffe, and Trajtenberg (2000)).

Table 2, Panel B, column (1), the number of cites refers to the log transformation of one plus the total number of citations received on all firm patents filed in a given year. And in column (2), we use “citation-weighted value” as the dependent variable. In column (1), the coefficient of the percentage of institutional holdings is positive and significant. Holding all other things constant, an increase in the proportion of institutional ownership in pharmaceutical firms yields a greater number of patent citations. Consistent with expectations, the same relationship holds when we use citation-weighted value in column (2). In columns (3) and (4), we only investigate firms who have received one or more FDA product approvals. This subsampling causes our number of observations to be reduced to 3063. Our results, however, remain similar; we find a positive and significant relationship between institutional ownership and FDA approvals. Overall, findings from Panel B of Table 2 suggest that large institutional investors enhance firm innovation.

The ability and features of investors can vary across institutions. Rong et al. (2017) find that different types of institutional investors, such as mutual funds, have a greater influence on innovation outcomes. Almazan, Hartzell, and Starks (2005), and Chen, Harford, and Kai (2007) divide institutions into two distinct categories. Independent institutions, which include mutual fund managers or investment advisers, and grey institutions, which include bank trusts or insurance companies. To strengthen our

monitoring hypothesis, we also divide institutional investors into their respective categories: mutual funds, investments, banks, pensions, or insurance. Our findings in columns (1) to (6), Panel C of Table 2 show that mutual funds and pension funds are positively and significantly related to total FDA approvals. This is consistent with Barabanov, Ozocak, Turtle, and Walker (2008), who find that mutual funds and pension funds have a greater monitoring ability.

In addition, Gaspar, Massa, and Matos (2005) highlight the differing motivation between short-term and long-term institutional investors. We consider institutional investors' horizon based on the duration of their holdings (Gaspar et al. (2005); Luong et al. (2017)). We calculate investor duration as the sum of shares owned by all institutions that hold the stock for more than one year, as a percentage of the firm's total number of shares outstanding. In a similar manner, we compute short-term holdings as the sum of shares owned by all institutions that hold the stock for less than one year, as a percentage of the firm's total number of shares outstanding. Our results indicate a significant positive benefit to innovation from longer-term investors. Overall, the results from Panel C, Table 2 document further evidence regarding how institutional investors enhance firms' innovation.

### 5.2. Institutional ownership and innovation output: other medical discoveries

Our findings suggest a positive relationship between institutional ownership and firm innovation. Next, we examine the possible channels institutional ownership employs to incentivize innovation. We then attempt to address the identification strategies and endogeneity concerns by employing different tests. In Table 3, we test how institutional ownership can enhance other types of medical discoveries.

In Table 3, we break down pharmaceutical firms' innovation outcomes in categories. We use the log transformation of the total number of approved medical devices, the log transformation of the total number of drug approvals, and the log transformation of the total number of pre-market approvals as the dependent variable, respectively. We regress each medical innovation output on the percentage of institutional ownership and interpret our findings.

**Table 3**  
Institutional Ownership and FDA Approved Medical Products.

Dependent Variable			
Sample	Ln(MedicalDeviceApp.) <sub>t+1</sub> (1)	Ln(FDA DrugApp.) <sub>t+1</sub> (2)	Ln(PreMarketApp.) <sub>t+1</sub> (3)
Inst. Own%	0.063 [0.001]***	0.093 [0.001]***	0.028 [0.001]***
Log(Asset)	0.040 [0.001]***	0.036 [0.001]***	0.023 [0.001]***
Tobin's Q	0.001 [0.632]	0.001 [0.117]	0.001 [0.206]
RnD	0.008 [0.364]	-0.002 [0.802]	0.003 [0.641]
Book Leverage	-0.001 [0.354]	0.001 [0.712]	-0.011 [0.714]
Tangibility	-0.004 [0.971]	0.117 [0.100]	0.182 [0.010]**
ROA	0.004 [0.001]***	0.003 [0.001]***	0.002 [0.358]
HHI Index	0.285 [0.021]**	-0.216 [0.088]*	-0.047 [0.628]
Log(Firm Age)	0.084 [0.001]***	0.121 [0.001]***	0.184 [0.001]***
Free Cash Flow	-0.009 [0.038]**	-0.003 [0.346]	-0.002 [0.601]
Year/Firm Fixed Effect	YES	YES	YES
N	6,329	6,329	6,329
R <sup>2</sup>	5%	11%	12%

Table 3 Shows the impact of institutional ownership on medical innovation. Medical innovation is measured three different ways, as the log transformation of the number of medical devices applications, the number of FDA applications, and the number of pre-market applications. We run firm and year fixed effects but omit the coefficients. P-values are presented in brackets represents \* < 0.10, \*\* < 0.05, \*\*\* < 0.0, significance levels.

Table 3 documents a positive and significant relation between medical innovation and institutional ownership. In column (1), the coefficient of Ins. Own% is significantly positive at the one-percent level. Increased levels of institutional ownership increase the number of FDA-approved products a firm receives. Similarly, we find that higher levels of institutional ownership are associated with more FDA-approved drugs, as well as pre-market approvals from FDA. Table 3 suggests that institutional ownership can improve innovative activities of pharmaceutical firms in our sample.

### 5.3. Institutional ownership and innovation output: phase I – phase II – phase III drugs

In the next stage, we examine the medical innovation by examining a unique dataset of drugs during Phase I – Phase II – Phase III FDA process. Phase I trials refer to new drugs, treatments, or combinations of treatments deemed safe for human consumption. The length of Phase I can be several months to years. Approximately 70% of Phase I drugs move to the next phase. Phase II clinical trials focus on the safety and effectiveness of a new treatment. The focus of the Phase II drug trial is the drug's side effects. A study can take up to two years and approximately 33% of Phase II drugs move to the next phase. Lastly, Phase III clinical trials test successful phase II clinical trials. The purpose of the Phase III primary objective is the observation of effectiveness, as well as adverse reactions. The length of the study is between one to four years.

Measuring innovation by examining the pharmaceutical drug approval process is unique. We examine the impact of institutions on the different stages of clinical testing because firms may receive a positive market reaction if one drug moves to the next stage. Each stage adds or destroys firm value based on the outcome. For example, Alnylam pharma gained 32.7% in September after positive results from an important Phase III clinical trial.<sup>9</sup> In

contrast, Celgene lost 30% in value in October when their Phase III drug failed.<sup>10</sup>

Panel A of Table 4 documents the relationship between the success of Phase I – II – III drug trials and institutional ownership. In Panel A, we document that institutional ownership increases the number of clinical trials for Phase I – Phase II – Phase III drugs, respectively. We find that institutional ownership is positively related to the number of patents licensed by pharmaceutical firms. In summary, institutional holdings yield a greater number of patents licensed to other firms. In Panel B, we calculate the difference between the length of time associated with each clinical testing phase. We identify whether institutional investors guide innovation by reducing the time between the first and last stage of clinical examination. In column (1), our dependent variable is the difference between the number of Phase I drugs and number of Phase III drugs. We find that institutional ownership lowers the range of Phase III and Phase I drugs. The same relationship holds when we test the differences between Phase I and Phase II testing, as well as Phase II and Phase III, respectively. In the last column, we count the cumulative number of drugs under all phases. We find that higher institutional ownership leads to a greater number of medical discoveries under clinical testing. Finally, in Panel C, we conduct an ordered logistic model for better evaluation of the clinical testing process. The dependent variable is coded one, two, or three for Phase I, Phase II, or Phase III drugs, respectively. From columns (1) to (3), we report the marginal effect for each outcome. In column (1), all other things being constant, a one percent increase in institutional ownership means that pharmaceutical firms will be 1% more likely to have a drug under Phase I testing. In column (2), all other things remaining constant, an increase in institutional ownership will increase firms' chances of having a Phase II drug by 1.5%. In column (3), all other things remaining constant, an increase in institutional ownership will increase a firm's profitabil-

<sup>9</sup> <http://globalmacrodigest.com/alnylam-pharmaceuticals-rallied-32-7-september/>

<sup>10</sup> <https://www.fool.com/investing/2017/11/03/why-celgene-crashed-30-in-october-and-what-now.aspx>



**Table 4**  
Institutional Ownership and Phase I - II - III Drug Approvals.

Panel A. Phase I - II - III Approvals				
Dependent Variable				
Sample	Ln(PhaseI) <sub>t+1</sub> (1)	Ln(PhaseII) <sub>t+1</sub> (2)	Ln(PhaseIII) <sub>t+1</sub> (3)	Ln(LicensedPatent) <sub>t+1</sub> (4)
Inst. Own%	0.049 [0.001]***	0.063 [0.001]***	0.066 [0.001]***	0.035 [0.001]***
CONTROLS	YES	YES	YES	YES
Year/Firm Fixed Effect	YES	YES	YES	YES
N	6,329	6,329	6,329	6,329
R <sup>2</sup>	7%	7%	7%	8%
Panel B. Difference Between Drug Phases				
Dependent Variable				
Sample	Diff(PhaseI-PhaseIII) (1)	Diff(PhaseI-PhaseII) (2)	Diff(PhaseII-PhaseIII) (3)	Cumulative Phase (4)
Inst. Own%	-0.667 [0.001]***	-0.455 [0.001]***	-0.933 [0.001]***	0.380 [0.001]***
CONTROLS	YES	YES	YES	YES
Year/Firm Fixed Effect	YES	YES	YES	YES
N	3,063	3,063	3,063	6,329
R <sup>2</sup>	8%	8%	8%	7%
Panel C. Ordered Logistic				
Dependent Variable				
Sample	Phase I (1)	Phase II (2)	Phase III (3)	Phase (4)
Inst. Own%	0.010 [0.001]***	0.015 [0.001]***	0.035 [0.001]***	0.750 [0.001]***
CONTROLS	YES	YES	YES	YES
Year/Firm Fixed Effect	YES	YES	YES	YES
N	6,329	6,329	6,329	6,329
R <sup>2</sup>	8%	8%	8%	7%

Table 4 Shows the impact of institutional ownership on medical innovation for different stages of drugs. In Panel A, our dependent variable is log transformation of different stages of drug approvals. In Panel B, we calculate the difference between two different phases of drugs. In Panel C, we run ordered logistic regression for different drug levels. For the brevity of our results, we only report the variable of interest. We run firm and year fixed effects but omit the coefficients. P-values are presented in brackets represents \* < 0.10, \*\* < 0.05, \*\*\* < 0.0, significance levels.

ity by 3.5%. In column (4), we run ordered logit for all groups. All other things being constant, with a greater share of institutional ownership, pharmaceutical firms are more likely to be in higher phases of clinical testing. For a one percent increase in institutional ownership, we would expect a 0.750 increase in the log odds of being in a higher level of drug phases, given that all of the other variables in the model are held constant. Our results from Table 4 have significant implications. First, we show that institutional ownership increases the number of drugs under all phases of clinical testing. Then, we document that the distance between basic testing (Phase I) and advanced testing (Phase III) is lower when the percentage of institutional ownership is higher. Finally, we report that firms with a greater share of institutional ownership are more likely to be in higher levels of clinical testing (i.e., Phase III).

#### 5.4. Institutional ownership and innovation output: approval duration

Institutional investors are associated with strong monitoring power (Aghion et al. (2013)), thus helping firms increase their innovation performance. In our study, we document that pharmaceutical firms obtain more FDA approvals (i.e., patents, medical devices) with better medical testing quality (i.e., Phase III drugs). However, the distinct channel by which institutional investors influence pharmaceutical innovation outcome have not been documented in previous studies. We fill this gap by examining the “filing-to-approval” dates of medical products with the FDA. We investigate whether product approval times are shorter for pharmaceutical firms with higher institutional holding levels. First, we calculate the approval date for patents by taking the difference of approval date minus the filing date (measured in “days”) for 3202

unique drug patents. We also identify the approval dates for 5445 unique pre-market approvals and 7099 unique medical devices. We run our regressions at the drug-year level because each medical discovery has a distinct time-to-approval.

In Table 5, we measure how institutional investors increase innovation quality by examining the approval times of submitted products in FDA. We report the results of both OLS regression and survival analysis. In column (1) and (2), we employ patent approval duration as a dependent variable. We find a positive and significant coefficient for institutional investors, suggesting that pharmaceutical firms with higher institutional ownership have shorter approval duration. In column (2), OLS regression finds that firms with a greater percentage of institutional ownership terminate the approval process faster. In columns (3) and (4), we conduct the same survival analysis and OLS method for pre-market approvals. Consistent with expectations, the survival model in column (3) suggests that institutional ownership is associated with faster approval duration for pre-market approved products. In column (4) we run the OLS model: all other things remaining constant, larger institutional ownership significantly lowers the number of days for pre-market approvals. We perform both survival analysis and OLS for medical device approval days in column (5) and column (6). We document that pharmaceutical firms with a greater share of institutional ownership experience faster approval duration for their medical devices.

#### 5.5. Institutional ownership and innovation output: firm size

In this section, we run different tests to eliminate concerns about pharmaceuticals’ firm size effects on the innovation outcome. For large pharmaceutical firms, patents can be acquired through

**Table 5**  
Institutional Ownership and Survival Analysis : Approval Duration.

Dependent Variable	Survival Patent Approval		Survival Pre-Market Approval		Survival Medical Device Approval	
	Duration (1)	OLS Duration (2)	Duration (3)	OLS Duration (4)	Duration (5)	OLS Duration (6)
Inst. Own%	0.045 [0.019]**	−0.413 [0.001]***	0.334 [0.033]**	−0.162 [0.001]***	0.188 [0.021]**	−0.353 [0.001]***
CONTROLS	YES	YES	YES	YES	YES	YES
N	3,202	3,202	5,554	5,554	7,099	7,099
R <sup>2</sup>		22%		15%		6%

Table 5 Shows the impact of institutional ownership on medical innovation duration of approval. We calculate the duration of approval by taking the difference between product approval date minus product submission date. We run survival analysis in column (1), (3), (5), and report the marginal effects from Cox regression. In column (2), (4), and (6), our dependent variable is log transformation of number of days to approval. For the brevity of our results, we only report the variable of interest. We run firm and year fixed effects but omit the coefficients. P-values are presented in brackets represents \* <0.10, \*\* <0.05, \*\*\* <0.0, significance levels.

M&A; for small pharmaceutical firms, R&D may be the only way to produce patents. The effect of M&As on innovation in the pharmaceutical industry has been investigated in prior studies. For example, Comanor and Scherer (2011) discuss the effect of the recent merger wave among the largest pharmaceutical companies on the rate of innovation for policy makers. Ornaghi (2009) documents that merged firms have, on average, worse performance than the group of non-merging firms. Richman, Mitchell, Vidal, and Schulman (2016) discuss whether mergers change the concentration in the industry, thus leading to fewer discoveries. On the other hand, Haucap and Stiebale (2016) examine European pharmaceutical firms. They find that, following a merger, firms suffer a decline in both patenting and R&D as compared to their non-merging rivals. In addition, Vyas and Narayanan (2016) examine the mergers in pharmaceuticals in India. The authors find that acquisitions appear to have a negative impact on R&D intensity. Jarvis (2010) finds that big pharmaceutical companies try to supplement decreasing revenues by acquiring competitors with promising innovation. Koenig and Mezick (2004) show that pharmaceutical companies that engaged in M&A activity achieved more favorable post-merger R&D productivity scores than before. We extend this research by studying corporate governance factors that affect pharmaceutical innovation (e.g., institutional ownership). In Panel A–B–C of Table 6, we run six different regressions based on firm size. We introduce three different firm size measures as a) total assets, b) market capitalization, and c) total sales. We divide our sample based on median values, such as whether a firm has lower than median total assets vs. higher than median total assets etc.

Our results document the positive effect of institutional ownership on FDA approval, regardless of the sample. The influence of institutional ownership on innovation is, however, more pronounced for smaller firms. We report slightly larger coefficients on firms that are below the median value. We interpret these results as small firms being “forced” to innovate and, furthermore, allocate their capital more wisely across their investments. Similar to our results, Hicks and Hegde (2005) support strong incentives for small innovative firms to actively patent their inventions and become specialist suppliers of intermediate technological inputs. So (2015) finds that small firms may be, indeed, the most effective way to induce innovation in certain disease treatments and Baldwin (1995) supports innovation as a key to success in small firms. Sahut and Peris-Ortiz (2014) discuss that small businesses provide a better environment for entrepreneurship and innovation. Ibdunni, Iyiola, and Ibdunni (2014) also document that there is a significant relationship between product innovation and the survival of small and medium enterprises. Moreover, Ortega-Argilés and Moreno (2007) find that product differentiation and innovation are important to explain small firms’ survival. Overall, our results from Panel A, B, and C of Table 6 document that institutional owner-

ship positively affects the total number of FDA approved products and the effects are not driven by firm size.

### 5.6. Institutional ownership and innovation output: innovation quality

Our study documents the relationship between institutional investors and pharmaceutical firm innovation. Our results, however, have not described the quality of a firm’s innovation. We perform additional tests to confirm the “quality” of innovation. We define innovation quality as a firm’s ability to generate successful innovation that increases firm value. We introduce several variables to capture innovation quality. Our first variable used to measure product quality is product and market withdrawals. We hand-collect a unique FDA drug, medical device recalls, and market withdrawals between 2000 and 2014. Product recalls only happen to an innovation which is deemed unsafe or ineffective. If institutional ownership increases innovation quality, a firm’s products should have a lower chance of malfunctioning. The second quality variable is post-market drugs and biologic safety evaluations. We use safety evaluation data to examine if a firm’s FDA-approved products fail to meet safety evaluations after approvals. Finally, we use the Public Access to Court Electronic Records (PACER) database and hand-collect patent lawsuits. We examine the likelihood of the firm being involved in patent infringements litigation.

For brevity, we only report the variable of interest. In Panel D, we employ a unique FDA product recall database. Most pharmaceutical firms recall a product after the FDA raises serious concerns. Human drugs, animal drugs, medical devices, vaccines, blood and blood products, and transplantable human tissue are subjected to recalls by FDA. Products that are forced to be withdrawn from the market are not signals of innovation quality. Panel D documents that institutional ownership not only lowers the number of FDA recalls but also the likelihood of FDA recalls. In Panel E, we use post-market safety evaluations data to examine if pharmaceutical firms are involved in a safety-related violation. FDA standards have increased and new product safety rules have been implemented, causing the likelihood of a product safety evaluation to increase. We find that institutions are associated with a lower number of safety violations. Lastly, Panel F examines whether pharmaceutical firms are involved in patent lawsuits (either as defendant or plaintiff). We show that a greater percentage of institutional ownership lowers the total number of patent infringements filed for pharmaceutical firms. Similarly, institutional ownership also lowers the likelihood of facing patent lawsuits in our sample firms. Overall, Table 6 documents that institutional ownership not only increases the number of FDA-approved products, but also leads to greater product quality, measured as a reduction in market recalls, safety evaluations, and lawsuits.

**Table 6**  
Institutional Ownership and Innovation Quality.

Panel A. Total Asset		
Dependent Variable		
Sample	Ln(TotalApproval) <sub>t+1</sub>	
	(1)	(2)
Inst. Own%	0.799 [0.001]***	0.211 [0.001]***
CONTROLS	YES	YES
Year/Firm Fixed Effect	YES	YES
N	3,200	3,129
R <sup>2</sup>	5%	5%
Panel B. Market Capitalization		
Dependent Variable		
Sample	Ln(TotalApproval) <sub>t+1</sub>	
	(1)	(2)
Inst. Own%	0.911 [0.001]***	0.312 [0.032]**
CONTROLS	YES	YES
Year/Firm Fixed Effect	YES	YES
N	3,215	3,114
R <sup>2</sup>	6%	7%
Panel C. Total Sale		
Dependent Variable		
Sample	Ln(TotalApproval) <sub>t+1</sub>	
	(1)	(2)
Inst. Own%	0.599 [0.012]**	0.011 [0.076]*
CONTROLS	YES	YES
Year/Firm Fixed Effect	YES	YES
N	3,098	3,231
R <sup>2</sup>	7%	7%
Panel D. Product Recalls		
Dependent Variable		
Sample	Ln(TotalRecall)	Prob = Recall
	(1)	(2)
Inst. Own%	-0.057 [0.001]***	-0.904 [0.001]***
CONTROLS	YES	YES
Year/Firm Fixed Effect	YES	YES
N	6,329	6,329
R <sup>2</sup>	5%	3%
Panel E. Post Market Safety Evaluations		
Dependent Variable		
Sample	Ln(PostMarketEval)	Prob = PostMarketEval
	(1)	(2)
Inst. Own%	-0.079 [0.022]**	-0.285 [0.056]*
CONTROLS	YES	YES
Year/Firm Fixed Effect	YES	YES
N	6,329	6,329
R <sup>2</sup>	4%	4%
Panel F. Patent Lawsuit		
Dependent Variable		
Sample	Ln(TotalLawsuit)	Prob = Lawsuit
	(1)	(2)
Inst. Own%	-0.057 [0.033]**	-0.318 [0.015]**
CONTROLS	YES	YES
Year/Firm Fixed Effect	YES	YES
N	6,329	6,329
R <sup>2</sup>	8%	6%

In Table 6, we test the relationship between institutional ownership and FDA approvals based on median values of total assets, market capitalization, and total sale in Panel A, Panel B, and Panel C, respectively. In Panel D, use product recall as dependent variable. In Panel E, we use post market safety evaluations for dependent variable. And in Panel F, we use patent lawsuits as dependent variable. For the brevity of our results, we only report the variable of interest. We run firm and year fixed effects but omit the coefficients. P-values are presented in brackets represents \* < 0.10, \*\* < 0.05, \*\*\* < 0.0, significance levels.

### 5.7. Institutional ownership and insurance effect: alternative explanations

Manso (2011) argues that innovation is a long and tedious process with high risk involved (success or failure) and additional tolerance for failure may promote innovation. If the environment is not “failure tolerant”, it may discourage managers or employees from innovating or taking part in high-risk projects with a greater risk of failure. Incentives that are less sensitive to performance may motivate managers. For example, Aghion et al. (2013) find that institutional investors can provide partial insurance to executives with career concerns due to the high risk of failure from innovative activities. The authors show that CEO turnover is less sensitive to firm performance when the presence of institutional investors is high. Similarly, Luong et al. (2017) document that if firms have a greater share of institutional ownership, the sensitivity of managerial turnover and CEO compensation to firm performance are weakened.

Institutional investors may allow executives to focus on risky and long-term innovation projects and eliminate some of their career and reputational concerns. Based on these findings, we also test if institutional investors stimulate innovation output by eliminating managerial punishment for innovation failures. We expect that executive turnover and compensation should be less sensitive to firm performance in the presence of high institutional investors. We collect CEO turnover data from the Lexis Nexis database between 2000 and 2014 and CEO compensation data from S&P Capital IQ for S&P500 firms. The resulting matched sample contains 2448 firm-year observations. To test the effect of institutional investors on the executive turnover-performance sensitivity, we follow Aghion et al. (2013) and Luong et al. (2017). We perform a logit model where the dependent variable is CEO turnover, and is equal to one if the CEO leaves the firm *i* during year *t*; zero otherwise. To examine the effect of institutional ownership on pay-for-performance sensitivity, we follow Hartzell and Starks (2003). Our dependent variable is ΔCEO Cash which refers to the change in the level of cash and bonus compensation.

Table 7 exhibits how institutional ownership influences the CEO's career concerns and pay-for-performance sensitivity. We follow Aghion et al. (2013) and Ward et al. (2017) to test if managers career concerns are related to the innovation process. In column (1) of Table 7, we observe that higher ROA growth is associated with a lower probability that the CEO will be replaced. In column (2), we find that interaction term of Inst. Own% × Δ(ROA) is positive and significant which suggests that the adverse effect of performance on CEO turnover is mitigated by institutional ownership. Our results suggest CEO performance–turnover sensitivity is lower when institutional ownership is present in pharmaceutical firms. In column (3), (4), and (5), we test pay-for-performance for CEOs in our sample. First, we find that changes in shareholder wealth are positively related to changes in CEO compensation. In column (4) and (5), the coefficient estimate for the interaction term, Inst. Own.% × Δ(Wealth) is negative and significant, suggesting that greater institutional ownership weakens the CEO's pay-for-performance sensitivity (Luong et al. (2017)). Overall, the results of column (1) - (5) show that institutional ownership enhances innovation by lowering the career concerns of managers following unsuccessful innovation (Ederer and Manso (2013); Luong et al. (2017)).

In Panel B, we follow Aghion et al. (2013) and measure how competition can affect innovation among pharmaceutical firms. Competition is measured by 1 – Lerner index (Aghion et al. (2013) and is interacted with institutional holdings. We hypothesize that when market competition is higher and institutional ownership is present, the number of FDA approvals a firm receives is higher. Consistent with Aghion et al. (2013) and Ward et al. (2017), competition

**Table 7**  
Economic Mechanism, Insurance Effect and Career Concerns.

Panel A.					
Dependent Variable					
Sample	CEO Turnover (1)	CEO Turnover (2)	$\Delta$ CEO.Cash (3)	$\Delta$ CEO.Cash (4)	$\Delta$ CEO.Equity (5)
$\Delta(\text{ROA})_{t-1}$	-0.445 [0.001]***	-0.332 [0.001]***			
Inst. Own% x $\Delta(\text{ROA})_{t-1}$		0.445 [0.033]**			
Inst. Own%		-0.667 [0.998]		0.121 [0.318]	0.101 [0.388]
$\Delta(\text{Wealth})_{t-1}$			0.378 [0.039]**	0.712 [0.013]**	0.788 [0.039]**
Inst. Own% x $\Delta(\text{Wealth})_{t-1}$				-0.667 [0.031]**	-0.220 [0.011]**
CONTROLS	YES	YES	YES	YES	YES
Year Fixed Effect	YES	YES	YES	YES	YES
N	2,448	2,448	2,448	2,448	2,448
R <sup>2</sup>	10%	12%	10%	12%	11%

Panel B.				
Dependent Variable				
Sample	Ln(TotalApproval) <sub>t+1</sub>		High Competition (3)	Low Competition (4)
	(1)	(2)		
Lerner Index <sub>t-1</sub>	0.022 [0.001]***		0.127 [0.012]**	0.887 [0.339]
Inst. Own% x Lerner Index <sub>t-1</sub>	0.339 [0.045]**	0.012 [0.057]*		
Inst. Own%	0.441 [0.089]*		0.551 [0.033]**	0.012 [0.044]**
CONTROLS	YES	YES		
Year Fixed Effect	YES	YES		
N	6,329	6,329	3,002	3,327
R <sup>2</sup>	12%	11%	10%	10%

In [Table 7](#), we test the relationship between institutional ownership, executive career concerns, and FDA In Panel A, we employ CEO turnover, and CEO pay indicators as dependent variable. In Panel B, our dependent variable is log transformation of total FDA approvals. For the brevity of our results, we only report the variable of interest. We run firm and year fixed effects but omit the coefficients. P-values are presented in brackets represents \* < 0.10, \*\* < 0.05, \*\*\* < 0.0, significance levels.

(Lerner index) has a positive association with total FDA approvals, while the coefficient of institutional ownership also remains positive and significant. In column 3 and column 4, we split our sample based on the median values of the Lerner index ([Aghion et al. \(2013\)](#)). We find that the coefficient of institutional ownership is large, positive, and significant in the high competition sample compared to the low competition sample. Our results show that, in a more competitive environment, institutional investors affect the behavior of managers, where we observe a positive relationship between the interaction of institutions and market competition. The results of [Table 7](#) emphasize the ability of institutional investors to alleviate managers' career and reputation concerns, thus encouraging long-term investments in innovative medical projects.

### 5.8. Institutional ownership and innovation: endogeneity concerns

The evidence in our study supports our research hypothesis; however, the relationship between institutional holdings and medical innovation could be endogenously determined. One significant concern is reverse causality; the possibility that firms with higher medical innovation attract more institutional investors. A positive association between institutional ownership and pharmaceutical firm innovation does not necessarily imply that the percentage share of institutional investors increases firm innovation performance ([Luong et al. \(2017\)](#)). We address this concern by employing two separate approaches. First, we use instrumental variable (IV) to estimate exogenous variations in institutional ownership ([Bena](#)

[et al. \(2014\)](#)). Second, we use firms' internal instruments and GMM estimation ([Rong et al. \(2017\)](#)).

For our first instrument, we follow [Aghion et al. \(2013\)](#), who regress institutional ownership on a firm's inclusion in the S&P 500. We carefully identify relevance and exclusion criteria of instrument selection. [Aghion et al. \(2013\)](#) suggest that fund managers are benchmarked against S&P 500 index, which increases institutional ownership. As an additional test, we follow [Chi et al. \(2015\)](#) and calculate alpha, beta, and turnover. Alpha is defined as the excess return on individual stock relative to the market index. Beta is the beta coefficient for an individual stock and turnover is the annual trading volume of an individual stock, normalized by the total shares outstanding.

[Table 8](#) shows the IV estimation results. In column (1), we regress the percentage of institutional holdings on inclusion in the S&P 500 index. In the second stage of column (2), we use predicted institutional ownership and document a positive and significant coefficient. All other things being equal, a greater presence of institutional investors is positively associated with increased innovation outcomes. Our finding is consistent with [Aghion et al. \(2013\)](#). To support the validity of our instrument, we investigate changes in institutional ownership and patents around the time a stock is added to S&P 500 index. Using a ten-year window, we show that a large increase in institutional ownership is documented after a firm is included in S&P 500 in [Fig. 1](#), Panel A. In Panel B of [Fig. 1](#), we document that the number of cumulative, normalized citations increases after the firm is listed in S&P 500.



**Table 8**  
Institutional Ownership and Total FDA Approvals.

Panel A.					
Dependent Variable					
Sample	1st Stage Inst. Own% (1)	2nd Stage Ln(TotalApproval) (2)	1st Stage Inst. Own% (3)	2nd Stage Ln(TotalApproval) (4)	GMM Ln(TotalApproval) (5)
Inst. Own%					0.013 [0.029]**
Predicted Inst. Own%		0.667 [0.034]**		0.339 [0.029]**	
S&P500	2.445 [0.001]***				
Alpha			3.221 [0.001]***		
Beta			-0.331 [0.001]***		
Turnover			-0.001 [0.059]*		
F-test of instruments	25.670		30.903		
P-Value	0.000***		0.000***		
Anderson-Rubin Chi-Square		34.881		16.554	
P-Value		0.000***		0.000***	
P-value for AR(2) Test					0.57
P-value for Hansen Test					0.44
CONTROLS	YES	YES	YES	YES	YES
Year Fixed Effect	YES	YES	YES	YES	YES
N	6,329	6,329	6,329	6,329	5,011
R <sup>2</sup>	21%	16%	17%	11%	11%
Panel B.					
Dependent Variable					
Sample	Heckman Ln(TotalApproval) (1)	Diff-in-Diff Ln(TotalApproval) (2)	Propensity Ln(TotalApproval) (3)	Windsorize Ln(TotalApproval) (4)	
Inst. Own%	0.556 [0.032]**	0.322 [0.091]*	0.775 [0.045]**	0.168 [0.012]**	
Inst. Own%*Post Years		0.557 [0.001]***			
Post Years		0.005 [0.334]			
Mills Ratio	0.108 [0.129]				
CONTROLS	YES	YES	YES	YES	YES
Year Fixed Effect	YES	YES	YES	YES	YES
N	6,329	6,329	1,154	577	
R <sup>2</sup>	21%	16%	8%	15%	

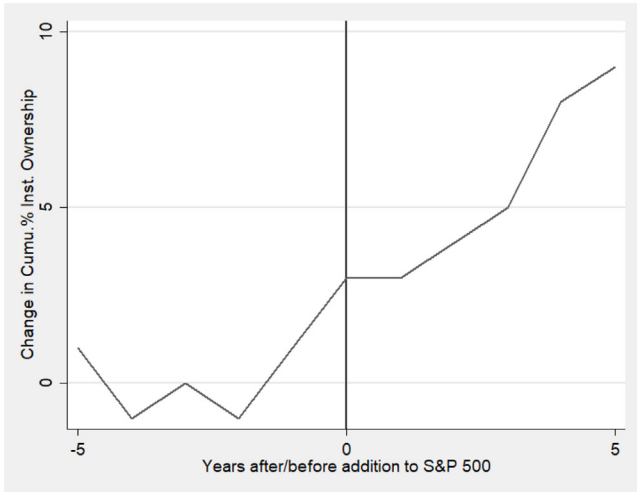
In Table 8, we perform two stage IV estimation where dependent variable is institutional ownership in the first stage. In the second stage, we use predicted institutional ownership as explanatory variables. In Panel B, we run further robustness tests by employing different samples and qualifications. For the brevity of our results, we only report the variable of interest. We run firm-year fixed effects but omit the coefficients. P-values are presented in brackets represents \* <0.10, \*\* <0.05, \*\*\* <0.0, significance levels.

Although our statistical results ensure that the S&P 500 meets the relevance criteria, we cannot directly observe the exclusion criteria of the instrument. It is still possible that some unobservable factors may affect both institutional ownership and innovation outcome.

In column (3), we use alpha, beta, and turnover to predict institutional ownership. The first stage instruments are significantly related to institutional holdings. In column (4), predicted institutional ownership is positively and significantly associated with medical innovation outcomes. This finding is consistent with Chi et al. (2015). Finally, in column (5), we estimate the difference GMM model. We employ  $\Delta \text{Inst.Own}\%_{i,t-3}$  as well as its further lags as the instruments for  $\Delta \text{Inst.Own}\%_{i,t-1}$ . We test for second-order serial correlation in  $\Delta \varepsilon_{i,t}$  using AR(2), where the null hypothesis is no serial correlation. Our AR(2) results show no significant second-order autocorrelation. Our GMM test is assumed to be well specified. The results indicate that institutional ownership increases the number of patents granted to pharmaceutical firms in our sample.

In Panel B of Table 8, we perform additional tests for endogeneity concerns. In column (1), we conduct the Heckman two-stage model. Some firms may not apply for any patents or seek any approval from FDA. To control for the decision to apply for patents, the first stage has a binary variable of zero and one (one if the firm has any patents or approvals) as a dependent variable. Then the impact of institutional ownership on the number of patents is determined in the second stage. We report the results from second stage regression with the Mills Ratio. Our results document the positive relationship between institutional investors and innovation. IV and GMM may not eliminate all endogeneity concerns. In column (2), we employ the difference-in-difference approach using inclusion in the S&P500 as an exogenous event. Post-years is equal to one following the firm's inclusion in the S&P500. The interaction term of institutional ownership and post-years indicates that firms experience a positive innovation outcome after being listed in the S&P500. In column (3), we conduct propensity matching based on size (total-asset) and book-to-market. We match each FDA-approved firm with a non-FDA approved firm and

a. Effect of Being Added to the S&P 500



b. Effect of Being Added to the S&P 500

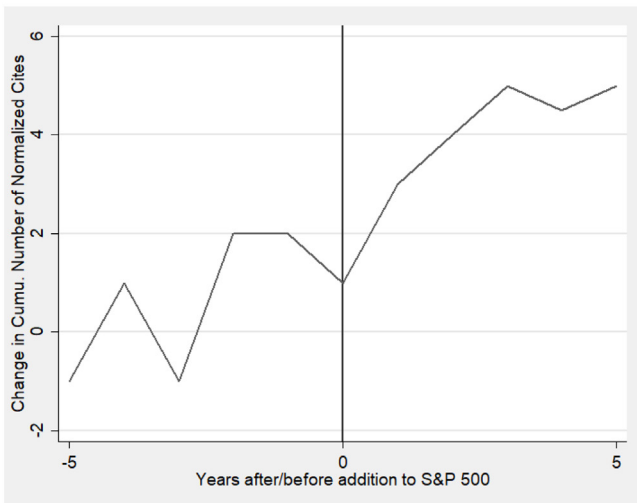


Fig. 1. (a) Effect of Being Added to the S&P 500. (b) Effect of Being Added to the S&P 500.

report the baseline regressions. Institutional ownership continues to play a positive and significant role in the firms' innovation process. Patents are right-skewed because many pharmaceutical firms may have no FDA approval. The results could be impacted by a few outliers with a large number of patents. We drop the firms with no FDA approval and winsorize 1% of the most extreme observations. Column (4) shows that institutional ownership positively influences innovation outcome.

5.9. Institutional ownership and innovation: causality

Institutional investors may choose to invest in more innovative firms, causing our results to be subject to causality concerns. To alleviate this concern, we conduct a changes-in-changes regression. This illustrates how firm innovation changes following an increase in firm institutional ownership. We regress the change in the number of patents on the change in institutional ownership. If institutional ownership leads to greater innovation output, we should observe a significant positive relationship. The results of this model are presented in Table 9.

Table 9  
Changes-in-Changes Regressions.

Dependent Variable	ΔNumber of Patent	
	(1)	(2)
ΔInst. Own%t + 1	-0.115 [0.611]	
ΔInst. Own%	0.435 [0.011]**	
ΔInst. Own%t-1	0.709 [0.001]***	
ΔInst. Own%t-2	0.005 [0.055]*	
Inst. Own%t + 1		0.556 [0.851]
Inst. Own%t		0.112 [0.001]***
Inst. Own%t-1		0.709 [0.001]***
Inst. Own%t-2		0.006 [0.073]*
CONTROLS	YES	YES
N	2,011	2,011
R <sup>2</sup>	5%	5%

Table 9 Shows regressions the change in institutional ownership on the change in the number of patents. ΔInst. Own% is calculated as the change in institutional holdings between year t-1 and year t. For the brevity of our results, we only report the variable of interest. We run firm-year fixed effects but omit the coefficients. P-values are presented in brackets represents \* <0.10, \*\* <0.05, \*\*\* <0.0, significance levels.

If institutional holdings are, in fact, the cause of increased innovation output, our results should show significant and positive results for Inst. Own% and its corresponding lagged values. Positive and significant values for Inst. Own%t + 1 would raise causality concerns with our analysis. Column (1) of Table 9 shows the regression of change in the number of patents on the change in institutional ownership. Our results indicate a positive relationship between increased institutional holdings and innovation output. The results of Column (1) and Column (2) show a positive and significant effect on innovation following higher levels of institutional ownership. These results strengthen the causal relationship between institutional holdings and innovation output.

6. Conclusion

We investigate the relationship between institutional ownership and innovation in the medical industry. The prior literature describes the relationship as having two primary effects, the “monitoring effect” and the “insurance effect.”

The prior literature provides evidence for institutional investors as efficient monitors. Under efficient and effective monitoring, managers may be motivated to innovate in both more quantity and quality. The results of our study support these conclusions. Our results show that not only do firms owned by institutional investors innovate more (as measured by patent counts), but they also produce better quality innovations (as measured by citations, fewer recalls, and more efficient innovation outcomes).

The pharmaceutical industry has high barriers to entry and high innovation costs. This makes studying the effect of institutional investors in the pharmaceutical industry unique. DiMasi, Grabowski, and Hansen, (2016) survey pharmaceutical firms to estimate the cost of new drug development and document that the cost of pre-tax approval is approximately \$1395 million (2013 dollars). The high cost of drug development makes innovation investment in the pharmaceutical industry risky. This is where we argue the “insurance effect” of institutional investors provides a benefit. Our results show that higher institutional investor own-

ership is associated with more innovations overall. Furthermore, we show that institutional ownership lowers CEO turnover. These results support the “insurance effect.”

In conclusion, we find that institutional ownership increases the quantity of innovation (“insurance effect”), the quality of innovation (“monitoring effect”), and the quality of innovation (“monitoring effect”) in the medical industry. We do this using patent counts, citations, and other measures unique to the pharmaceutical industry. Our results have implications for firm innovation as well as ownership structure. We highlight the importance of the relationship between ownership structure and firm performance.

Additionally, our results support the results of [Aghion et al. \(2013\)](#) among others.

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### Appendix A. Definition of Variables

Variables	Definition	Source
<b>Panel A. Institutional Ownership</b>		
Inst. Own%	Total institutional ownership in fraction of shares outstanding	S&PCapital IQ Database
Max. Inst. Own%	Percentage of shares outstanding held by the firm's largest institution	S&PCapital IQ Database
Top 5 Own	Percentage of shares outstanding held by a firm's top 5 institutional investors	S&PCapital IQ Database
Top 10 Own	Percentage of shares outstanding held by a firm's top 10 institutional investors	S&PCapital IQ Database
Top Block Hold.	Percentage of shares outstanding held by a firm's institutional investors whose holdings are greater than 5%	S&PCapital IQ Database
Mutual Funds	Percentage of holding by Mutual funds	S&P Capital IQ
Investment	Percentage of holding by Investment banks	S&P Capital IQ
Banks	Percentage of holding by Banks	S&P Capital IQ
Pension	Percentage of holding by Pension Funds	S&P Capital IQ
Insurance	Percentage of holding by Mutual funds	S&P Capital IQ
Long Term	Sum of shares owned by all institutions that hold the stock for more than 1 year, as a percentage of the firm's total number of shares outstanding.	S&P Capital IQ
Short Term	Sum of shares owned by all institutions that hold the stock for less than 1 year, as a percentage of the firm's total number of shares outstanding.	S&P Capital IQ
<b>Panel B. FDA Variables</b>		
Total Patent	Total number of drug patents for firm <i>i</i> at year <i>t</i> .	fda.gov
Total FDA Approval	Total number of FDA drug approval for firm <i>i</i> at year <i>t</i> .	fda.gov
Total Medical Device Approval	Total number of medical device approval for firm <i>i</i> at year <i>t</i> .	fda.gov
Total Pre-Market Approval	Total number of pre-market approval for firm <i>i</i> at year <i>t</i> .	fda.gov
Total Licensed Patent	Total number of licenced patents for firm <i>i</i> at year <i>t</i> .	S&PCapital IQ Database
Total Phase I Drugs	Total number of drugs under Phase I testing for firm <i>i</i> at year <i>t</i> .	S&PCapital IQ Database
Total Phase II Drugs	Total number of drugs under Phase II testing for firm <i>i</i> at year <i>t</i> .	S&PCapital IQ Database
Total Phase III Drugs	Total number of drugs under Phase III testing for firm <i>i</i> at year <i>t</i> .	S&PCapital IQ Database
Number of Cites	Total number of patent citations <a href="#">Hall et al. (2000)</a> .	NBER Patent Database
Citation-Weighted Value	Value of patents as measured by citations <a href="#">Hall et al. (2000)</a> .	NBER Patent Database
Total Recall	Total number of product recall initiated by FDA for the firm.	fda.gov
Recall%	Binary variable and equal to one if firm has at least one product recall at year <i>t</i> , zero otherwise.	fda.gov
Total Post Market Evaluations	Total medical products that failed post-market safety evaluations	fda.gov
Post Market Evaluations%	Binary variable and equal to one if firm has at least one product that, zero otherwise, failed post-market safety evaluations	fda.gov
Total Patent Lawsuit	Total Number of Patent Litigations	PACER
Lawsuit%	Binary variable and is equal to one if firm is facing at least one patent lawsuit, zero otherwise	PACER
Decline in Approvals	Change in total patent approvals between year <i>t</i> and <i>t</i> -1 where positive values are replaced by zero.	fda.gov
Cumulative Phase Duration	Cumulative total number of Phase I - II - III products under clinical testing. Difference between product submission date minus product approval date, measured in days	S&PCapital IQ Database fda.gov
<b>Panel C. Control Variables</b>		
Book Leverage	Long-term debt divided by book value of assets	COMPUSTAT
Log(TotalAsset)	Log transformation of total assets	COMPUSTAT
ROA	Income before extraordinary items plus depreciation and amortization divided by book value of assets	COMPUSTAT
Tangibility	Ratio of fixed assets to book assets [ppent/at]	COMPUSTAT
Tobin's Q	Market value of assets divided by book value of assets	COMPUSTAT
Log(FirmAge)	Log transformation of firm age	COMPUSTAT
HHI Index	Herfindahl index based on the firm's sales in a given 4-digit SIC industry.	COMPUSTAT
Free Cash Flow	Operating income before depreciation minus taxes plus interest expense plus dividends paid	COMPUSTAT
RnD	Firms' R&D expenditure normalized by total assets	COMPUSTAT
CEO Turnover	Binary variable and is equal to one if the CEO leaves the firm during year <i>t</i> , zero otherwise	Nexis Lexis
ΔCEO.Cash	The change in the level of cash and bonus compensation for CEO <i>i</i> in year <i>t</i>	S&PCapital IQ Database
Δ(Wealth)	The change in market value of the firm between year <i>t</i> -1 and <i>t</i>	S&PCapital IQ Database
S&P500	Binary variable if the firm is in S&P 500 index, and zero otherwise	S&PCapital IQ Database
Alpha	Excess return on individual stock relative to the market index	S&PCapital IQ Database
Beta	Market beta coefficient for an individual stock	S&PCapital IQ Database

Turnover	Annual trading volume of an individual stock normalized by the total shares outstanding	S&PCapital IQ Database
Lerner Index	Median gross margin from the entire Capital IQ database in the firm's three-digit industry	S&PCapital IQ Database
CEO Turnover	Binary variable and is equal to one if firm replaces CEO, zero otherwise	S&PCapital IQ Database
ΔCEO_Cash	Change in CEO cash compensation (bonus and salary)	S&PCapital IQ Database
ΔCEO_Equity	Change in CEO compensation including cash, option, and equity.	S&PCapital IQ Database

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