THE FDA REVOLVING DOOR: EVIDENCE FROM NEW DRUG REVIEW

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A DISSERTATION

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

Business Administration – Accounting – Doctor of Philosophy

2023

ABSTRACT

This study examines the ex-ante incentives and ex-post consequences of the revolving door between FDA reviewers and the pharmaceutical industry. The ex-ante incentives arise because regulatory agency employees are frequently hired by the industry they previously regulated. Anticipation of future industry employment could motivate FDA reviewers to be more lenient in the review process for new drugs. Using a comprehensive dataset linking 724 reviewers' career trajectories and 1,121 drug applications reviewed for the period 2009-2019, I find that FDA revolvers in supervisory positions approve lower-quality new drugs, which is consistent with revolvers exhibiting leniency. FDA revolvers in more junior positions exert more effort during the review process, consistent with revolvers' motivation to provide an ability signal to potential future employers. With respect to ex-post consequences, I find that firms that hire junior FDA reviewers have higher subsequent drug quality, suggesting junior revolvers deploy their specialized expertise after they join the industry. Senior revolver review experience is positively associated with a greater likelihood of new drug direct approval, implying an applied expertise in navigating the new drug approval process. My study contributes to accounting literature by shedding light on how firms can align future employees' goals in anticipation of employee selection. I also show that revolving door incentives influence the FDA's new drug approval process, indicating that policymakers should consider the full picture of revolving door effects in regulatory design.

To my parents, who gave me life and strength.
To Jun, Kenny, and Aiden, who complete my world.

ACKNOWLEDGEMENTS

This thesis marks the end of a long and memorable journey to discover my true self, encompassing eight years' medical school life, ten years' industry experience, and seven years' training in accounting. I could not have completed it without the dedicated support of my advisors, my family, and friends I met along the way.

My heartful thanks go to my advisor, Dr. Ranjani Krishnan, for her consistent and unconditional support throughout my accounting Ph.D. study. I am deeply grateful for her unwavering support and mentorship to help maximize my potential and achieve my life goals. She has been a constant source of inspiration and encouragement, always pushing me to strive for excellence and providing insightful feedback on my research work. Her wealth of knowledge and expertise in a variety of areas has been instrumental in shaping my research direction and helping me overcome numerous challenges along the way. She not only gives advice on academic career advancement, but also acts as a role model and aspires me to become my best self. The moments when she assisted me with manuscript revisions during her family emergencies, held faith in me through my self-doubt, and went out of her way to find formulas for my baby are indelibly etched in my memory. Her passion for research and teaching, humility, compassion, intellect, and work ethic, will forever inspire me.

I would also like to express my sincere gratitude to Dr. Mario Schabus, co-chair of my dissertation committee. He has dedicated significant amount of time on guiding my dissertation. I truly appreciate his support, patience, empathy, and always positive mindset. I also gratefully acknowledge the continuous guidance and support I received from my dissertation committee members, Dr. Kyonghee Kim and Dr. Leslie Papke. I will always remember how Kyonghee guided me on my first accounting study with great patience, encouragement, and expertise. Leslie taught

me invaluable data analysis knowledge and skills in her class, which is fundamental for me to transition from a practitioner to a researcher.

My sincere thanks also go to Dr. Regis O'Keefe and Dr. Di Chen, co-advisors of my biomedical research training, who played a pivotal role in introducing me to the world of academia. As a world-renowned orthopedic surgeon, medical researcher, and leader of the American Orthopedic Association (AOA), Regis established the first image of what a successful scholar should be in my mind. Being a top orthopedic researcher, Di's passion to advance human knowledge, dedication to nurture the next generation of scholars, and extraordinary courage to explore the unknown have a lasting influence on my final decision to come back to academia. I am fortunate to have had them as my advisors in my early career. They stood behind my choice to change from medical to accounting, and they fully supported my decision to pursue a doctoral degree in accounting after ten years' working in the industry.

In the past several years, I had the good fortune of learning from extraordinary faculty members and receiving their help in various aspects. Particularly, I sincerely appreciate the relentless support of the Accounting and Information Systems department Chairpersons, Dr. Chris Hogan and Dr. Marilyn Johnson, and our Ph.D. directors, Dr. Kevin Markle and Dr. Kenneth Bills. I am also grateful to Dr. Adam Presslee, Dr. John (Xuefeng) Jiang, Dr. Isabel (Yanyan) Wang, Dr. Musaib Ashraf, Dr. Martin Holzhacker, Dr. Richard Saouma, and Dr. Jeffrey Wooldridge. Along this Ph.D. journey, I also met fantastic friends who accompanied and encouraged me during difficult times. Particularly, I would like to thank Dr. Aishwarya Deore, Dr. Hariharan Ramasubramanian, Dr. James Anderson, Dr. Aaron Fritz, Dr. Anh Persson, Dr. Sarah Stuber, Dr. Joanna Shaw, Sangmok Lee, Shuting Wu, and Susan (Xinjie) Tang. I also want to thank Robert Cummings, Vice President of Tax in Stryker Corporation, my manager when I was employed with

Stryker. He offered complete understanding and support when I decided to leave the position to pursue an academic career.

Finally, I am continually grateful to my family. Specifically, I would like to express my deepest gratitude to my husband, Jun Ge, whose unparallel love, support, and sacrifices have made my academic journey possible. His daily three-hour commute to work, after we relocated to Okemos, enabled me to pursue my studies with minimal disruption. He also took on the primary care of our oldest son, Kenny, which allowed me to devote more time and energy to my research. Additionally, he provided solid support both financially and emotionally, which helped me to stay motivated and focused throughout this challenging process. Without his selfless devotion, completing this dissertation would not have been possible. I am forever grateful for his love and steadfast commitment to our family. I would like to extend my heartfelt appreciation to my parents, Juan Gu and Jiefang Yang. Despite having retired, they have willingly dedicated their time and effort to help care for our family, especially after the birth of my second child during the pandemic. Their tireless love and sacrifice have been invaluable in enabling me to complete my dissertation in the midst of an unprecedented pandemic with a young child and a newborn. I would like to dedicate a special thank you to my grandmother, Shengmei Wang. She was an essential part of my life from a young age, and her unconditional love have been a constant throughout my life. Sadly, she passed away in 2021, and the pandemic prevented me from saying my final goodbyes to her in person. Her unwavering faith in me and her love will always remain with me. Her legacy of kindness, strength, and perseverance will continue to inspire me in all my future endeavors, and I know that she would be immensely proud of this achievement. Last but not least, I want to thank my two wonderful children, Kenny and Aiden. Their presence in my life has afforded me the opportunity to comprehend the profound significance of existence. They make my life complete.

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I. INTRODUCTION

Firms often seek to hire employees with regulatory agency experience. For employees, agency experience provides opportunities to acquire human capital and develop connections that can be subsequently utilized to obtain employment in the associated industry (e.g., Che 1995; Salant 1995; Bar-Isaac and Shapiro 2011; Blanes I. Vidal, Draca, and Fons-Rosen 2012; Bertrand, Bombardini, and Trebbi 2014). This practice of hiring agency-employees, often referred to as a "revolving door," has been documented in a variety of industries.[1] A major concern with regulatory employees who exit an agency to join industry (here after referred to as revolvers) is their potential to jeopardize public interest by skewing regulatory outcomes in favor of industry for prospective lucrative jobs (e.g., Stigler 1971; Demski and Sappington 1987; Weingast and Moran 1983; Weingast 1984; Dal Bó 2006; Meghani and Kuzma 2011; Tabakovic and Wollmann 2018). The revolving door thus is often perceived as detrimental to public welfare and receives negative media attention.[2]

Theory and empirical evidence suggest that future employment opportunities could serve as an incentive to potential revolvers to signal their ability to potential employers leading to greater effort in the regulatory review process (e.g., Che 1995; Salant 1995; deHaan et al. 2015; Kempf 2020). After they join industry, revolvers can exploit their connections to benefit their employers, increasing the risk of regulatory capture. Alternatively, or in addition, they can increase the efficiency of the regulatory approval process through their expertise and information. Each agency is different, which makes regulatory context an important factor that could influence the drivers and consequences of revolving doors (e.g., Lucca, Seru, and Trebbi 2014; deHaan, Kedia, Koh,

[1] Typically, revolving door refers to a two-sided personnel movement between regulatory agency and regulated industry. In this study, I focus on the agency-to-industry revolving door.

[2] E.g., Outrage of the Month: Revolving Door to FDA Commissioner's Office Sows Distrust in Agency (Carome 2019); Speed of Revolving Door Between SEC and Private Sector is Shocking (McKenna 2018)

and Rajgopal 2015; Cornaggia, Cornaggia, and Xia 2016; Tabakovic and Wollmann 2018; Kempf 2020; Tenekedjieva 2021). In this paper, I focus on the U.S. Food and Drug Administration (FDA) and investigate (a) how revolvers are incentivized *ex-ante* by prospective employment opportunities to signal their ability and expertise to potential employers during the FDA review processes, and (b) the *ex-post* association between hiring revolvers and the outcome of subsequent new drug applications and the quality of newly developed drugs. I examine these questions in the context of the pharmaceutical industry.

The pharmaceutical industry is a critical component of healthcare sector, a sector accounts for one-fifth of the U.S. economy (Thakor and Lo 2015), and generates over $1.4 trillion annual revenue (Peña, Zavala, and Ruelas 2021). The industry is subject to a variety of regulations related to pricing, distribution, intellectual rights, and patenting. Primary oversight of the industry occurs through the FDA, whose objective is to ensure safety and efficacy of the medical products consumed by the public. The new drug development and marketing approval processes are complex and expensive, and entails an average of 12 years and an over $1 billion investment from the preclinical studies to the final FDA approval (Morgan, Grootendorst, Lexchin, Cunningham, and Greyson 2011; Van Norman 2016). Each day's delay in receiving marketing approval from the FDA costs a firm an average of $1 million (Abraham 2002; Polidoro 2020), leading to a robust industry demand for FDA employees.[3]

Despite the considerable investment on employee selection by firms, information asymmetry between hiring firms and job seekers persists (Oyer and Schaefer 2011). To acquire information about the regulatory employee's abilities, firms attempt to infer such information indirectly from their behavior during the review process (Spence 1973; Che 1995). There are two

[3] Per Janet Woodcock, former director of the FDA's Center for Drug Evaluation and Research, pharmaceutical firms can pay FDA staffers twice as much as the FDA pays (The Press Enterprise 2016).

widely debated and contradictory views on revolving doors. On one hand, revolvers could reduce the rigor of the oversight process *ex ante* to improve employment prospects with a firm. However, this may also lead to poor quality products (drugs) that may harm consumers (Cornaggia et al. 2016; Tabakovic and Wollmann 2018; Tenekedjieva 2021). On the other hand, FDA employees can signal the value of their expertise (Che 1995; De Chiara and Schwarz 2021) by being more thorough and critical during the regulatory process (Lucca et al. 2014; deHaan et al. 2015; Kempf 2020). I refer to the former perspective as the leniency effect, and the latter as the human capital effect.

Ex post, revolvers can exploit their networks from within locations of their previous employment to influence regulatory decision-making on behalf of their industry employers. This may potentially lead to the risk of regulatory capture (Vidal et al. 2012; Bertrand et al. 2014; Hong and Lim 2016; Jiang, Wang, and Wang 2018). Contrary to the regulatory capture view, hiring a revolver has the potential to improve the efficiency of the regulatory process by decreasing information asymmetry between the regulator and industry (Che 1995; Shive and Forster 2017). Revolvers accumulate technical and institutional knowledge during their employment with the regulator, and that can assist firms to navigate the review process and develop better products.

To study their antecedents and consequences, I identify FDA revolving door using data that link the career paths of 724 FDA drug reviewers and 1,121 new drug applications reviewed between 2009 and 2019. 381 (52.5%) of the 724 reviewers stay at the FDA as of the end of my test period. 202 (27.9%) left the FDA and joined nonprofit or educational organizations, or companies not in the pharmaceutical industry. The remaining 142 (19.6%) reviewers left the FDA and joined pharmaceutical firms that submitted new drug applications during the test period; I refer to these reviewers as "revolvers." I use two proxies for leniency signals: direct approvals of drug

applications, and rigor of the review process. Review process rigor is proxied by quality defects for the approved new drug using the number of post-market adverse events reported. For the effort signal, I use the proxy of days spent on reviewing an application. I find support for the leniency effect. While I do not find evidence that revolvers are more likely to grant direct approvals for applications, I find that revolvers reduce the rigor of their reviews, which results in lower quality new drugs. Compared to non-revolvers, revolvers are also likely to exert more effort when reviewing new drug applications, consistent with human capital effects.

My next set of tests parse out whether the extent of the signaling costs influence revolvers' decisions to invest in providing the signal (Spence 1973, 1974; 2002; Connelly, Certo, Ireland, and Reutzel 2011). Revolvers would likely be selective in their signaling to a set of prospective employers that are more attractive to them. Recent survey and prior studies suggest that location is the most important determinant of the job offer acceptance (Barber and Roehling 1993; Turban, Eyring, and Campion 1993; Powell and Goulet 1996; Ceridian 2018). Following Tabakovic and Wollmann (2018), I measure attractiveness of potential future employers with geographic proximity to a revolver's first post-FDA industry employer and first U.S. post-secondary alma mater. The intuition is that the actual first post-FDA employer is a signal of a revolver's revealed location preferences. Existing studies suggest that job seekers have a preference for jobs near their hometown and/or where they were educated (Boyd, Lankford, Loeb, and Wyckoff 2005; Reininger 2012; Tabakovic and Wollmann 2018). First post-secondary alma maters tend to be close to hometowns and indicate local roots (e.g., Briggs 2006; Kind and Volonté 2018). I find evidence that revolvers exhibit greater leniency (greater adverse events) and signal higher human capital (longer reviews) for potential employers, which end up being more attractive from a location perspective.

The costs and opportunities for revolvers to provide signals to prospective employers likely vary by seniority. I therefore examine the effect of reviewer seniority, which is associated with how much time and how many decision rights reviewers would possess. Junior reviewers have fewer decision rights, and thus encounter significantly higher costs for some types of signals, such as fast-tracking a potentially poor-quality application. By contrast, senior reviewers have less time at hand. Thus, signaling through extensive reviews is likely relatively more costly. Therefore, junior and senior revolvers may choose different signals (i.e., expertise or leniency). Consistent with this perspective, I find that senior revolvers exhibit leniency by reducing the rigor of the review process (more adverse events). Junior revolvers exert more effort (longer review times).

Finally, I investigate the consequences of hiring former-FDA drug reviewers on firms' new drug applications, and the quality of the approved drug. I use application-level data to find that firms that have employees with greater FDA reviewer experience also have greater new drug quality, proxied by fewer post-market adverse events. I also find that firms that hire FDA reviewers with greater experience enjoy an increased likelihood of receiving direct approval. However, the review cycle time (total time of the review processes) is not impacted by hiring more experienced FDA reviewers. These findings suggest that FDA revolvers' specialized knowledge and skills improve subsequent product quality for their employer.

This research makes several contributions. First, my study provides the first large-sample empirical evidence of FDA revolving door effects. My study adds to the emerging revolving door literature by demonstrating how future employment incentives impact FDA reviewers' review performance and how hiring FDA revolvers could influence the employers' subsequent new drug application and product quality. Although my analysis cannot speak to the net effects of revolvers, it does indicate the existence of benefits as well as costs. Thus, it adds to the literature that has

calibrated the costs of revolving doors and suggests that net effects of revolvers are less straightforward than often perceived by the public. Prospective lucrative industry jobs could incentivize talents to join and accumulate valuable expertise at regulatory agencies with lower pay (Che 1995; De Chiara and Schwarz 2021). Such expertise can later help reduce the information asymmetry between the agency and firms thus improve firms' compliance with the FDA. Therefore, a broad ban on revolvers could impede beneficial information flow between the FDA and pharmaceutical industry.

Second, my study contributes to management control systems (MCS) literature. A firm's employee selection strategy is a critical component of input-based controls (Simons 2000; Merchant and Otley 2006; Merchant and Van der Stede 2007). Information asymmetry between employers and job seekers makes it imperative that firms use input controls to match the skills needed by the firm and the skills of potential recruits. My study shows that potential FDA revolvers choose different types of signals, which firms can use to recruit and allocate revolvers to jobs that maximize their productivity. The results suggest that identifying and utilizing informative signals from potential employees could be integrated into a firms' employee selection strategy and thereby increase the effectiveness of matching.

Finally, I contribute to accounting literature by showing that firms can nudge goal-congruent actions even *before* the employee joins the firm. MCS are designed to influence the behavior of individuals towards the goals that are important for the organization (Flamholtz, Das, and Tsui 1985; Speklé 2001; Langfield-Smith 2006; Bedford and Malmi 2015). While extensive literature has examined the design of MCS instruments to influence the actions of employees inside the organizations (e.g., contractual controls, compensation, targets), sparse literature examines how firms influence the actions of important stakeholders when they are not yet a part of the

organization. My research shows that the attractiveness of a firm influences potential future employee behaviors, suggesting that firms could take steps to increase their attractiveness to the labor market.

The next sections are organized as follows: Section 2 reviews the institutional background and relevant literature; Section 3 describes data and empirical design; Section 4 reports the findings of the study; and Section 5 concludes.

II. SETTING, THEORY, AND RESEARCH QUESTIONS

Setting: FDA Regulation on New Drug Approvals[4]

All new drugs have to go through a rigorous multi-stage FDA process before they can be brought to the market. This process is expected to strictly follow a set of standards and (broadly) contains the following steps: first, after a substance is identified as a potential new drug, based on laboratory studies and drug prototype design, the firm files an investigational new drug (IND) application with the FDA requesting permission for clinical trials.[5] The purpose of clinical trials is to provide evidence supporting the safety and efficacy of new drugs and normally involves three stages, (Phase I to Phase III).[6] To incentivize and expedite the development of drugs that are intended to treat rare and serious conditions, the FDA offers various routes to facilitate the new drug development process, including classification as orphan drug, fast tracking, breakthrough therapy, and accelerated approval (see Appendix B for details). [7]

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[4] Information and details about the new drug development and application process are from the FDA website and related FDA guidance documents. The FDA webpages referred in this section are listed as below:
https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective
https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/review-team-responsibilities
https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review
https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-continued
https://www.fda.gov/patients/about-office-patient-affairs/learn-about-fda-advisory-committees
https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda

[5] 30 days after the IND recipient date, unless FDA notifies the firm otherwise, the IND application is "in effect" and the firm can commence clinical trials. Within these 30 days, the FDA may issue suggestions or mandatory changes, which can delay the start of clinical trials. https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application

[6] Per FDA, Phase I trials usually involve 20 to 100 human participants and main purpose is to test safety of the drug and establish the appropriate dosage. Phase II trials expand the participant pool to hundreds and aim to test the efficacy and side effects of the new drug. Phase III trials take thousands of participants and focus on testing the efficacy and monitoring of adverse reactions of the drug. https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

[7] Orphan drug designation: https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products
Fast track, breakthrough therapy, and accelerated approval designations: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

After successfully completing Phase III clinical trials, the firm can file a New Drug Application (NDA) with the Center for Drug Evaluation and Research (CDER) division of the FDA.[8] I focus on the NDA review process and do not study the steps before NDA submission, as the NDA review has a well-structured standard procedure and clearly designated timeframe. The new drug development processes, however, vary significantly across cases. An NDA should include all relevant clinical data about the drug as well as information about labeling, quality control, risk evaluation, and mitigation processes employed by the firm. An NDA costs $2 million in application fees. Original NDAs receive one of the two review designations: standard or priority review (FDA, CDER Review Designation Policy). The FDA new drug review team determines which review designation an NDA should receive based on its therapeutic nature.[9] The FDA has internally-designated timelines: review teams aim to complete reviews within 6 months of receipt for priority reviews, and 10 months for standard reviews (FDA, CDER Review Designation Policy). The FDA also assigns an NDA classification code at the filing date for a new drug application based on the chemical nature of the drug product. There are 15 NDA classification codes (see Appendix B).[10]

A review team is typically composed of specialists with varying expertise (e.g., medical officers, pharmacology specialists, statisticians, and microbiologists). Each reviewer will write an evaluation with his/her recommendations regarding the drug application. These written evaluations will then be considered by supervisors and directors. Throughout the review process,

[8] If the new drug is a biological product, e.g. monoclonal antibodies, the application is called Biological License Application (BLA). BLA contains similar information required to an NDA and goes through the same review processes. In this paper, I refer to both NDA and BLA as NDA for brevity.
[9] Priority review designation is assigned to NDAs for drugs that "treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies" (FDA, CDER Review Designation Policy).
[10] Classifying new drug applications into granular categories help promote consistency of the reviews across teams and divisions (FDA, CDER NDA Classification Codes).

the review team has the opportunity to maintain a collaborative relationship with the firm through different channels, such as regular mail, email, fax, or meetings. The FDA often requests additional information or simply provides status updates. Specifically, "reviewers can communicate directly with applicant firms for discipline-specific information requests" (FDA, CDER 21st Century Review Process, 31). Reviewers thus have considerable opportunity to interact with applicant firms through both informal inquires and formal meetings. Although the final outcome of a review is a team decision, reviewers have discretion on determining the outcome of the review in their specific disciplinary area. If the review team agrees on the new drug's safety and effectiveness based on the information submitted, the FDA issues the final approval. When questions arise and the review team cannot make a decision, an external advisory committee meeting is held to provide the team with independent advice. The FDA issues a complete response letter (CRL) if the review team determines that the application cannot be approved in its present form. Common reasons for denial are related to issues of safety and effectiveness, reflected in pre-market clinical studies (Sacks et al. 2014). Once the NDA is approved, the FDA uses two main channels to keep monitoring the safety and effectiveness of the new drug: (1) the applicant firm must submit periodic safety updates to the FDA, and (2) the FDA's MedWatch system allows physicians and consumers to report adverse events related to the drug.

Arguably, the best approach to study how the FDA revolving door shapes reviewer behavior is to observe interactions between NDA firms and reviewers. However, such data are sensitive and, to the best of my knowledge, unavailable. [11] I therefore chose a second-best approach: I studied variation in benefits (industry employment) and costs (time and effort, risk of being detected) of biasing reviews opportunistically. By linking benefits and costs to patterns in NDA

[11] I submitted FOIA request to the FDA, requesting formal meeting and other communication documents, but was informed such information is not available for the public.

outcomes (direct approval, review time, drug quality), I can show indirect evidence of incentives created by the revolving door from the FDA to the industry.

Ex-ante Revolving Door Incentives

Public interest theory posits that the goal of regulation is to pursue overall welfare (Laffont and Tirole 1991). In contrast to public interest theory, economists offer a revisionist approach to regulatory process and argue that regulatory employees can have narrow, self-interested goals such as job retention or future personal wealth (Stigler 1971; Dal Bó 2006). Future employment opportunities can therefore incentivize opportunistic behavior of regulatory employees who consider taking a lucrative industry job (Che 1995; Salant 1995). To firms, employees with desired qualifications is central to growth, viability, and survival (Jones and George 2016). Therefore, firms devote considerable resources to employee selection, a critical input-based control, to ensure talents with the right type of knowledge, skills, shared beliefs, and values are selected for the right positions (Merchant 1985; Simons 2000).

Theory and empirical evidence suggests that more effort placed on employee selection results in reduced agency costs and improved incentive alignment, especially when measuring an employee's output performance is difficult (Merchant 1985; Simons 2000; Merchant and Van der Stede 2007; Prendergast 2008; Campbell 2012). However, asymmetric information between a firm and a job seeker makes employee selection and matching one of the fundamental problems in personnel management (Oyer and Schaefer 2011). Firms value employee experience with regulatory agencies but cannot directly observe their qualities because of the absence of direct and publicly observable performance measures (Spence 1973; Che 1995). Firms then attempt to indirectly obtain information about the regulatory employee's qualification by observing their regulatory behavior. Accordingly, regulatory employees who are seeking industry employment

opportunities might signal their qualities during regulatory processes to potential employers (Spence 1973; 1974; 2002). The revolving doors thus have an incentive effect on the potential revolver's regulatory performance.

Che (1995) indicates that if firms value technical knowledge and skills, those who intend to join industry have incentives to acquire human capital during their tenure with the agency and signal these qualities to prospective industry employers by exerting greater regulatory effort. Thus, the revolving door could encourage the acquisition of high-quality expertise by regulators and result in better regulatory outcomes (e.g., Lucca et al. 2014; deHaan et al. 2015; Kempf 2020). From this perspective, revolving doors could motivate talent to join and accumulate valuable expertise at regulatory agencies (where pay is lower) in the anticipation of future lucrative industry jobs (De Chiara and Schwarz 2021). I refer to such incentives as "human capital effect."

On the other hand, if firms value qualifications that are unrelated or even hinder regulatory stringency, then regulatory outcomes may be undermined (Che, 1995). For example, one typical regulatory capture argument that has long been coupled with revolving door suggests that industry firms value favoritism shown by lenient regulators (e.g., they may demonstrate their understanding of firms' interests and their ability to influence regulatory decisions (Fox 1974; Che 1995; Dal Bó 2006)). As a result, regulatory employees can have incentives to signal their ability to influence and/or their congruency with firms' interests - effectively trading rigor for leniency towards firms where they seek future job opportunities (Cornaggia et al. 2016; Tabakovic and Wollmann 2018; Tenekedjieva 2021). I refer to the latter as a "leniency effect."

As pointed out, reviewers might be able to maximize their outside job opportunities by signaling expertise or leniency. However, in responding to incentives from industry employers' recruitment preferences, regulatory employees must choose the effective signals that can maximize

their net welfare (Spence 1973, 1974, 2002; Connelly et al. 2011). Therefore, when signaling is costly, job seekers are likely to selectively send signals to prospective employers that are more attractive to them in order to maximize the net returns of signaling. The revolving door incentive effects are thus not only contingent on employers' preferences but also on revolvers' preferences. The central notion of job market signaling theory is that there is a negative correlation between signaler's (in this study, revolvers) productive capability and cost (Spence 1973, 1974, 2002). To distinguish themselves from the rest, job seekers select the signals associated with the costs that they can afford but others cannot.

Spence (1973, 1974, 2002) emphasizes that signaling costs broadly include all types of costs such as psychic, monetary, and time. For example, revolvers' exerting effort to show off their expertise (human capital hypothesis), or influencing peers' decision-making (leniency hypothesis), are both costs of signaling borne by potential revolvers. Revolvers have varying levels of abilities and decision rights, leading to heterogeneous costs of signaling. Such costs may vary with a reviewer's seniority. A junior regulatory employee who wants to show leniency will need to invest significantly more effort to convince colleagues in a regulatory decision than a senior regulatory employee who has significantly more decision rights, has more experience and expertise and a higher standing amongst colleagues, and can thus convince colleagues relatively more easily. On a related note, the junior reviewer is more likely to be found out, which increases the expected reputational penalty. Senior regulatory employees, on the other hand, have significantly less time at hand. Therefore, signaling through extensively long regulatory reviews is likely relatively more costly for them than for junior reviewers. I exploit such variation in the costs of signaling along reviewers' seniority to understand the nuances of incentives created by the FDA revolving door.

Empirical studies on the relation between the revolving door and regulatory performance find mixed evidence. Some suggest that industry favors regulators' technical expertise, and therefore revolvers tend to be stricter regulators (Cohen 1986; Agarwal et al. 2014; Lucca et al. 2014; deHaan et al. 2015). Others find that regulators exhibit leniency towards prospective industry employers (Tabakovic and Wollmann 2018; Tenekedjieva 2021). For example, Agarwal et al. (2014) study supervisory decisions of US banking regulators and find that lenient regulators are less mobile into the financial industry, suggesting firms value technical expertise which is consistent with a human capital effect. Lucca et al. (2014) show that more bank regulators are hired by industry during periods of high enforcement. deHaan et al. (2015) find evidence that more aggressive SEC lawyers are more likely to be hired by private law firms. Tabakovic and Wollmann (2018) and Tenekedjieva (2021) show evidence of leniency exhibited by US patent examiner revolvers and insurance commissioner revolvers respectively.

Researchers further expand this strand of literature by examining revolving door incentive effects in private sector settings such as credit rating agencies and equity analysts. Again, evidence is mixed. Cornaggia et al. (2016) find that credit rating analysts inflated their future employers' bond rating prior to the employment transfer. Kempf (2020) finds that revolvers from rating agencies to investment banks tend to outperform their peers in terms of accuracy, with the exception of ratings related to the banks that later hired them. Lourie (2019) finds that revolving door equity analysts become more optimistic about their future employer while becoming more pessimistic about other firms during their final year.

This body of revolving door literature suggests that human capital effect and leniency effect are not mutually exclusive. The extant literature highlights the importance of the regulatory context in examining revolving door incentive effects. Federal agencies differ in many aspects such as

organizational structure, political support, public trust, employee expertise demands, historical ties with industry, and concerns for impressions of objectivity in the review process. Therefore, empirical analysis of revolving doors in various regulatory contexts is essential. The lure of ex-post-employment opportunities may predispose employees to make decisions in favor of the industry by undermining the review process. Particularly within the context of the FDA, substantial adverse effects can occur to the health and wellbeing of the citizenry that consume these products that emerge after the impaired regulatory oversight is completed.

The FDA ensures the safety and effectiveness of medical products that are available to the U.S. people. To pharmaceutical firms, the significant time (on average 12 years from lab tests to final drug approval) and capital investment (over $1 billion) on developing a new drug makes gaining the FDA approval a battle that cannot be lost. On the one hand, firms need valuable institutional and scientific knowledge from former FDA reviewers to ensure a more efficient navigation of the complex new drug development process and a better compliance with FDA regulation. The human capital hypothesis predicts that FDA revolvers will signal their quality to prospective employers by exerting more effort and demonstrating their expertise during the review process (Che 1995; Dal Bó 2006). This could be manifested in extended review time and/or higher standard of approval for a new drug application. On the other hand, firms also highly value a positive new drug application outcome, as a denial or even delay of approval generates excessive economic losses. From this perspective, a leniency effect predicts that FDA revolvers will signal to firms by reducing rigor towards firms where they seek future employment. Therefore, revolvers could grant more approvals and/or lower the standard of approving an application. In the context of FDA regulation, both expertise and leniency are highly valuable to firms. Therefore, it is difficult to predict how potential revolvers would signal to prospective employers.

The associated costs of the abovementioned job market signals are considerably high as biasing a review bears the risk of being seen through by peers or supervisors. Accordingly, to maximize the net return of costs, FDA revolvers are likely to be selective and signal to the firms that are more appealing to them, and the signaling costs could also differ with revolvers' seniority. In brief, how FDA revolvers choose to signal to prospective employers is an empirical question and could be contingent upon the attractiveness of potential employers and seniority of the employee.

Empirical evidence on the FDA revolving door is next to non-existing. The media has primarily scrutinized the practice of recruiting former FDA staffers in the pharmaceutical industry (e.g., Jennifer 1998; Lupkin 2016; Kolodny 2020). Bien and Prasad (2016) track the career path of 55 FDA medical officers from 2001 through 2010 and find that 27% of them left the FDA to work for the industry they previously regulated. In his interview with NPR (National Public Radio), one of the co-authors, Dr. Prasad explicitly point out that FDA reviewers "have a lot of autonomy" and "there is a lot of room for interpretation in deciding whether or not a cancer drug should be approved." [12] Indeed, a significant portion of approved cancer drugs employed "surrogate endpoints" in the clinical trials, which were not backed up by robust validation analysis and are not linked to better health outcomes for patients (Kim and Prasad 2016). No empirical studies further investigate the FDA revolving door effects on the new drug approval process.

Therefore, my first research question is: *How do revolvers signal their quality to prospective industry employers during the FDA review processes?*

[12] https://www.npr.org/sections/health-shots/2016/09/28/495694559/a-look-at-how-the-revolving-door-spins-from-fda-to-industry

The Consequences of Hiring a Revolver

The contradictory perspectives around the human capital effect and the leniency effect on the regulatory approval process extend into the post-revolving stage. Firms may hire former regulators both for their ability to navigate the regulatory process and network, and for their potential to influence their former employer (the agency) (Che 1995; deHaan et al. 2015). After joining the firms, revolvers could use their professional network and/or institutional knowledge to bias regulatory decisions in favor of their current employers. Thus, the revolver could indirectly facilitate regulatory capture whereby the firm is able to influence the behavior of the regulator to distort economic outcomes in favor of the firm (Stigler 1971; Laffont and Tirole 1991; De Chiara and Schwarz 2021). However, a revolver's valuable institutional expertise can also resolve information asymmetry between firms and regulators and facilitate not only firm regulatory compliance, but also increase the efficiency of the regulatory environment (e.g., Che 1995; Shive and Forster 2017).

Limited research examines the influences of revolvers in the post-revolving stages (Shive and Forster 2017; Barbosa and Straub 2017; Jiang et al. 2018; Jiang, Robinson, and Wang 2020; Emery and Faccio 2020). Shive and Forster (2017) documents that regulated firms become less risky after hiring a former financial regulator. Barbosa and Straub (2017) suggest that procurement prices lower after public procurement administrators joined the suppliers. Jiang et al. (2018) finds that hiring more structured finance rating analysts is associated with inflated rating of issuers' new issuances. Jiang et al. (2020) finds that firms have a lower tax rate volatility with reduction in effective tax rate after hiring former IRS employees with tax expertise. Emery and Faccio (2020) show that firms experience a reduction in the incidence of fines after hiring former regulators from fine-imposing agencies. These findings suggest that hiring revolvers could benefit the employers,

but whether the benefits are realized through utilizing the revolvers' expertise to improve performance or better navigate the regulatory process is not easy to disentangle and is contingent on context.

Former FDA reviewers, especially those with more authority (e.g., higher rank), could carry both technical expertise and ability of influence to their industry employers. FDA revolvers' technical expertise could help firms improve subsequent product quality and achieve better new drug application outcomes (e.g. higher likelihood to receive direct approval). FDA revolvers' influence ability could help employer firms better navigate the drug application process, thereby receiving more direct approvals even without improvement of the subsequent new drug's quality. Signaling theory suggests that employers learn job seekers' quality based on their signals and employers will allocate employees to jobs that can maximize their productivity (Spence 1973; 1974; 2002). When technical expertise and influence ability are not mutually exclusive, how firms infer an FDA reviewer's qualification from signals and the process of appropriate job allocation to maximize employee's value remains an open question.

Therefore, my second research question is: *How is hiring revolvers associated with the subsequent new drug applications and quality of these new drugs?*

III. DATA AND METHODOLOGY

Sample: New Drug Applications, Reviewers, and Revolvers

One key challenge in understanding the revolving door between agencies and industry is that data on employees' career paths are often unavailable. I overcome this by hand collecting reviewer names from publicly available new drug applications (NDAs) and track their career based on information from LinkedIn. My starting sample includes all FDA reviewers between 2009 and 2019 who are disclosed by the new drug review documents on the FDA website.[13] Please find an example of the list of reviewers in the review document in Appendix A1.[14] In total, I collect information about 1,738 unique reviewers, including job titles (e.g., director, team lead, manager, staff reviewer), educational information (e.g., M.D., PharmD, Ph.D., MS), and the application identification number of the new drugs they reviewed. Next, I collect FDA reviewers' career and education information from LinkedIn.[15] To exclude temporary workers such as interns, I require reviewers in my sample to have at least one year of work experience with the FDA. I was able to retrieve the LinkedIn profile of 1,035 out of 1,738 FDA-reviewers. After manual validation by an independent research assistant based on demographic characteristics and time period with the FDA, 311 reviewers are further excluded from my sample. Thus, my final sample includes 724 FDA reviewers who reviewed at least one new drug application between 2009 and 2019.

[13] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. My sample starts in 2009 as in 2008 the FDA made major changes to their NDA review process (https://www.fda.gov/drugs/laws-acts-and-rules/complete-response-letter-final-rule). The sample ends in 2019 to avoid the confounding impact of the COVID pandemic.

[14] Not all drug application approval documents contain such a reviewer list. When the list of reviewer is not available, I search through the document and collect reviewer information scattered in the document.

[15] LinkedIn is the world's largest professional network and has over 830 million members worldwide. I employ a software to download LinkedIn profiles in batches. The software used is LeadGrabber Pro. The strategy I use to locate individuals with FDA work experience is searching for any profile that with FDA, U.S. Food and Drug Administration, Food and Drug Administration, Center for Drug Evaluation and Research, or CDER in their past or current job description, and with residency country as the U.S. I download 12,538 LinkedIn profiles that fulfilled my search criteria.

Next, I retrieve the following (other than reviewer) information from NDA documents: applicant firm name, application number, receipt date, approval or denial date, drug name, submission classification, and review process designation (standard vs. priority).[16] Appendix A2 presents an example of a list of FDA original NDA approvals for one month. Appendix A3 (A4) presents an example of an approval (denial) letter. I collect additional new drug application characteristics, including whether it receives orphan product, fast track, breakthrough therapy, or accelerated approval designation from various FDA data sources.[17] I manually collected advisory committee meeting contents from the FDA's online meeting calendar to determine whether a drug application was ever discussed in such a meeting.[18] From 2009 to 2019, there are in total 1,325 original new drug applications. I exclude 81 new drug applications that are "Medical Gas," as this type of new drugs undergoes a significantly faster review process and rarely receives denial (FDA, CDER NDA Classification Codes). 123 applications were excluded as they did not include sufficient reviewer career path information.

Following exclusions, the merged dataset has 724 unique reviewers and 1,121 unique new drug applications, representing 90.1% of total valid new drug applications during the test period. This dataset is at reviewer-application level and has 7,352 observations. Reviewers that left the FDA to join a pharmaceutical firms that submitted at least one new drug application during the test period are identified as a "revolver" reviewer and are assigned a binary variable *Revolver*.[19]

[16] The FDA only disclose drug application information for those that have received final approvals. I submitted FOIA to the FDA, requesting for all new drug applications submitted during the test period but was informed that applications that have not yet received an approval are confidential and are therefore not available to the public.
[17] https://www.fda.gov/drugs/nda-and-bla-approvals/nda-and-bla-calendar-year-approvals; https://www.fda.gov/drugs/nda-and-bla-approvals/fast-track-approvals; https://www.fda.gov/drugs/nda-and-bla-approvals/breakthrough-therapy-approvals; https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approvals
[18] https://www.fda.gov/advisory-committees/advisory-committee-calendar
[19] I track FDA reviewers' career paths 1.5 years (2009-May 2021) after the test period (2009-2019) to maximize the post-FDA career information for the reviewers only appear in the later years of my test period.

Reviewers still stay with the FDA and reviewers who left to join employers other than pharmaceutical firms are considered "non-revolvers."

Table 1.1 presents the descriptive summary of the FDA reviewers and the FDA new drug applications in my sample. Among the 724 FDA reviewers, 142 (19.6%) left the FDA and joined pharmaceutical firms that submitted new drug application(s) during the test period. 202 (27.9%) left the FDA and joined nonprofit, educational organizations, or other companies.[20] 381 (52.5%) are still with the FDA as of May 2021. During the test period, 452 pharmaceutical companies submitted 1,121 new drug applications to the FDA and received final approval.[21] 695 (62.0%) new drug applications from 308 companies were reviewed by at least one FDA revolver. 426 (38.0%) new drug applications from 232 companies were reviewed only by non-revolvers. 81.7% of revolvers and 79.5% non-revolvers reviewed multiple new drug applications, with 38.7% revolvers and 44.5% non-revolvers reviewed more than 5 applications (Table 1.2). At the application level, 74.6% new drug applications were submitted by firms that have submitted multiple new drug applications during the test period (Table 1.3).

Dependent Variables: Direct Approval, Review Time, Adverse Events

How to infer a reviewer's intention from observed characteristics and outcomes of reviews is not obvious. Similarly, whether decisions can be attributed to newly hired revolvers (which is a challenge for my second research question) is unclear. Therefore, I construct a combination of tests to identify possible mechanisms underlying FDA revolving door incentives and outcomes. In the FDA new drug review setting, leniency can be manifested in granting more direct approvals to new drug applications, or lowering the standard of approving a new drug. To demonstrate expertise,

[20] Treating the reviewers who left FDA and joined nonprofit, educational organizations, or other types of companies as non-revolvers, or excluding them from the tests does not qualitatively impact my results.
[21] Information related to the new drug submissions that have not received the final approval is confidential and is not available to public.

FDA reviewers can exert more effort on the reviewing work, which could result in more rigorous regulatory actions, e.g., more scrutinization during the review process. Accordingly, I use two proxies for leniency signals and one proxy for signaling effort. *DirectApproval* is an indicator variable and equals to one if a new drug application was approved by the FDA without receiving any denials (complete response letter, CRL) during the review process. Receiving direct approval is what pharmaceutical firms strongly desire and their goal of the tremendous investments in the development of a new drug. Therefore, granting more direct approvals to new drug applications submitted by a firm is the strongest leniency signal an FDA reviewer can demonstrate.

Agency theory has long pointed out that efforts of agents are either impossible or prohibitively costly to be observed (Lambert 2001). Bonner and Sprinkle (2002) first propose a comprehensive construct of effort, which includes direction (which task to engage), duration (length of time allocated to the task), and intensity (amount of attention devoted to the task during a fixed period of time). In the setting of my study, observing effort intensity of reviewers on a drug application is close to impossible.[22] Which application a reviewer selected to work (effort direction) on and how long he/she spent on it (overall length of time on reviewing the application) are observable. In the study, I employ the amount of time spent on reviewing an application *to* proxy the review effort FDA reviewers exert on new drug applications.[23] *lgReviewTime* is the log of the total days between the new drug application recipient date and the final approval date. Reviewers can raise questions or/and request additional materials from applicant firms during the review process. Such interactions and inquiries will extend the overall review timeline. An alternative

[22] There is no work log to document how much work a reviewer conducted during a fixed length of time on a specific task, therefore, it is impossible to justify effort intensity a reviewer renders on a drug application.
[23] Consistent with the definition of effort in agency literature, time could be used as a measure of effort (Baiman 1982, 1990; Sprinkle 2000). Accordingly, time has been used in prior studies as the proxy of effort (Pratt and Awasthi 1990; Libby and Lipe 1992; Bettman, Johnson, and Payne 1990; Sprinkle 2000).

interpretation of review time is that reviewers with lower ability would need more time on reviewing the applications. If review time reflects a reviewer's ability, time is expected to be consistent across reviews for a particular reviewer. In my following tests, this alternative interpretation is ruled out.

lgAdvEvent proxies for drug quality and is defined as the log of one plus the number of post-market adverse event for an approved drug as of the end of the testing period. Relatively more post-market adverse events suggest lower quality of a drug and lax oversight during new drug review processes. I obtain adverse event reports from the FDA Adverse Event Reporting System (FAERS)[24] from 2009 to 2019. As drugs approved earlier have more time to accumulate adverse event reports, I include year fixed effects in all empirical specifications to control for this pattern. Both *lgReviewTime* and *lgAdvEvent* are winsorized at 1 and 99 percentiles to remove extreme values.

The same set of dependent variables are used to test my second research question – namely, the association between hiring FDA revolvers and firms' subsequent new drug application and quality. If revolvers are hired for their institutional and technical knowledge and skills, firms would expect to have improved compliance with the FDA, which could manifest in reduced post-market adverse events. The improved drug quality could lead to more direct approvals. If revolvers are hired for their ability to influence regulatory decisions, firms would expect to see a higher likelihood of receiving direct approval without improvement in new drug quality. The association between hiring revolvers and review time is ambiguous; revolvers with rich institutional and

[24] This database only includes post-market adverse events; that is, it does not consider adverse events before a drug has been approved. I only use the initial report for each adverse event case and drop any supplemental or additional follow up reports for the same case. Each adverse event case is associated with one or more drugs with their new drug application numbers. If multiple drugs are involved in one adverse event case, the FDA indicates which drug is the primary suspect drug. In the study, I only focus on the primary suspect drug. The count of adverse event reports is therefore defined as the aggregated number of initial adverse event reports for a drug if it is the primary suspect drug.

technical knowledge could help firms be more prepared when submitting a new drug application which could shorten the review time. These revolvers could also be more thorough when responding to the FDA's questions/inquires which will extend review time. Similarly, revolvers with a strong ability to influence the FDA review team may or may not be able to shorten the review cycles. It is possible that such revolvers could influence the review team to reduce the review timeline, but to interact with and influence the review team could also be time consuming.

Revolving Door Incentives – Baseline Model

In the absence of an exogeneous shock, I largely rely on (1) a sequence of tests that together rule out many alternative explanations, and (2) firm or reviewer fixed effects. To examine whether revolvers show differential reviewing behavior relative to non-revolvers towards the same firm, I use the ordinary least squares (OLS)[25] model:

$$Y_{ij} = \beta_0 + \beta_1 Revolver_i + \sum \beta_x Control\ Variables + Firm\ Fixed\ Effects + \sum \beta_k\ Other\ Fixed\ Effects + \epsilon_{ij} \quad (1)$$

Y_{ij} is *DirectApproval, lgReviewTime,* or *lgAdvEvent* of application *j* which was reviewed by reviewer *i* (i.e., the unit of observation is the reviewer-application level). The variable of interest is $Revolver_i$, which equals 1 if reviewer *i* left the FDA to join a pharmaceutical firm between January 2009 and May 2021. When the dependent variable is *DirectApproval* or *lgAdvEvent*, β_1 is expected to be positive if the revolver exhibits leniency during the review process. When the dependent variable is *lgReviewTime*, β_1 is expected to be positive if the revolver exerts more efforts on the review. One key advantage of my data is that over 70% of reviewer-application observations are associated with firms that have submitted multiple new drug applications during

[25] The fixed effects used in the estimating models violate the conditional serial independence assumption of logit estimator. Therefore, for binary dependent variable *DirectApproval*, I also use the linear regression model (Kwak, Martin, and Wooldridge 2021).

the test period. For example, 47.9% reviewer-application observations are associated with firms that submitted more than 10 applications (Table 1.3). Among the 1,121 unique applications, 62.0% (695) were reviewed by at least one revolver, while the rest were not associated with any revolvers (Table 1.1). Given the firm fixed effects, I compare differences in outcomes attributed to being a revolver *vs* a non-revolver, within the same applicant firm.

Control Variables

I include several additional control variables and fixed effects to account for unobservable factors that may be associated with the review outcome and/or drug quality. Year fixed effects control for time trends.[26] I include submission classification fixed effects and review team size fixed effects. New drug applications are classified into fifteen categories based on the nature of the new drug and the review procedures are largely consistent within a given category.[27] The size of a review team can reflect the complexity of a new drug, and could therefore influence the review outcomes and the number of adverse events reported in the future. The median sized review team has 6 reviewers in the sample, and I categorize review team size into quartiles. When the dependent variable is *lgReviewTime* or *lgAdvEvent*, I control for the number of rejections. The number of rejections an application received between initial submission and final approval is positively associated with the review time. Rejections also indicate a lower quality of the new drug when it was first submitted to the FDA and thus implies potential quality concerns.

I include a list of control variables associated with the new drug application and reviewers' characteristics. Indicator variables are created for each of the special designations the FDA could

[26] I use drug application approval year fixed effects in my tests.

[27] As introduced in Section 2.1, if the new drug is a biological product, e.g., monoclonal antibodies, the application is called Biological License Application (BLA) instead of NDA. BLA contains similar information required to an NDA and goes through the same review processes. However, the FDA does not designate a submission classification to BLA. In this paper, I include BLA as an additional type of submission classification. Whether to have BLA as a separate indicator variable or include it as a submission classification does little impact to my test results.

assign to new drug applications: orphan product, fast track, breakthrough therapy, accelerated approval, and priority review. I also include an indicator variable for whether an application was discussed in an advisory committee meeting. Additionally, I use the number of total beneficiaries of a drug reported under Medicare Part D Plan between 2013 and 2019 to proxy for the scope of the drug usage and include this control variable in all my estimating models. For reviewers' characteristics, I control for reviewers' seniority by creating an indicator variable, *Seniority*, which is one if the reviewer has a job title such as "chief," "director," "manager," "team lead," or "supervisor." Reviewers' tenure with the FDA is also included as a control variable. I include indicator variables for gender, highest degree received, and whether the reviewer received an undergraduate education in the U.S. I cluster all standard errors by firm and reviewer. The full description of each of these variables is in Appendix B1.

FDA Incentives and Revolvers' Location Preferences

The baseline model compares the regulatory behavior between revolvers and non-revolvers towards the applications submitted by the same firm. I next examine whether revolvers *selectively* bias their reviews towards firms they more strongly desire to join. Given that biasing a review is costly, revolvers should alter their signaling based on their preference with regard to the prospective employers. That is, they should send the strongest signal to the firms they want to join. As explained in the next paragraph, I measure a revolver's location preference as proximity to their first industry employer, or proximity to first U.S. post-secondary alma mater.[28]

[28] Very few revolvers have reviewed an application of a firm they end up joining. In the sample, 32 (0.44%) reviewer-application observations are associated with 15 firms that later hired the reviewer(s) who ever reviewed their new drug application. This low percentage could be the result that the former FDA reviewers trying to avoid conflict of interests posed by the FDA Post-Employment Restrictions. Under-representation of revolvers who joined a firm that they ever reviewed in my sample could be another reason. Following Tabakovic and Wollmann (2018), I infer the set of prospective employers from observable location information associated with revolvers.

Recent survey and prior studies suggest that location is the most important determinant for workers' job choices (Barber and Roehling 1993; Turban et al. 1993; Powell and Goulet 1996; Tabakovic and Wollmann 2018; Ceridian 2018). Therefore, a revolver's first industry job may reveal his/her actual location preferences. The first observable location information I exploit for cross sectional variation is the revolver's first industry hirer's geographic location. Prior studies in sociology, management, psychology, and economics have long suggested that workers prefer jobs near their hometown or where they received education (Sjaastad 1962; Schwartz Aba 1973; Boyd, Lankford, Loeb, and Wyckoff 2005; Dahl and Sorenson 2010a; Dahl and Sorenson 2010b; Dahl and Sorenson 2012; Reininger 2012; Tabakovic and Wollmann 2018; Yonker 2016; Yonker 2017). First (often undergraduate) alma-maters tend to be close to hometowns and indicate local roots (e.g., Briggs 2006; Kind and Volonté 2018). Therefore, the second observable location information I employ is the revolver's first U.S. post-secondary alma mater's geographic location. I posit that, for revolvers, firms located closer to their preferred geographic location are more attractive potential employers. I construct *ProximityApptoHirer(logged)*, which is the natural logarithm of one plus the distance (in kilometers) between the FDA applicant firm and the revolver's first pharmaceutical firm employer.[29] This variable is only applicable to revolvers as non-revolvers stay within the FDA, which causes a smaller sample. The second distance variable, *ProximityApptoEdu(logged)*, measures the proximity between the FDA applicant and the reviewer's first U.S. post-secondary school. To facilitate interpretation, these two measures are multiplied with -1; i.e., larger values mean closer to the preferred location. Both measures are

[29] To construct distance measures, I use the latitude and longitude of the U.S. firms' headquarters' city. For international companies, I use their major U.S. division's (e.g., U.S. headquarters, North American headquarters, or the most prominent U.S. subsidiary) city. For international companies without a major presence in the U.S., I use their headquarters' city.

winsorized at 99 percentiles to remove extremely large values. I test the following cross-sectional model:

$$Y_{ij} = \beta_0 + \beta_1 ProximityMeasure_{ij} + \beta_2 Revolver \times ProximityMeasure_{ij} +$$

$$\sum \beta_x Control\ Variables + \ Reviewer\ Fixed\ Effects + \ \sum \beta_k Other\ Fixed\ Effects + \epsilon_{ij} \quad (2)$$

In this model, I replace firm fixed effects with reviewer fixed effects to examine within-reviewer differences on reviewing applications submitted by different firms.[30] The interaction term $Revolver \times ProximityMeasure_{ij}$ picks up how the association between review outcome and a revolver's review varies with proximity. I expect revolvers to be more lenient (dependent variable is *DirectApproval* or *lgAdvEvent*) and/or show more effort (dependent variable is *lgReviewTime*) for firms closer to their actual first employer or their alma mater. When the proximity variable measures the distance between the applicant firm and the revolver's actual first employer, only the subsample of revolvers is used, and the interaction term is dropped. Thus, β_1 is expected to be positive. When the proximity variable measures the distance between the applicant firm and the revolver's alma mater, β_1 indicates the association between non-revolver's review outcome and the proximity to their alma mater. Since non-revolvers do not have the incentive to send any signals to applicant firms, β_1 is expected to be insignificant. β_2 shows relative to non-revolvers, the differential review performance revolvers exhibit in the increase of proximity to their alma maters, and is expected to be positive.

I add a location fixed effect for geographic division[31] of the applicant firms. Other fixed effects remain the same as in equation (1). Drug application characteristics control variables are included. I also add three firm characteristic control variables in this model, *lgApplication*,

[30] To exclude potential confounding effects, I exclude the 32 observations that are associated with firms that hired their FDA reviewers.

[31] Based on Census Bureau Regions and Divisions: https://www2.census.gov/geo/docs/maps-data/maps/reg_div.txt

PublicFirm, and *RevolverHirer*. *lgApplication* is the natural logarithm of one plus the number of total new drug applications by a firm during the test period. It proxies a firm's R&D investment intensity and familiarity of the new drug application process. *PublicFirm* is a binary variable and equals 1 if a firm has ever been publicly listed. Firms that hired FDA revolvers may be systematically different from firms that never hired revolvers. *RevolverHirer* is a binary variable which equals 1 if the FDA applicant firm ever hired a former FDA reviewer during the test period. Standard errors are clustered by reviewer and geographic division.

This set of tests can also address the potential endogeneity concern. If examine revolvers' review performance towards their actual future employers, any omitted variable that varies with the employers and the review outcomes generates endogeneity issues. For example, reviewers can bias their review based on a firm's historic reputation or perceived image based on the reviewer's personal experience. Using the geographic proximity measures addresses such concerns as to bias the estimate, the omitted variables must vary with the geographic locations and review outcomes. Additionally, the proximity to reviewer's alma mater addresses potential reversal causality concern, as the alma mater's location is determined before the drug review occurs.

Revolving Door Incentives and Reviewer's Seniority

Reviewers choose the effective signal that can set them apart from their peers (Spence, 1973, 1974, 2002). Signaling costs are likely associated with reviewers' seniority which determines decision rights. To further examine whether and how seniority may affect FDA revolvers' choice of signals to industry firms, I augment equation (1) with the addition of an interaction term of *Revolver* and *Seniority*, and keep fixed effects and control variables the same as in equation (1):

$$Y_{ij} = \beta_0 + \beta_1 Revolver_i + \beta_2 Seniority_{ij} + \beta_3 Revolver \times Seniority +$$

$$\sum \beta_x Control\ Variables + Firm\ Fixed\ Effects + \sum \beta_k\ Other\ Fixed\ Effects + \epsilon_{ij} \quad (3)$$

A positive β_1 would indicate that, relative to junior non-revolvers, junior revolvers exhibit leniency (*DirectApproval* and *lgAdvEvent*) and/or exert more efforts (*lgReviewTime*) during the review process. β_1+β_2 shows whether senior revolvers exhibit differential review performance when compared to senior non-revolvers, and a positive sign suggests senior revolvers demonstrate leniency (*DirectApproval* and *lgAdvEvent*) and/or more efforts (*lgReviewTime*). Control variables and fixed effects and are the same as in equation (1).

The Consequences of Hiring a Revolver

Next, I investigate how hiring revolvers is associated with the subsequent new drug applications and the quality of these new drugs. Specifically, I test the impact of hiring former FDA reviewers: whether firms' chances of receiving direct approval on new drug applications increase, if review cycles (in terms of time) shorten, and if the number of adverse event report decrease. Following Jiang et al. (2018), I construct the variable, *RevolverExp(logged)*, at the firm-year level to measure the intensity of the FDA new drug application knowledge possessed by a firm through recruiting prior FDA reviewers. *RevolverExp(logged)* is computed as the natural logarithm of one plus the *RevolverExp*, where *RevolverExp* is the sum of past FDA new drug review experience (in months) of all revolving FDA reviewers who work for the pharmaceutical company during the year of the new drug submission. I use *application-level* data to investigate whether employing more prior FDA reviewers affects a firm's subsequent new drug application process and quality. The model is defined below.

$$Y_{fj} = \beta_0 + \beta_1 RevolverExp(logged)_{fj} + \sum \beta_j Control\ Variables + Firm\ Fixed\ Effects +$$

$$\sum \beta_k\ Other\ Fixed\ Effects + \epsilon_{fj} \quad (4)$$

FDA revolvers' institutional and technical knowledge, as well as influence ability, are expected to improve firms' subsequent new drug application review outcome and/or new drug quality. As discussed in section 3.2, β_1 is expected to be positive when the dependent variable is *DirectApproval* and/or negative when the dependent variable is *lgAdvEvent*. It is difficult to predict the sign of β_1 for *lgReviewTime*. In this estimating model, drug characteristics control variables are included. Fixed effects are the same as in equation (1). Standard errors are clustered by firm.

To further test whether hiring FDA revolvers with different seniority has different effects on the outcome of subsequent new drug applications and quality of these new drugs, I replace *RevolverExp(logged)* with two variables that measure the cumulative FDA review experience by seniority, *SeniorRevolverExp(logged)* and *JuniorRevolverExp(logged),* in equation (5).

$$Y_{fj} = \beta_0 + \beta_1 SeniorRevolverExp(logged)_{fj} + \beta_2 JuniorRevolverExp(logged)_{fj} + \sum \beta_j Control\ Variables + Firm\ Fixed\ Effects + \sum \beta_k\ Other\ Fixed\ Effects + \epsilon_{fj} \quad (5)$$

IV. RESULTS

Descriptive Statistics

Table 2.1 presents the descriptive statistics for the sample of reviewer-applications used in my analyses. The *reviewer-application-level* sample includes 7,352 observations. 77% of the observations are associated with direct-approved new drug applications. The average (median) review time is 489 (311) days and the average (median) adverse events received by a new drug throughout the test period is 2,674 (153), indicating that these two variables are right skewed due to the existence of few large values in the sample. 19% of the observations involve revolvers and 55% of the observations are associated with senior reviewers. The distance between the FDA applicant firm and the revolver's first pharmaceutical firm employer averages (median) at 1,686 (641) kilometers, and the distance between the FDA applicant firm and the reviewer's U.S. alma mater average (median) at 1,781 (992) kilometers.

Table 2.2 shows the descriptive statistics for the sample at the application level. This sample has 1,121 observations and 39% (440) of the applications were submitted by firms that later hired at least one former FDA reviewer (*RevolverHirer*). The average total revolver experience (in months) is 119.8, the average (median) total senior revolver experience (in months) is 30.86, and the average (median) total junior revolver experience (months) is 85.42.

Appendix C1 presents the summary statistics of the reviewer characteristics and Panel B shows the results of a *t*-test that the revolver group mean differs from the non-revolver group. From various perspectives, including FDA job seniority, FDA experience, gender, whether they received undergraduate education in the U.S., and the highest degree received, revolvers do not have significant differences from non-revolvers. These results show that FDA reviewers are welcome by the industry regardless of their backgrounds, implying that FDA new drug regulatory experience is highly valuable to firms.

Empirical Results

How Do Revolvers Signal to Prospective Industry Employers During the FDA Review Processes?

The results of model 1 are presented in Table 4.1 (columns 1-3 with controls and 4-6 without controls). The coefficient on *Revolver* is positive but insignificant when the dependent variable is *DirectApproval*. This finding suggests that (regarding the applications submitted by the same firm and compared with non-revolvers) FDA revolvers are *not* likely to alter the final decisions on the new drug applications to grant more direct approvals. FDA reviewers tend to exert more effort during the review process, manifested in spending significantly longer time on new drug applications compared to non-revolvers (Table 4.1 columns (2) and (5)). On average, relative to non-revolvers, revolvers spend about 15 days longer on reviewing the applications submitted by the same firm.[32] Furthermore, the new drugs reviewed and approved by revolvers are associated with lower quality, proxied by the significantly more post-market adverse event reports (Table 4.1 column (3) and (6)). This evidence suggests that revolvers demonstrate lax oversight during the new drug review process, resulting in lower quality drugs approved to be marketed. Taken together, results in Table 4.1 provide initial evidence that FDA revolvers show differential regulatory performance to applicant firms relative to non-revolvers.

Receiving direct approval on the application is highly desired by the applicant firms. Therefore, granting more direct approvals could serve as a strong signal to prospective industry employers. However, the final approval decision is made collectively by the review team thus could be difficult to be influenced by individual reviewers. Each reviewer is responsible for a specific aspect of the application package and reviewers have the discretion to determine the review recommendation of the part that they review. These could explain that although FDA

[32] Coefficient on *Revolver* is 0.029, corresponding to 2.9% increase of review time. The average review time is 489 days. 489*0.029 = 15 (days)

revolvers are not associated with higher likelihood of granting direct approvals to applications, they tend to relax the rigor of regulatory review. Such findings are consistent with the prediction based on the leniency effect. FDA revolvers also tend to spend more time on reviewing the new drug applications, consistent with a human capital effect. This finding is consistent with Lourie (2019), who finds that revolving door equity analysts show favoritism (leniency) to their future employers while they also issue more frequent reports (efforts) about their hiring of firms to gain visibility.

Next, I test whether revolvers strategically bias their regulatory review towards more attractive prospective employers. Table 5.1 presents the regression results on the proximity between FDA applicant firms to revolvers' first industry employer, *ProximityApptoHirer(logged)* (equation (2)). To facilitate interpretation, it is reversed by multiplying with -1. Therefore, the larger the value, the closer the firm is located to the revolver's first industry employer. As non-revolvers do not have industry employers, this test uses a subset of the full sample with only revolvers. Appendix D1 lists the distribution of FDA applicant firms by state, and Appendix D2 demonstrates the distribution for domestic firms. Out of the 452 FDA applicant firms, 391 firms are in the U.S. and distribute across 35 states. Some states are heavily represented, including California and New Jersey, each has over 70 applicant firms. To minimize the confounding effect, I exclude the 32 observations associated with firms that hired their reviewers (Tabakovic & Wollman 2018).

Results are consistent with my main results and expectations around proximity. Table 5.1 column (1) and (4) show that revolvers are not associated with higher likelihood of granting direct approvals regardless of the proximity of FDA applicant to their first industry hirers. The coefficients on *ProximityApptoHirer(logged)* are positive and significant when the dependent

variables are *lgReviewTime* and *lgAdvEvent*; when the FDA applicant firms are in closer proximity to revolvers' preferred locations, FDA revolvers are more likely to demonstrate additional efforts on reviewing the applications. Although the new drug applications submitted by more closely located firms do not have higher chances to receive direct approvals from revolvers, these new drugs have more adverse events reported afterwards, suggesting leniency from revolvers during the review process. The result on *lgReviewTime* also rules out the alternative interpretation that review time simply reflects reviewers' ability instead of effort (i.e., lower-ability reviewers would need longer to review an application). If the latter was the case, review time would not systematically vary with firm's proximity to the revolver's preferred work location.

Table 6.1 shows the results on the second proxy of revolvers' preferred work locations – proximity to their first U.S. post-secondary alma mater. I augment equation (2) with *ProximityApptoEdu(logged)* as the variable of interest. Appendix E1 lists the distribution of reviewers' U.S. alma maters by state, and Appendix E2 virtually demonstrates the distribution. I was able to track the educational background of the 669 reviewers out of the total of 724. Their first post-secondary U.S. alma maters are more widely distributed than the FDA applicant firms, across 43 states. California, Maryland, New York, and Virginia are the four states with 40 or more reviewers' alma maters.

I include reviewer fixed effect in all estimating models to account for reviewer specific factors that do not change over time. Therefore, the main effect of *Revolver* is absorbed by this fixed effect. Non-resolvers do not demonstrate differential reviewing behavior towards firms located in different proximity to their U.S. alma mater, as the coefficients on *ProximityApptoEdu(logged)* are insignificant across three dependent variables (columns (4) to (6)). This evidence rules out the alternative explanation that reviewers bias their reviews due to

emotional attachment - to support or interact more with firms located closer to their alma maters. Consistent with the results from prior tests, the coefficients on the interaction term are insignificant for *DirectApproval*, suggesting that compared to non-revolvers, revolvers do not have differential likelihood of issuing direct approvals to prospective employers. The significant positive coefficients on *Revolver* × *ProximityApptoEdu(logged)* when the dependent variables are *lgReviewTime* and *lgAdvEvent* show that, relative to non-revolvers, revolvers show extra efforts and leniency when reviewing applications from firms in closer proximity to their preferred work-locations.

Taken together, the results from the two sets of tests on firms' proximity to revolvers' preferred geographic locations provide evidence that revolvers systematically bias their new drug regulatory review towards the firms that are more attractive as future employers. Most of existing revolving door studies show that revolvers bias towards their future (actual) employers (Cornaggia et al. 2016; Tabakovic and Wollmann 2018; Lourie 2019; Kempf 2020), with the exception of Tabakovic and Wollmann (2018) which shows that this bias spills over to more appealing firms. My findings are consistent with Tabakovic and Wollmann (2018), indicating that FDA revolvers selectively signal to a set of firms that are more attractive to them.

Next, I investigate whether revolvers with different seniority signal differently to industry firms. Results of equation (3) are presented in Table 8.1. The one coefficient on *Revolver* that is significant across three dependent variables is in column (2), where the dependent variable is *lgReviewTime*. The coefficients on *Revolver* are insignificant in columns (1) and (3). These findings suggest that, relative to junior non-revolvers, junior revolvers signal to industry firms by exerting additional efforts during the review process only. Junior revolvers are not associated with leniency behavior such as granting more direct approvals or lax oversight during the review. The

sum of the coefficients for *Revolver* and *Revolver* × *Seniority* is insignificant for *lgReviewTime* ($p > 0.10$), indicating that senior revolvers do not spend more time on reviewing the applications compared to senior non-revolvers. In addition, the sum of the coefficients on *Revolver* and *Revolver* × *Seniority* is positive and significant for *lgAdvEvent* ($p = 0.02$). This finding suggests that, relative to senior non-revolvers, senior revolvers are more likely to reduce the rigor during the review process. As a result, drugs with lower quality pass the examination.

These findings indicate that junior revolvers signal to industry firms by exerting more effort, which is consistent with human capital effect. Senior revolvers, on the other hand, do not exert mores efforts during the review process. Instead, they signal to industry firms by demonstrating leniency during the review which results in lower quality new drugs, consistent with leniency effect. Scant revolving door studies differentiate the biasing behavior by revolvers' seniority. Kempf (2020) briefly compares the sensitivity of being hired by an investment bank to credit rating analyst's performance between junior and senior analysts. My findings suggest that revolvers could choose different signals to industry firms during the regulatory process based on the signaling costs (e.g., decision power, available time).

How is Hiring Revolvers Associated with Subsequent New Drug Applications and Quality of These New Drugs?

Next, I examine whether the regulatory employee's employment by the pharmaceutical firms is associated with subsequent new drug applications and product quality of the employers. Table 8.1 presents the regression results of equation (4) without (column (1) to (3)) and with full set of control variables (column (4) to (6)). In columns (2) and (5), the coefficients on *RevolverExp(logged)* are insignificant, suggesting that hiring FDA revolvers does not impact the review cycles. In columns (1) and (4), the coefficients on *RevolverExp(logged)* are positive and

significant, suggesting that having more FDA new drug regulatory experience could be beneficial on increasing the likelihood of receiving direct approvals on subsequent new drugs. Meanwhile, in columns (3) and (6), the coefficients on *RevolverExp(logged)* are negative and significant, suggesting that FDA revolvers' expertise is associated with better compliance with the FDA new drug regulation. Therefore, their industry employers see improved new drug quality, which is manifested in reduced post-market adverse events. These findings indicate that hiring former FDA reviewers could help firms better navigate the drug application process and achieve a more favorable application outcome.[33]

To further investigate whether hiring former FDA reviewers with different seniority is associated with differential *ex-post* effects, I conduct the following test: Table 9.1 shows the results of estimating model (5). Coefficient on *SeniorRevolverExp(logged)* is positive and significant in column (1), while coefficients on *SeniorRevolverExp(logged)* are insignificant in columns (2) and (3). These findings show that post-revolving, more FDA senior reviewer experience is associated with higher likelihood to gain direct approvals for the firm's subsequent new drug applications. Nevertheless, senior reviewer experience is not associated with review time change or significant subsequent product quality improvement.[34] Acquiring more junior reviewer experience is associated with improved subsequent new drug quality, manifested in significantly fewer post-market adverse events (column (3)). However, junior reviewer experience does not seem to be related with direct approvals or length of review cycle. Taking these results together, hiring junior and senior FDA revolvers has differential impacts on industry firms' subsequent new drug

[33] An alternative way to interpret the increased likelihood of direct approvals on subsequent new drug applications is that FDA revolvers could influence the FDA decision making on these new drugs. However, in my tests, there is no evidence to justify this alternative explanation.

[34] It is noteworthy to mention that although the coefficients are insignificant on *SeniorRevolverExp(logged)* for *lgReviewTime* ($p < 0.20$) and *lgAdvEvent* ($p < 0.15$) in my tests, the negative sign on these two coefficients imply that senior FDA revolvers could also impact review cycle and drug quality.

application and product quality. Senior revolvers are more likely to facilitate firms receiving direct approvals through better navigating of the review process, evidenced by an increased likelihood of direct approval without significant improvement of drug quality. Junior revolvers tend to benefit their employers by utilizing their technical knowledge and skills to enhance the new drug quality, evidenced by decreased adverse event reports of subsequent new drugs. Overall, hiring former FDA reviewers is associated with favorable effects to the hiring firms and evidence from my tests suggests such personnel flow reduces the information asymmetry between the FDA and the regulated firms.

Robustness Tests

Although I winsorize the two proximity measures at 99% in my tests, to further ensure that my results in Table 5.1 and Table 6.1 are not driven by the extreme values in these two variables, I categorize *ProximityApptoHirer(logged)* and *ProximityApptoEdu(logged)* into 5 quantiles, and re-estimate the results in Table 5.1 and 6.1 using equation (2). Table 10.1 presents the regression results, and they are consistent with the findings reported in Table 5.1 and 6.1. These findings suggest that the results of FDA revolvers systematically bias their regulatory oversight towards more appealing potential employers are not driven by extreme distance values in the sample.

In the application-level sample, less than 40% of the observations are associated with the firms that ever hired any FDA revolvers, leaving no variation in the variable of interest for more than half of the observations. To mitigate the possible bias on the estimation of equation (4) and (5), I use the subsample of firms that hired at least one FDA revolver during the test period and re-estimate the results in Table 8.1 and 9.1. Table 11.1 presents the results from this test, and they are largely consistent with Table 8.1 and 9.1. Results from this test provide additional confidence in my findings on the FDA revolving door consequences after revolvers joined the industry.

Among the 724 FDA drug reviewers in my sample, 88 received internal promotion during the test period. To disentangle the potential cofounding effect of internal promotion opportunities on review behavior, I exclude the reviewers who were promoted to a higher rank in my sample and re-run the main tests. Results still hold qualitatively and quantitatively (Table 12.1-15.1).

V. CONCLUSION

In this study, I examine the consequences of the FDA revolving door, which refers to the practice of pharmaceutical firms hiring former FDA new drug reviewers. Exploiting the manually collected data that link FDA reviewer career paths and the new drug application they reviewed, I examine both pre- and post-revolving consequences. My study therefore provides a comprehensive picture of the effects of the FDA revolving door. My results show that motivated by *ex-post* industry employment, FDA revolvers demonstrate both effort and leniency towards industry firms. Specifically, revolvers bias their regulatory review towards a set of more attractive prospective employers – those located in closer proximity to revolvers' preferred location (proxied by first industry employer location and prior alma mater location). I further find that senior revolvers are likely to reduce the rigor of the review process, while junior revolvers demonstrate more efforts in reviewing drug applications. This finding suggests that signaling costs differ across revolvers with different seniority, indicating their intentional selection of different signals. Moving on to the post-revolving stage, I find that hiring former-FDA reviewers is positively associated with subsequent new drug application outcome and improved new drug quality. Specifically, more senior reviewer experience is positively associated with direct approvals, while more junior reviewer experience is associated with improved subsequent new drug quality. These findings suggest that the differential qualifications associated with revolvers' seniority are properly materialized by the employers.

The importance of my study lies on documenting the prevalence of the FDA revolving door phenomenon and showing that *ex ante*, revolvers exhibit differential review behavior, and *ex post*, former FDA reviewer experience could help firms better comply with the FDA. My research provides rich evidence that the net effects of FDA revolving doors are not as straightforward as

perceived by the public. My study also speaks to input-based management control design. Firms can consider integrating control mechanisms that could better track, infer, and utilize informative signals into their employee selection strategy for a more effective talent matching. Further, extensive studies have focused on the design of MCS instruments to incentivize goal congruent actions of employees. My study suggests that organizations could utilize appropriate MCS to influence the behavior of important stakeholders even those not within the organization, e.g., potential employees.

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APPENDIX A1: EXAMPLE OF THE FDA NEW DRUG APPROVAL INFORMATION

Figure A1: Example of The FDA New Drug Approval Information

Original NDA and Original BLA Approvals
July 2012

This report includes NDAs [including NDAs for new molecular entities (NMEs)] and BLAs (including new biological products) approved for the first time during the selected month. Original BLA/NDA approvals by CBER are ***not*** included in Drugs@FDA. This report does not include approved NDA or BLA supplements, approved ANDAs, or tentatively approved ANDAs/NDAs.

Click on the Drug Name and Application Number to see information about the drug (for example, regulatory history, labeling, reviews by FDA staff).

This report was produced on July 27, 2022.

Month: July Year: 2012 Search

< Previous Month Next Month >

CSV Excel Print

Approval Date	Drug Name	Active Ingredients	Submission Classification	Review Priority	Company
07/11/2012	XIMINO NDA #201922	MINOCYCLINE HYDROCHLORIDE	Type 3 - New Dosage Form	Standard	JOURNEY
07/16/2012	PREPOPIK NDA #202535	CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE	Type 1 - New Molecular Entity	Standard	FERRING PHARMS INC
07/17/2012	QSYMIA NDA #022580	PHENTERMINE HYDROCHLORIDE; TOPIRAMATE	Type 4 - New Combination	Standard	VIVUS
07/20/2012	KYPROLIS NDA #202714	CARFILZOMIB	Type 1 - New Molecular Entity	Standard	ONYX THERAP
07/23/2012	TUDORZA PRESSAIR NDA #202450	ACLIDINIUM BROMIDE	Type 1 - New Molecular Entity	Standard	COVIS
07/26/2012	RAYOS NDA #202020	PREDNISONE	Type 3 - New Dosage Form	Standard	HORIZON
07/26/2012	VASCEPA NDA #202057	ICOSAPENT ETHYL	Type 5 - New Formulation or New Manufacturer	Standard	AMARIN PHARMS

APPENDIX A2: EXAMPLE OF FDA REVIEWER LIST

Figure A2: Example of FDA Reviewer List

CDTL and Summary Review for Regulatory Action

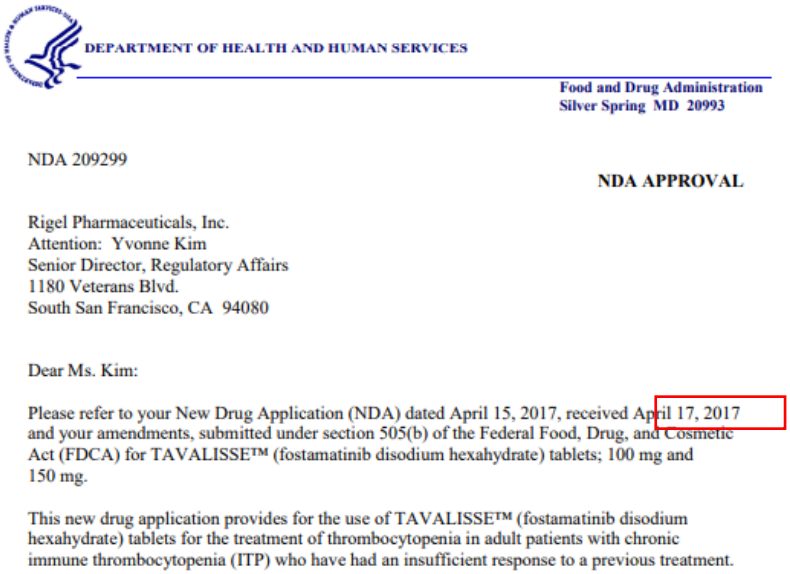
Date	15 July 2015
From	Jill A Lindstrom, MD
Subject	CDTL and Acting Deputy Division Director Summary Review
NDA #	207917
Applicant Name	Galderma Research and Development, LLC
Date of Submission	17 September 2014
PDUFA Goal Date	17 July 2015
Proprietary Name / Established (USAN) Name	Epiduo Forte Adapalene and benzoyl peroxide
Dosage Forms / Strength	Gel, 0.3%/2.5%
Proposed Indication(s)	Topical treatment of acne vulgaris
Action	*Approval*

Material Reviewed/Consulted OND Action Package, including:	**Names of discipline reviewers**
Medical Officer Review	Jane Liedtka, MD
Statistical Review	Matthew Guerra, PhD
Pharmacology Toxicology Review	Kumar Mainingi, PhD
CMC Review	Gene Holbert, PhD
CMC Microbiology	Erika Pfeiler, PhD
Clinical Pharmacology Review	Chinmay Shukla, PhD
DPP	Melinda McLawhorn
OSE/DMEPA	Carlos Mena-Grillasca, RPh
PLT	Nathan Caulk, MS BSN RN

OND=Office of New Drugs
DPP=Division of Professional Promotion (formerly part of Division of Drug Marketing, Advertising and Communication)
OSE= Office of Surveillance and Epidemiology
DMEPA=Division of Medication Error Prevention and Analysis
PLT=Patient Labeling Team (formerly part of DRISK)

APPENDIX A3: EXAMPLE OF AN APPROVAL LETTER

Figure A3: Example of an Approval Letter



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209299

NDA APPROVAL

Rigel Pharmaceuticals, Inc.
Attention: Yvonne Kim
Senior Director, Regulatory Affairs
1180 Veterans Blvd.
South San Francisco, CA 94080

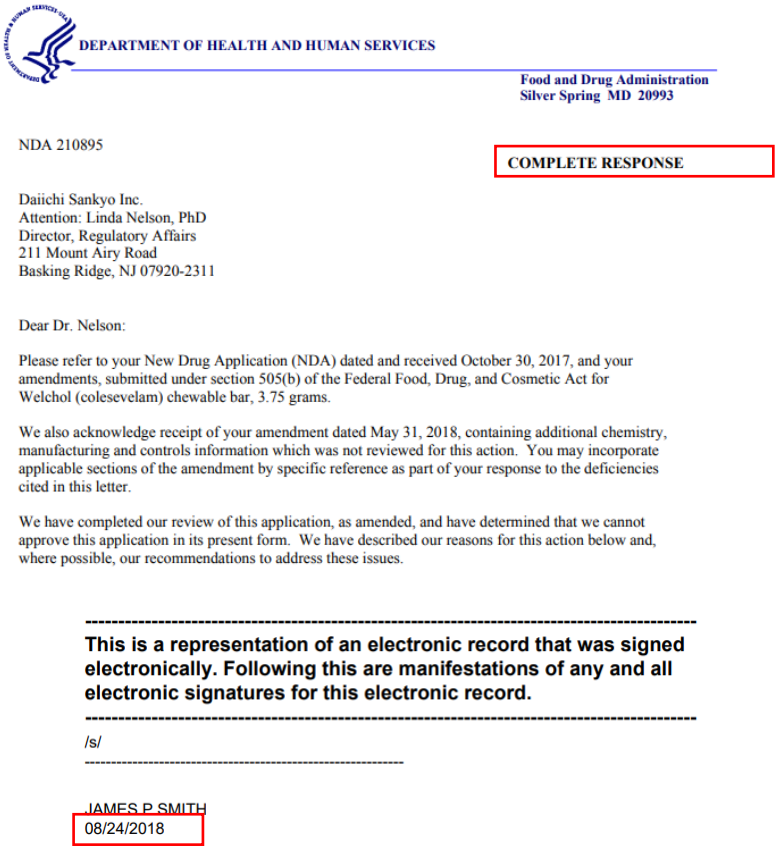
Dear Ms. Kim:

Please refer to your New Drug Application (NDA) dated April 15, 2017, received April 17, 2017 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TAVALISSE™ (fostamatinib disodium hexahydrate) tablets; 100 mg and 150 mg.

This new drug application provides for the use of TAVALISSE™ (fostamatinib disodium hexahydrate) tablets for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

APPENDIX A4: EXAMPLE OF COMPLETE RESPONSE LETTER (DENIAL)

Figure A4: Example of Complete Response Letter (Denial)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 210895

COMPLETE RESPONSE

Daiichi Sankyo Inc.
Attention: Linda Nelson, PhD
Director, Regulatory Affairs
211 Mount Airy Road
Basking Ridge, NJ 07920-2311

Dear Dr. Nelson:

Please refer to your New Drug Application (NDA) dated and received October 30, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Welchol (colesevelam) chewable bar, 3.75 grams.

We also acknowledge receipt of your amendment dated May 31, 2018, containing additional chemistry, manufacturing and controls information which was not reviewed for this action. You may incorporate applicable sections of the amendment by specific reference as part of your response to the deficiencies cited in this letter.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JAMES P SMITH
08/24/2018

APPENDIX B1: VARIABLE DESCRIPTION

Table B1: Variable Description

Variables	Description
Dependent Variables	
DirectApproval	Indicator variable that equals 1 if an application was *direclty* approved (i.e., without any rejection).
lgReviewTime	The natural logarithm of the number of days between the first submission date and the final approval of a new drug application. Winsorized at 1% and 99%.
lgAdvEvent	The natural logarithm of one plus the number of adverse events reported as of 12/31/2019 for a drug. Winsorized at 1% and 99%.
Explanatory Variables	
Revolver	Indicator variable that equals 1 if an FDA reviewer left the FDA and was hired by an FDA new drug applicant (company).
ProximityApptoHirer(logged)	-1 mutiplies the natural logarithm of one plus the distance (in kilometers) between the FDA applicant (*DistanceApptoHirer*) and the revolver's first pharmaceutical firm employer. Winsorized at 99%.
ProximityApptoEdu(logged)	-1 mutiplies the natural logarithm of one plus the distance (in kilometers) between the FDA applicant (*DistanceApptoEdu*) and the revolver's first U.S. post-secondary school. Winsorized at 99%.
RevolverExp(logged)	The natural logarithm of one plus the RevolverExp, where RevolverExp is the sum of past FDA new drug review experience (in months) of all revolving FDA reviewers who work for the pharmaceutical company during the year of new drug submissions.
Seniority	Indicator variable equals 1 if a reviewer has a senior job title such as "chief," "director," "manager," "team lead," "supervisor."

Table B1 (cont'd)

Variables	Description
Explanatory Variables (cont'd)	
SeniorRevolverExp(logged)	The natural logarithm of one plus the SeniorRevolverExp, where SeniorRevolverExp is the sum of past FDA new drug review experience (in months) of all revolving FDA reviewers who work for the pharmaceutical company during the year of new drug submissions and previously held senior job titles. I define senior FDA reviewers as reviewers with the job title such as "chief," "director," "manager," "team lead," "supervisor."
JuniorRevolverExp(logged)	The natural logarithm of one plus the JuniorRevolverExp, where JuniorRevolverExp is the sum of past FDA new drug review experience (in months) of all revolving FDA reviewers who work for the pharmaceutical company during the year of new drug submissions and previously held junior job titles. I define junior FDA reviewers as reviewers with the job title such as "reviewer," "evaluator," "staff."

Table B1 (cont'd)

Variables	Description
Control Variables and Fixed Effects	
Year	Year a new drug application is approved.
Submission Category	Submission classification for an application: 0 - BLA New biologic product 1 - Type 1 New molecular entity 2 - Type 1/4 Type 1, New molecular entity, and Type 4, New combination 3 - Type 2 New active ingredient 4 - Type 2/3 Type 2, New active ingredient, and Type 3, New dosage form 5 - Type 2/4 Type 2, New active ingredient and Type 4, New combination 6 - Type 3 New dosage form 7 - Type 3/4 Type 3, New Dosage Form, and Type 4, New combination 8 - Type 4 New combination 9 - Type 5 New formulation or other differences 10 - Type 6 New indication or claim, same applicant 11 - Type 7 Previously marketed but without an approved NDA 12 - Type 8 Rx to OTC 13 - Type 9 New indication or claim, drug not to be marketed under type 9 NDA after approval 14 - Type 10 New indication or claim, drug to be marketed under type 10 NDA after approval
Orphan	Indicator variable which equals 1 if a new drug has an orphan designation from the FDA. A drug that is intended to prevent, diagnose or treat a rare disease or condition can be granted orphan designation. Companies develop an orphan drug receive financial incentives such as tax credits, exemption from user fees, and a potential seven years of market exclusivity after approval.

Table B1 (cont'd)

Variables	Description
Control Variables and Fixed Effects	
FastTrack	Indicator variable which equals 1 if a new drug receives a fast track designation from the FDA. A drug that is intended to treat serious conditions and fill an unmet medical need can request fast track to facilitate the development and expedite the review process.
Breakthrough	Indicator variable which equals 1 if a new drug receives a breakthrough therapy designation from the FDA. A drug that is intended to treat a serious condition and has preliminary clinical evidence showing that it has substantial improvement over existing therapy can request breakthrough therapy designation to expedite the development and review process.

Table B1 (cont'd)

Variables	Description
Accelerated	Indicator variable which equals 1 if a new drug receives the accelerated approval designation from the FDA. A drug that is intended to treat serious conditions and fill an unmet medical need can request accelerated approval designation to use surrogate endpoint as clinical evidence for review.
Priority	Indicator variable which equals 1 if a new drug application has a priority designation for the review process. There are two routes of application processing: standard and priority. This is an indicator variable that equals 1 if an application was submitted with priority processing. The timeline goal set up for the FDA to complete the review and issue an official action letter of the agency's decision is within 6 months of receipt for priority review, and 10 months for standard review.
lgBeneficiary	The natural logarithm of number of total beneficiaries of a drug reported under Medicare Part D Plan between 2013 and 2019.
USUndergrad	Indicator variable which equals 1 if a reviewer received undergraduate education in the U.S.
Tenure	The number of years of FDA experience a reviewer has up to the current year.
Male	Indicator variable which equals 1 if a reviewer is a male.
PHD	Indicator variable which equals 1 if a reviewer has a PhD degree.
MD	Indicator variable which equals 1 if a reviewer has a MD degree.
PHARMD	Indicator variable which equals 1 if a reviewer has a PharmD degree.
RevolverHirer	Indicator variable equals 1 if a firm ever hired a former FDA reviewer between 2009 and 2019.
lgApplication	The natural logarithm of one plus the number of total new drug applications by a firm between 2009 and 2019.
PublicFirm	Indicator variable equals 1 if a firm is or was publicly listed.
Review Team Size	The number of reviewers in a review team for a new drug application by 4 quantiles.
# of Rejection	Number of rejections an application has received between initial submission and final approval.

APPENDIX C1: SUMMARY STATISTICS OF REVOLVERS AND NON-REVOLVERS

Table C1: Summary Statistics of Revolvers and Non-Revolvers

Variables	N	Mean	Std. Dev.	P25	Median	p75
Seniority	724	0.27	0.45	0	0	1
USUndergrad	669	0.64	0.48	0	1	1
TenureMost	724	7.87	5.64	4	6	10
Male	724	0.49	0.50	0	0	1
BS	724	0.01	0.12	0	0	0
MS	724	0.08	0.27	0	0	0
MD	724	0.13	0.33	0	0	0
PHARMD	724	0.16	0.37	0	0	0
PHD	724	0.62	0.49	0	1	1

Notes: *Seniority* is a binary variable, which equals 1 if the reviewer's highest job title with the FDA is "chief," "director," "manager," "team lead," or "supervisor." *USUndergrad* is a binary variable, which equals 1 if the reviewer received his/her undergraduate education in the U.S. *TenureMost* is the number of years of FDA experience a reviewer has as of the end of the test period. Male is a binary variable, which equals 1 if the reviewer is a male. *BS, MS, MD, PHARMD,* and *PHD* are all indicator variables, which equal 1 if the reviewer's highest educational degree is such.

APPENDIX C2: DIFFERENCES BETWEEN REVOLVERS AND NON-REVOLVERS

Table C2: Differences Between Revolvers and Non-Revolvers

	Revolver (n=142)	Non-Revolver (n=582)	t-Stat of Difference
Seniority	0.26	0.27	-0.34
USUndergrad	0.65	0.64	0.18
TenureMost	7.25	8.02	-1.47
Male	0.52	0.48	0.93
BS	0.02	0.01	0.83
MS	0.08	0.08	0.22
MD	0.16	0.12	1.39
PHARMD	0.16	0.16	0.11
PHD	0.57	0.63	-1.36

Notes: This table presents the results of a *t-test* that compares means of revolvers and non-revolvers. Revolvers are those worked with the FDA but left and joined a pharmaceutical company that submitted at least one new drug application during the test period. Non-revolvers are those stayed with the FDA or left for other organizations.

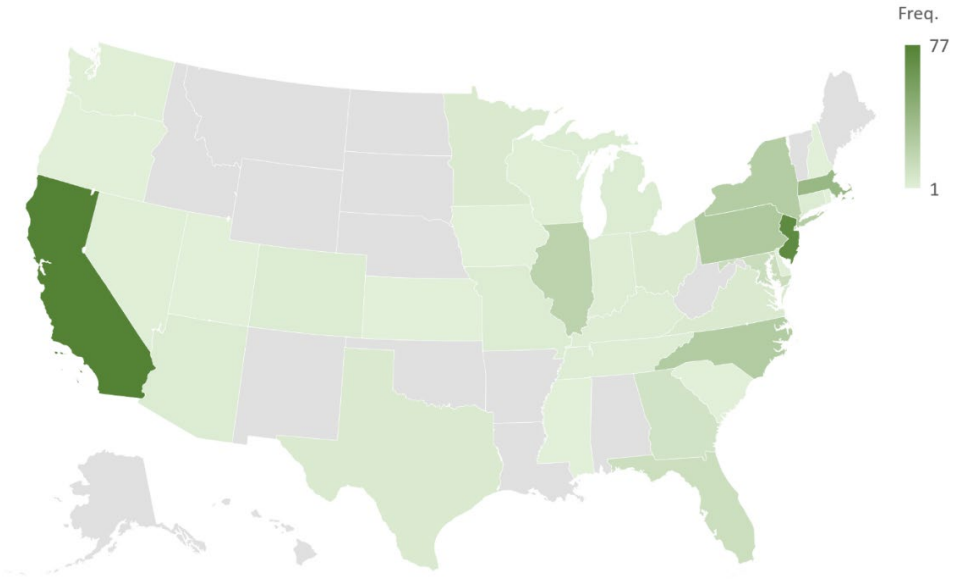
APPENDIX D1: STATE LOCATION OF FDA APPLICANT FIRMS

Table D1: State Location of FDA Applicant Firms

State	Freq.	Percent	Cum.
AZ	4	0.88	0.88
CA	77	17.04	17.92
CO	4	0.88	18.81
CT	4	0.88	19.69
DC	1	0.22	19.91
DE	2	0.44	20.35
FL	13	2.88	23.23
GA	10	2.21	25.44
IA	1	0.22	25.66
IL	21	4.65	30.31
IN	3	0.66	30.97
KS	1	0.22	31.19
KY	3	0.66	31.86
MA	40	8.85	40.71
MD	14	3.10	43.81
MI	4	0.88	44.69
MN	5	1.11	45.80
MO	4	0.88	46.68
MS	1	0.22	46.90
NC	26	5.75	52.65
NH	1	0.22	52.88
NJ	71	15.71	68.58
NV	2	0.44	69.03
NY	25	5.53	74.56
OH	5	1.11	75.66
OR	1	0.22	75.88
PA	28	6.19	82.08
RI	1	0.22	82.30
SC	1	0.22	82.52
TN	3	0.66	83.19
TX	5	1.11	84.29
UT	1	0.22	84.51
VA	5	1.11	85.62
WA	2	0.44	86.06
WI	2	0.44	86.50
Int'l	61	13.50	100.00
Total	452	100	

APPENDIX D2: DISTRIBUTION OF FDA APPLICANT FIRMS

Figure D2: Distribution of FDA Applicant Firms



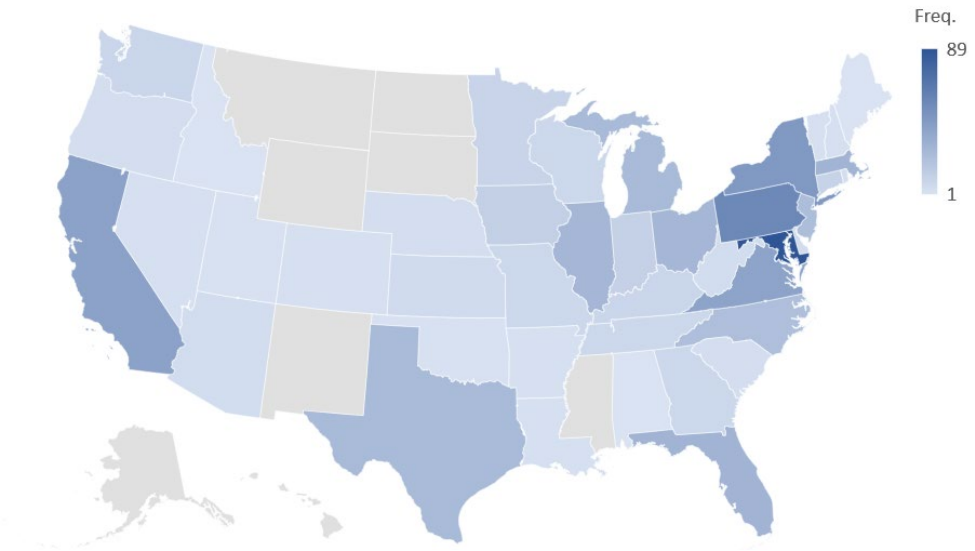
APPENDIX E1: STATE LOCATION OF FDA REVIEWERS' U.S. ALMA MATERS

Table E1: State Location of FDA Reviewers' U.S. Alma Maters

State	Freq.	Percent	Cum.
AL	1	0.15	0.15
AR	3	0.45	0.60
AZ	5	0.75	1.35
CA	41	6.13	7.47
CO	3	0.45	7.92
CT	11	1.64	9.57
DC	22	3.29	12.86
DE	5	0.75	13.60
FL	30	4.48	18.09
GA	8	1.20	19.28
IA	13	1.94	21.23
ID	1	0.15	21.38
IL	28	4.19	25.56
IN	12	1.79	27.35
KS	6	0.90	28.25
KY	9	1.35	29.60
LA	3	0.45	30.04
MA	30	4.48	34.53
MD	89	13.30	47.83
ME	1	0.15	47.98
MI	26	3.89	51.87
MN	10	1.49	53.36
MN	10	1.49	53.36
MO	8	1.20	54.56
NC	23	3.44	58.00
NE	4	0.60	58.59
NH	3	0.45	59.04
NJ	24	3.59	62.63
NV	3	0.45	63.08
NY	47	7.03	70.10
OH	28	4.19	74.29
OK	2	0.30	74.59
OR	4	0.60	75.19
PA	57	8.52	83.71
RI	4	0.60	84.30
SC	4	0.60	84.90
TN	8	1.20	86.10
TX	26	3.89	89.99
UT	2	0.30	90.28
VA	40	5.98	96.26
VT	3	0.45	96.71
WA	9	1.35	98.06
WI	8	1.20	99.25
WV	5	0.75	100.00
Total	669	100%	

APPENDIX E2: DISTRIBUTION OF FDA REVIEWERS' U.S. ALMA MATERS

Figure E2: Distribution of FDA Reviewers' U.S. Alma Maters



Tables

Table 1.1: Descriptive Summary of Sample, 2009-2019

	Number
Number of FDA Applicants (Companies)	452
Number of FDA Applicants Reviewed by Revolver(s)	308
Number of FDA Reviewers	724
Number of Revolvers (FDA to Pharmaceutical Industry)	142
Number of New Drug Applications	1,121
Number (median) of Revolvers per Drug Application	1
Number of Application Reviewed by Only Non-revolvers	426
Number of FDA Applications Reviewed by Revolver(s)	695

Table 1.2: Distribution of Application Reviewed per Reviewer

	Revolver			Non-Revolver		
# Application Reviewed	Freq.	Percent	Cum.%	Freq.	Percent	Cum.%
1	26	18.31	18.31	119	20.45	20.45
2-5	61	42.96	61.27	204	35.06	55.50
6-10	22	15.50	76.76	109	18.74	74.23
11-20	17	11.96	88.73	70	12.03	86.25
21-50	9	6.31	95.07	61	10.48	96.74
>50	7	4.92	100	19	3.23	100
Total	142	100%		582	100%	

Table 1.3: Distribution of Application Submitted per Firm

	Application Level			Reviewer-Application Level		
# Application Submitted	Freq.	Percent	Cum.%	Freq.	Percent	Cum.%
1	285	63.05	25.42	1,719	23.38	23.38
2-5	342	30.51	55.93	2,115	28.77	52.15
6-10	123	10.98	66.90	802	10.91	63.06
11-15	74	6.60	73.51	512	6.96	70.02
16-20	144	12.85	86.35	1,059	14.41	84.43
>20	153	13.66	100	1,145	15.57	100
Total	1,121	100%		7,352	100%	

Table 2.1: Summary Statistics - Reviewer-Application Level Sample

	N	Mean	Std. Dev.	p25	Median	p75
DirectApproval	7352	0.77	0.42	1.00	1.00	1.00
ReviewTime (in days)	7352	489	501	272	311	463
lgReviewTime	7352	5.93	0.64	5.61	5.74	6.14
AdvEvent (count)	7352	2,674	7,996	5	153	1,326
lgAdvEvent	7352	4.68	3.18	1.79	5.04	7.19
Revolver	7352	0.19	0.39	0.00	0.00	0.00
DistanceApptoHirer (in km)	1364	1,686	2,220	140	641	3,546
ProximityApptoHirer(logged)	1364	-6.19	1.96	-8.17	-6.46	-4.95
DistanceApptoEdu (in km)	6842	1,781	2,124	366	992	2,638
ProximityApptoEdu(logged)	6842	-6.78	1.32	-7.88	-6.90	-5.90
Seniority	7352	0.55	0.50	0.00	1.00	1.00
Orphan	7352	0.26	0.44	0.00	0.00	1.00
FastTrack	7352	0.18	0.38	0.00	0.00	0.00
Breakthrough	7352	0.10	0.30	0.00	0.00	0.00
Accelerated	7352	0.08	0.27	0.00	0.00	0.00
Priority	7352	0.34	0.47	0.00	0.00	1.00
AdvisoryCom	7352	0.14	0.35	0.00	0.00	1.00
lgBeneficiary	6221	8.10	3.46	5.80	8.17	10.54
USUndergrad	6842	0.64	0.48	0.00	1.00	1.00
Tenure	7352	8.88	5.95	4.00	7.00	12.00
Male	7352	0.51	0.50	0.00	1.00	1.00
PHD	7352	0.58	0.49	0.00	1.00	1.00
MD	7352	0.12	0.33	0.00	0.00	0.00
PHARMD	7352	0.21	0.41	0.00	0.00	0.00
PublicFirm	7352	0.66	0.47	0.00	1.00	1.00
Application	7352	10.37	11.46	2.00	5.00	17.00
RevolverHirer	7352	0.46	0.50	0.00	0.00	1.00
lgApplication	7352	1.64	1.26	0.69	1.61	2.83
Year	7352	2015	3	2012	2015	2017
Submission Classification	7352	4.57	4.21	1.00	2.00	9.00
Review Team Size	7352	2.90	1.04	2.00	3.00	4.00
# of Rejection	7352	0.30	0.60	0.00	0.00	0.00

Notes: Table 2 Panel A presents means, standard deviations, 25%, median, and 75% values for variables used in tests of pre-revolving effects on FDA reviewers' review performance.

Table 2.2: Summary Statistics - Application Level Sample

	N	Mean	Std. Dev.	p25	Median	p75
DirectApproval	1121	0.75	0.43	1.00	1.00	1.00
lgReviewTime	1121	5.96	0.66	5.68	5.73	6.24
lgAdvEvent	1121	4.13	2.94	1.39	4.38	6.27
RevolverExp (in months)	1121	119.80	360.88	0.00	0.00	52.00
RevolverExp(logged)	1121	1.46	2.51	0.00	0.00	3.97
SeniorRevolverExp (in months)	1121	30.86	105.67	0.00	0.00	0.00
SeniorRevolverExp(logged)	1121	0.62	1.74	0.00	0.00	0.00
JuniorRevolverExp (in months)	1121	85.42	279.99	0.00	0.00	0.00
JuniorRevolverExp(logged)	1121	1.27	2.32	0.00	0.00	0.00
Orphan	1121	0.22	0.42	0.00	0.00	0.00
FastTrack	1121	0.14	0.35	0.00	0.00	0.00
Breakthrough	1121	0.07	0.26	0.00	0.00	0.00
Accelerated	1121	0.05	0.23	0.00	0.00	0.00
Priority	1121	0.29	0.45	0.00	0.00	1.00
AdvisoryCom	1121	0.11	0.31	0.00	0.00	1.00
lgBeneficiary	931	8.26	3.52	5.89	8.36	10.68
RevolverHirer	1121	0.39	0.49	0.00	0.00	1.00
Year	1121	2014	3	2011	2014	2017
Submission Classification	1121	5.43	4.17	1.00	7.00	10.00
Review Team Size	1121	2.35	1.11	1.00	2.00	3.00
# of Rejection	1121	0.32	0.63	0.00	0.00	1.00

Notes: Table 2 Panel B presents means, standard deviations, 25%, median, and 75% values for variables used in tests of post-revolving effects on firms' subsequent new drug applications and product quality.

Table 3.1: Pairwise Correlations Matrix - Reviewer-application level sample

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
(1) DirectApproval	1								
(2) lgReviewTime	-0.717*	1							
(3) lgAdvEvent	-0.020	-0.020	1						
(4) Revolver	-0.023	0.033*	0.103*	1					
(5) ProximityApptoHirer(log)	0.089*	-0.033	0.144*	.	1				
(6) ProximityApptoEdu(log)	0.006	0.010	0.027*	-0.025*	0.388*	1			
(7) Seniority	-0.043*	0.039*	0.035*	0.014	0.021	-0.018	1		
(8) Orphan	0.147*	-0.246*	0.060*	-0.053*	0.017	-0.055*	-0.022	1	
(9) FastTrack	0.143*	-0.252*	0.026*	-0.018	-0.019	-0.026*	-0.039*	0.324*	1
(10) Breakthrough	0.178*	-0.313*	-0.023	-0.029*	-0.015	-0.056*	-0.064*	0.294*	0.239*
(11) Accelerated	0.113*	-0.225*	0.061*	-0.042*	0.021	-0.029*	-0.034*	0.373*	0.158*
(12) Priority	0.209*	-0.430*	0.081*	-0.018	0.02	-0.02	-0.050*	0.444*	0.470*
(13) AdvisoryCom	-0.095*	0.089*	0.338*	0.071*	0.057*	0.032*	0.041*	-0.354*	-0.176*
(14) lgBeneficiary	-0.066*	0.174*	0.270*	0.055*	0.017	-0.012	0.021	0.055*	0.007
(15) USUndergrad	-0.045*	0.039*	-0.012	-0.048*	-0.124*	0.036*	0.011	-0.030*	0.005
(16) Tenure	-0.027*	0.052*	-0.032*	-0.075*	0.037	-0.002	0.321*	-0.026*	-0.012
(17) Male	0.020	-0.025*	0.008	0.023	0.105*	-0.061*	-0.045*	0.001	0.029*
(18) PHD	0.044*	-0.050*	-0.043*	-0.064*	0.021	-0.082*	-0.108*	0.004	0.002
(19) MD	-0.001	0.033*	0.040*	0.087*	-0.061*	-0.048*	0.143*	-0.013	-0.011
(20) PHARMD	-0.045*	0.023*	0.014	0.015	0.031	0.101*	0.049*	-0.005	0.004
(21) PublicFirm	0.081*	-0.090*	0.155*	0.031*	0.122*	0.075*	-0.042*	-0.040*	0.025*
(22) lgApplication	0.111*	-0.101*	0.158*	0.031*	0.245*	0.177*	-0.024*	-0.121*	-0.089*
(23) RevolverHirer	0.160*	-0.178*	0.227*	0.030*	0.232*	0.120*	-0.037*	0.007	0.044*
(24) Year	0.183*	-0.148*	-0.508*	-0.199*	0.038	-0.027*	-0.090*	0.128*	0.162*
(25) Submission Classification	-0.127*	0.179*	-0.153*	0.004	-0.063*	0.044*	0.045*	-0.305*	-0.261*
(26) ReviewTeam Size	0.083*	-0.113*	0.201*	0.013	0.049	-0.032*	-0.027*	0.195*	0.164*
(27) # of Rejection	-0.877*	0.745*	0.009	0.022	-0.080*	-0.005	0.042*	-0.157*	-0.129*

Table 3.1 (cont'd)

	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)
(1) DirectApproval									
(2) lgReviewTime									
(3) lgAdvEvent									
(4) Revolver									
(5) ProximityApptoHirer(log)									
(6) ProximityApptoEdu(log)									
(7) Seniority									
(8) Orphan									
(9) FastTrack									
(10) Breakthrough	1								
(11) Accelerated	0.392*	1							
(12) Priority	0.424*	0.292*	1						
(13) AdvisoryCom	-0.149*	-0.201*	-0.211*	1					
(14) lgBeneficiary	-0.083*	0.019	0.059*	0.047*	1				
(15) USUndergrad	-0.029*	-0.022	-0.016	0.005	-0.007	1			
(16) Tenure	-0.019	-0.027*	-0.027*	-0.005	-0.009	0.077*	1		
(17) Male	0.02	0.013	0.019	-0.012	-0.001	-0.114*	-0.046*	1	
(18) PHD	0.030*	0.004	0.000	-0.013	-0.024*	-0.255*	-0.044*	0.247*	1
(19) MD	-0.026*	-0.029*	-0.012	-0.002	0.040*	0.042*	0.095*	-0.036*	-0.436*
(20) PHARMD	-0.018	0.01	0.008	0.017	0.000	0.212*	0.032*	-0.191*	-0.603*
(21) PublicFirm	0.107*	0.083*	0.057*	0.067*	0.072*	-0.017	-0.038*	0.015	0.016
(22) lgApplication	0.064*	0.022	-0.022	0.166*	0.010	-0.004	-0.026*	0.001	0.021
(23) RevolverHirer	0.166*	0.095*	0.116*	0.087*	0.040*	-0.018	-0.033*	0.026*	0.015
(24) Year	0.214*	0.076*	0.128*	-0.336*	-0.158*	-0.071*	0.040*	0.066*	0.123*
(25) Submission Classification	-0.216*	-0.171*	-0.376*	0.147*	-0.195*	0.033*	0.02	-0.005	0.003
(26) ReviewTeam Size	0.170*	0.206*	0.250*	-0.080*	0.183*	0.008	-0.017	0.009	0.01
(27) # of Rejection	-0.160*	-0.101*	-0.176*	0.074*	0.098*	0.041*	0.042*	-0.013	-0.049*

Table 3.1 (cont'd)

	(19)	(20)	(21)	(22)	(23)	(24)	(25)	(26)	(27)
(1) DirectApproval									
(2) lgReviewTime									
(3) lgAdvEvent									
(4) Revolver									
(5) ProximityApptoHirer(log)									
(6) ProximityApptoEdu(log)									
(7) Seniority									
(8) Orphan									
(9) FastTrack									
(10) Breakthrough									
(11) Accelerated									
(12) Priority									
(13) AdvisoryCom									
(14) lgBeneficiary									
(15) USUndergrad									
(16) Tenure									
(17) Male									
(18) PHD									
(19) MD	1								
(20) PHARMD	-0.192*	1							
(21) PublicFirm	0.002	-0.020	1						
(22) lgApplication	-0.014	-0.017	0.512*	1					
(23) RevolverHirer	0.003	-0.022	0.486*	0.752*	1				
(24) Year	-0.039*	-0.116*	-0.018	-0.054*	-0.018	1			
(25) Submission Classification	-0.027*	0.021	-0.203*	-0.130*	-0.276*	-0.134*	1		
(26) ReviewTeam Size	0.029*	-0.043*	0.135*	0.154*	0.240*	-0.006	-0.385*	1	
(27) # of Rejection	0.011	0.036*	-0.091*	-0.117*	-0.175*	-0.157*	0.149*	-0.071*	1

Table 3.1 (cont'd)

Notes: Table 3.1 presents the Pearson correlations among variables used in the analyses for pre-revolving effects on FDA reviewers' review performance. Note that *DistanceApptoHirer(logged and reversed)* only exists for revolvers. * $p<.05$

Table 3.2: Pairwise Correlations Matrix - Application level sample

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
(1) DirectApproval	1								
(2) lgReviewTime	-0.710*	1							
(3) lgAdvEvent	-0.025	-0.028	1						
(4) RevolverExp(log)	0.138*	-0.172*	0.025	1					
(5) SeniorRevolverExp(log)	0.106*	-0.112*	-0.106*	0.686*	1				
(6) JuniorRevolverExp(log)	0.127*	-0.152*	0.024	0.943*	0.558*	1			
(7) Orphan	0.121*	-0.211*	0.051	0.038	-0.001	0.028	1		
(8) FastTrack	0.118*	-0.210*	0.036	0.057	-0.006	0.034	0.302*	1	
(9) Breakthrough	0.156*	-0.276*	0.013	0.226*	0.102*	0.179*	0.295*	0.262*	1
(10) Accelerated	0.091*	-0.186*	0.067*	0.109*	0.031	0.106*	0.339*	0.152*	0.369*
(11) Priority	0.178*	-0.398*	0.067*	0.127*	0.075*	0.107*	0.425*	0.476*	0.413*
(12) AdvisoryCom	-0.067*	0.049	0.268*	-0.011	-0.061	-0.008	-0.312*	-0.166*	-0.135*
(13) lgBeneficiary	-0.070*	0.134*	0.226*	-0.017	-0.037	0.001	0.067*	0.038	-0.045
(14) RevolverHirer	0.130*	-0.161*	0.243*	0.719*	0.445*	0.680*	0.026	0.053	0.174*
(15) Year	0.166*	-0.111*	-0.470*	0.254*	0.278*	0.226*	0.128*	0.154*	0.189*
(16) Submission Classification	-0.092*	0.156*	-0.176*	-0.216*	-0.102*	-0.223*	-0.298*	-0.279*	-0.233*
(17) Review Team Size	0.075*	-0.120*	0.215*	0.216*	0.053	0.230*	0.185*	0.196*	0.202*
(18) # of Rejection	-0.873*	0.720*	-0.001	-0.144*	-0.096*	-0.136*	-0.128*	-0.104*	-0.140*

Table 3.2 (cont'd)

	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)
(1) DirectApproval									
(2) lgReviewTime									
(3) lgAdvEvent									
(4) RevolverExp(log)									
(5) SeniorRevolverExp(log)									
(6) JuniorRevolverExp(log)									
(7) Orphan									
(8) FastTrack									
(9) Breakthrough									
(10) Accelerated	1								
(11) Priority	0.271*	1							
(12) AdvisoryCom	-0.168*	-0.187*	1						
(13) lgBeneficiary	0.031	0.077*	0.037	1					
(14) RevolverHirer	0.101*	0.127*	0.065*	0.065*	1				
(15) Year	0.061*	0.133*	-0.291*	-0.129*	-0.043	1			
(16) Submission Classification	-0.183*	-0.391*	0.142*	-0.206*	-0.243*	-0.097*	1		
(17) Review Team Size	0.231*	0.252*	-0.086*	0.196*	0.251*	-0.031	-0.391*	1	
(18) # of Rejection	-0.084*	-0.157*	0.046	0.084*	-0.145*	-0.133*	0.117*	-0.088*	1

Notes: Table 3.2 presents the Pearson correlations among variables used in the analyses for post-revolving effects on firms' subsequent new drug applications and product quality. * $p<.05$

Table 4.1: Analysis of Revolvers and Non-revolvers Review Outcomes

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
Revolver	**0.011**	**0.030*****	**0.127****	**0.007**	**0.029*****	**0.098***
	(0.009)	(0.009)	(0.056)	(0.011)	(0.010)	(0.057)
Drug Characteristics:						
Orphan				-0.013	0.021	-0.277
				(0.045)	(0.062)	(0.296)
Fasttrack				-0.024	-0.042	-0.127
				(0.049)	(0.048)	(0.334)
Breakthrough				0.007	-0.143**	-0.115
				(0.038)	(0.072)	(0.379)
Accelerated				0.069	-0.143**	0.129
				(0.047)	(0.070)	(0.493)
Priority				0.188***	-0.342***	0.439*
				(0.039)	(0.048)	(0.264)
AdvisoryCom				-0.024	0.271***	0.946***
				(0.056)	(0.102)	(0.309)
lgBeneficiary				0.000	-0.001	0.204***
				(0.007)	(0.006)	(0.031)
Reviewer Characteristics:						
Seniority				-0.001	-0.019**	-0.090**
				(0.009)	(0.008)	(0.046)

Table 4.1 (cont'd)

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
USUndergrad				-0.004	-0.001	-0.151***
				(0.008)	(0.006)	(0.044)
Tenure				-0.001	0.002**	0.004
				(0.001)	(0.001)	(0.003)
Male				-0.017**	-0.009	0.024
				(0.007)	(0.008)	(0.046)
PhD				0.020**	-0.011	-0.013
				(0.010)	(0.010)	(0.103)
MD				0.024*	0.011	0.123
				(0.013)	(0.014)	(0.117)
PharmD				-0.003	-0.005	0.025
				(0.013)	(0.015)	(0.110)
Constant	0.765***	5.924***	4.662***	0.715***	6.047***	4.569***
	(0.002)	(0.003)	(0.017)	(0.068)	(0.058)	(0.174)
Observations	7,343	7,343	7,343	5,794	5,794	5,794
Adj R2	0.478	0.757	0.717	0.494	0.805	0.723
Cluster	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer
Fixed Effects:	Firm, Year, Sub. Class., Rev. Team Size, # of Rejection (model (2), (3), (5) & (6) only)					

Notes: This table presents the estimation from equation (1) which examines the differential review performance between FDA revolvers and non-revolvers towards new drug applications submitted by the same firm. The variable of interest is *Revolver*, an indicator which equals 1 if an FDA reviewer left the agency and joined a pharmaceutical firm that submitted at least one new drug application during the test period. Firm, Year, Submission Classification, and Team Size fixed effects are included in all columns. Number of Rejection fixed effects are additionally included when the DVs are *lgReviewTime* or *lgAdvEvent*. Standard errors are clustered by firm and reviewer and reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table 5.1: Analysis of Review Performance on the Proximity to Revolvers' First Employers

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
ProximityApptoHirer(logged)	**0.016**	**0.033****	**0.128****	**0.012**	**0.025***	**0.116****
	(0.012)	(0.013)	(0.045)	(0.015)	(0.014)	(0.047)
Drug Characteristics:						
Orphan				0.072	-0.047	0.510***
				(0.058)	(0.081)	(0.136)
Fasttrack				-0.108**	0.139*	-0.532
				(0.042)	(0.080)	(0.544)
Breakthrough				0.029	-0.160	0.132
				(0.059)	(0.098)	(0.184)
Accelerated				0.020	-0.184*	-0.274
				(0.053)	(0.100)	(0.390)
Priority				0.146**	-0.477***	0.470
				(0.050)	(0.085)	(0.283)
AdvisoryCom				-0.064	0.340***	0.755***
				(0.038)	(0.081)	(0.140)
lgBeneficiary				-0.004	-0.008	0.180***
				(0.008)	(0.010)	(0.037)
Firm Characteristics:						
lgApplication				0.005	0.019	-0.250
				(0.027)	(0.032)	(0.162)
PublicFirm				0.086	-0.086	0.613**
				(0.072)	(0.070)	(0.197)
RevolverHirer				0.051	-0.127	0.990***
				(0.076)	(0.089)	(0.291)

Table 5.1 (cont'd)

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
Constant	0.655***	6.167***	6.305***	0.574***	6.370***	4.109***
	(0.072)	(0.084)	(0.268)	(0.144)	(0.155)	(0.398)
Observations	1,221	1,221	1,221	1,093	1,093	1,093
Adj R2	0.160	0.141	0.477	0.204	0.304	0.530
Cluster	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.
Fixed Effects:						
Reviewer	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Submission Classification	YES	YES	YES	YES	YES	YES
Rev. Team Size	YES	YES	YES	YES	YES	YES
Geographic Division	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Notes: This table presents the estimation from equation (2) which examines the different review performance FDA revolvers demonstrate towards firms located in different proximity to their first industry hirers. The variable of interest is *ProximityApptoHirer(logged)*, a continuous variable measuring the proximity between the applicant firm and the revolver's first industry employer. Standard errors are clustered by reviewer and geographic division and reported in parentheses. Control variables are included in columns (4) through (6). *** p<0.01, ** p<0.05, * p<0.1

Table 6.1: Analysis of Review Performance on the Proximity to Revolvers' U.S. Alma Mater

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
ProximityApptoEdu(logged)	0.005	0.002	-0.069	0.007	-0.001	-0.056
	(0.008)	(0.007)	(0.039)	(0.008)	(0.009)	(0.072)
Revolver* x *ProximityApptoEdu(logged)	**0.004**	**0.020****	**0.195****	**0.008**	**0.023****	**0.170****
	(0.016)	(0.007)	(0.059)	(0.019)	(0.008)	(0.063)
Drug Characteristics:						
Orphan				0.060	0.003	0.577***
				(0.036)	(0.047)	(0.110)
Fasttrack				-0.034	-0.012	-0.213
				(0.031)	(0.031)	(0.213)
Breakthrough				-0.002	-0.120***	0.089
				(0.028)	(0.015)	(0.191)
Accelerated				0.058*	-0.090	0.221
				(0.027)	(0.084)	(0.341)
Priority				0.149***	-0.354***	0.350*
				(0.035)	(0.013)	(0.153)
AdvisoryCom				-0.044	0.222***	1.008***
				(0.032)	(0.044)	(0.185)
lgBeneficiary				-0.001	-0.006	0.194***
				(0.006)	(0.003)	(0.034)
Firm Characteristics:						
lgApplication				0.003	-0.003	-0.291***
				(0.026)	(0.010)	(0.059)
PublicFirm				-0.007	0.020	0.320**
				(0.047)	(0.030)	(0.136)
RevolverHirer				0.093	-0.051	1.022***
				(0.053)	(0.029)	(0.100)

Table 6.1 (cont'd)

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
Constant	0.730***	5.964***	4.526***	0.616***	6.124***	2.914***
	(0.038)	(0.042)	(0.229)	(0.073)	(0.109)	(0.475)
Observations	6,210	6,210	6,210	5,338	5,338	5,338
Adj R2	0.090	0.642	0.509	0.130	0.708	0.546
Cluster	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.
Fixed Effects:						
Reviewer	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Submission Classification	YES	YES	YES	YES	YES	YES
Review Team Size	YES	YES	YES	YES	YES	YES
Geographic Division	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Notes: This table presents the estimation from equation (2) which examines the different review performance FDA revolvers demonstrate towards firms located in different proximity to their first industry hirers. *ProximityApptoEdu(logged)* is a continuous variable measuring the proximity between the applicant firm and the reviewer's first U.S. post-secondary alma mater. Reviewer fixed effects are included in all columns. Standard errors are clustered by reviewer and geographic division and reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table 7.1: Analysis of Revolver and Non-revolver Review Performance by Reviewer Seniority

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*
Revolver	**-0.005**	**0.048*** **	**-0.038**
	(0.013)	(0.014)	(0.060)
Seniority	-0.008	-0.010	-0.088*
	(0.010)	(0.008)	(0.049)
Revolver X Seniority	**0.041**	**-0.035****	**0.199****
	(0.028)	(0.018)	(0.090)
Drug Characteristics:			
Orphan	0.023	0.030	0.241
	(0.046)	(0.056)	(0.317)
Fasttrack	-0.020	-0.014	-0.242
	(0.048)	(0.049)	(0.347)
Breakthrough	0.033	-0.133**	0.308
	(0.045)	(0.066)	(0.348)
Accelerated	0.004	-0.145**	0.253
	(0.052)	(0.065)	(0.415)
Priority	0.184***	-0.352***	0.455**
	(0.041)	(0.052)	(0.210)
lgBeneficiary	-0.024	0.272***	0.708**
	(0.051)	(0.080)	(0.307)
Reviewer Characteristics:			
USUndergrad	-0.007	-0.002	-0.087**
	(0.011)	(0.006)	(0.044)
Tenure	-0.001	0.001**	-0.000
	(0.001)	(0.001)	(0.003)
Male	-0.012	-0.009	0.037
	(0.009)	(0.007)	(0.044)
PHD	0.016	-0.005	-0.002
	(0.011)	(0.012)	(0.068)
MD	0.038*	0.016	0.076
	(0.020)	(0.013)	(0.087)
PHARMD	-0.006	0.004	0.010
	(0.013)	(0.014)	(0.085)
Constant	0.720***	6.040***	3.227***
	(0.063)	(0.052)	(0.319)
Sum of *Revolver + Revolver x Seniority*	**0.037** **(0.023)**	**0.013** **(0.010)**	**0.161**** **(0.072)**
Observations	5,794	5,794	5,794
Adj R2	0.517	0.813	0.744
Cluster	Firm,Reviewer		
Fixed Effects:	Firm, Year, Sub. Class., Rev. Team Size, # of Rejection (model (2)&(3) only)		

Table 7.1 (cont'd)

Notes: This table presents the estimation from equation (3) which examines the different review performance between FDA revolvers and non-revolvers based on their seniority towards new drug applications submitted by the same firm. *Seniority* is a binary variable which equals to 1 if a reviewer has "Chief," "Director," "Manager," "Team Lead," or "Supervisor" title. Firm fixed effects are included in all columns. Standard errors are clustered by firm and reviewer and reported in parentheses. *** $p<0.01$, ** $p<0.05$, * $p<0.1$

Table 8.1: Analysis of Impacts of Hiring FDA Revolvers on Firms' Subsequent New Drug Applications and Product Quality

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
RevolverExp(logged)	**0.025***	**-0.017**	**-0.186****	**0.029****	**-0.011**	**-0.168****
	(0.013)	(0.012)	(0.079)	(0.014)	(0.012)	(0.079)
Orphan				-0.002	0.011	0.194
				(0.041)	(0.055)	(0.283)
Fasttrack				-0.005	-0.044	0.113
				(0.046)	(0.063)	(0.383)
Breakthrough				0.009	-0.173**	0.135
				(0.033)	(0.086)	(0.436)
Accelerated				0.073	-0.165*	-0.033
				(0.058)	(0.098)	(0.457)
Priority				0.199***	-0.311***	0.119
				(0.035)	(0.045)	(0.180)
AdvisoryCom				-0.039	0.241***	0.549
				(0.058)	(0.082)	(0.342)
lgBeneficiary				-0.001	-0.003	0.170***
				(0.007)	(0.005)	(0.031)
Constant	0.724***	5.965***	4.709***	0.674***	6.031***	3.593***
	(0.025)	(0.024)	(0.151)	(0.066)	(0.061)	(0.278)
Observations	835	835	835	703	702	702
Adj R2	0.077	0.601	0.521	0.101	0.655	0.508
Cluster	Firm	Firm	Firm	Firm	Firm	Firm
Fixed Effects:						
Firm	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Sub. Class.	YES	YES	YES	YES	YES	YES
Rev. Team Size	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Table 8.1 (cont'd)

Notes: This table presents the estimation from equation (4) which examines the effect of acquiring more FDA reviewer knowledge on the firm's subsequent new drug application as well as product quality. *RevolverExp(logged)* is a continuous variable which measures the cumulative recruited former FDA reviewers' work experience in months up to the submission year of a new drug application. Firm fixed effects are included in all columns. Standard errors are clustered by firm and are reported in parentheses. *** $p<0.01$, ** $p<0.05$, * $p<0.1$

Table 9.1: Impacts of FDA Revolvers on Firms' Subsequent New Drugs

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*
SeniorRevolverExp(logged)	**0.026****	**-0.015**	**-0.115**
	(0.011)	(0.011)	(0.080)
JuniorRevolverExp(logged)	**0.009**	**0.001**	**-0.145***
	(0.015)	(0.013)	(0.076)
Orphan	0.005	0.007	0.177
	(0.040)	(0.054)	(0.318)
Fasttrack	0.002	-0.050	0.049
	(0.051)	(0.064)	(0.366)
Breakthrough	0.033	-0.180**	0.037
	(0.039)	(0.089)	(0.438)
Accelerated	0.079	-0.170*	-0.071
	(0.059)	(0.101)	(0.545)
Priority	0.184***	-0.306***	0.166
	(0.032)	(0.046)	(0.277)
AdvisoryCom	-0.050	0.242***	0.567*
	(0.057)	(0.081)	(0.310)
lgBeneficiary	0.001	-0.001	0.158***
	(0.007)	(0.006)	(0.030)
Constant	0.685***	6.024***	3.629***
	(0.064)	(0.061)	(0.308)
Test of Differences: SeniorRevolverExp (logged) = JuniorRevolverExp (logged)	*p=0.38*	*p=0.40*	*p=0.81*
Observations	703	703	703
R-squared	0.326	0.736	0.632
Adj R2	0.107	0.648	0.510
Cluster	Firm	Firm	Firm
Fixed Effects:			
Firm	YES	YES	YES
Year	YES	YES	YES
Sub. Class.	YES	YES	YES
Rev. Team Size	YES	YES	YES
# of Rejection		YES	YES

Table 9.1 (cont'd)

Notes: This table presents the estimation from equation (5) which examines the effect of acquiring more FDA senior or junior reviewer knowledge on the firm's subsequent new drug application as well as product quality. *SeniorRevolverExp(logged)* is a continuous variable which measures the cumulative recruited former FDA senior reviewers' work experience in months up to the submission year of a new drug application. *JuniorRevolverExp(logged)* is a continuous variable which measures the cumulative recruited former FDA junior reviewers' work experience in months up to the submission year of a new drug application. Standard errors are clustered by firm and are reported in parentheses. *** $p<0.01$, ** $p<0.05$, * $p<0.1$

Table 10.1: Sensitivity Tests on the Proximity Measures

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
ProximityApptoHirer(5 quantile)	**0.024**	**0.033***	**0.227****			
	(0.021)	(0.018)	(0.069)			
ProximityApptoEdu (5 quantile)				0.009	0.085	0.040
				(0.009)	(0.064)	(0.077)
Revolver* x *ProximityApptoEdu (5 quantile)				**-0.018**	**-0.160***	**-0.230*****
				(0.010)	(0.072)	(0.061)
Control Variables	Included	Included	Included	Included	Included	Included
Constant	0.580***	6.117***	2.715***	6.097***	2.840***	3.069***
	(0.122)	(0.106)	(0.495)	(0.091)	(0.422)	(0.225)
Observations	1,093	1,093	1,093	5,338	5,338	5,338
Adj R2	0.207	0.279	0.541	0.705	0.551	0.539
Cluster	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.
Fixed Effects:						
Reviewer	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Sub. Class.	YES	YES	YES	YES	YES	YES
Rev Team Size	YES	YES	YES	YES	YES	YES
Geographic Division	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Table 10.1 (cont'd)

Notes: This table presents the results of re-estimation for Table 5 and Table 6 but using categorized instead of continuous proximity measures. Control variables are the same as in Table 5 and Table 6. Standard errors are clustered by reviewer and geographic location and reported in parentheses. *** $p<0.01$, ** $p<0.05$, * $p<0.1$

Table 11.1: Sensitivity Tests on *ex post* FDA Revolving Door Consequences Using Subsample of Revolver Hirers

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
RevolverExp(logged)	**0.028***	**-0.012**	**-0.256*****			
	(0.015)	(0.018)	(0.093)			
SeniorRevolverExp(logged)				**0.025****	**-0.014**	**-0.097**
				(0.011)	(0.014)	(0.090)
JuniorRevolverExp(logged)				**0.008**	**0.004**	**-0.222****
				(0.015)	(0.017)	(0.090)
Control Variables	Included	Included	Included	Included	Included	Included
Constant	0.669***	5.898***	4.522***	0.693***	5.867***	4.497***
	(0.085)	(0.095)	(0.411)	(0.086)	(0.095)	(0.539)
Observations	382	382	382	382	382	382
Adj R2	0.137	0.615	0.470	0.149	0.614	0.486
Cluster	Firm	Firm	Firm	Firm	Firm	Firm
Fixed Effects:						
Firm	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Sub. Class.	YES	YES	YES	YES	YES	YES
Rev. Team Size	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Notes: This table presents the results of re-estimation for Table 8 and Table 9 but using the subsample of applications that were submitted by only revolver hirers (firms that ever hired an FDA revolver during the test period). Control variables are the same as in Table 8 and Table 9. Standard errors are clustered by firm and are reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table 12.1: Revolvers and Non-revolvers Review Outcomes – No Internal Promotion Sample

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
Revolver	**0.001**	**0.035*** **	**0.077***	**0.003**	**0.030*** **	**0.041***
	(0.009)	**(0.010)**	**(0.032)**	**(0.010)**	**(0.012)**	**(0.019)**
Drug Characteristics:				Yes	Yes	Yes
Reviewer Characteristics:				Yes	Yes	Yes
Constant	0.761***	5.929***	4.663***	0.718***	6.037***	4.613***
	(0.002)	(0.003)	(0.018)	(0.071)	(0.060)	(0.190)
Observations	5,121	5,121	5,121	4,052	4,052	4,052
Adj R2	0.481	0.759	0.709	0.497	0.805	0.718
Cluster	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer
Fixed Effects:	Firm, Year, Sub. Class., Rev. Team Size, # of Rejection (model (2), (3), (5) & (6) only)					

Notes: This table presents the estimation results from equation (1) using the sample without reviewers who received internal promotion during the test period. The variable of interest is *Revolver*, an indicator which equals 1 if an FDA reviewer left the agency and joined a pharmaceutical firm that submitted at least one new drug application during the test period. Firm, Year, Submission Classification, and Team Size fixed effects are included in all columns. Number of Rejection fixed effects are additionally included when the DVs are *lgReviewTime* or *lgAdvEvent*. Standard errors are clustered by firm and reviewer and reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table 13.1: Review Performance on the Proximity to Revolvers' First Employers – No Internal Promotion Sample

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
ProximityApptoHirer(logged)	**0.019**	**0.049*** **	**0.140** **	**0.020**	**0.030** **	**0.144** **
	(0.014)	(0.015)	(0.044)	(0.016)	(0.015)	(0.052)
Drug Characteristics:				Yes	Yes	Yes
Firm Characteristics:				Yes	Yes	Yes
Constant	0.616***	6.298***	6.217***	0.539***	6.389***	4.135***
	(0.083)	(0.101)	(0.267)	(0.156)	(0.157)	(0.383)
Observations	968	968	968	857	910	857
Adj R2	0.285	0.257	0.543	0.346	0.381	0.616
Cluster	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.
Fixed Effects:						
Reviewer	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Submission Classification	YES	YES	YES	YES	YES	YES
Rev. Team Size	YES	YES	YES	YES	YES	YES
Geographic Division	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Notes: This table presents the estimation from equation (2) using the sample without reviewers who received internal promotion during the test period. This set of tests examines the different review performance FDA revolvers demonstrate towards firms located in different proximity to their first industry hirers. The variable of interest is *ProximityApptoHirer(logged)*, a continuous variable measuring the proximity between the applicant firm and the revolver's first industry employer. Standard errors are clustered by reviewer and geographic division and reported in parentheses. Control variables are included in columns (4) through (6). *** p<0.01, ** p<0.05, * p<0.1

Table 14.1 Review Performance on the Proximity to Revolvers' U.S. Alma Mater – No Internal Promotion Sample

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*	(4) *DirectApproval*	(5) *lgReviewTime*	(6) *lgAdvEvent*
ProximityApptoEdu(logged)	0.004	0.001	-0.062	0.005	-0.001	-0.042
	(0.010)	(0.009)	(0.050)	(0.010)	(0.011)	(0.064)
***Revolver* x**	-0.002	0.020*	0.185*	0.003	0.022*	0.152*
ProximityApptoEdu(logged)	(0.014)	(0.010)	(0.084)	(0.016)	(0.011)	(0.078)
Drug Characteristics:				Yes	Yes	Yes
Firm Characteristics:				Yes	Yes	Yes
Constant	0.739***	5.977***	4.715***	0.622***	6.126***	3.104***
	(0.057)	(0.055)	(0.285)	(0.091)	(0.114)	(0.420)
Observations	4,346	4,346	4,346	3,710	3,710	3,710
Adj R2	0.096	0.646	0.513	0.146	0.711	0.545
Cluster	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.	Reviewer, Geo. Div.
Fixed Effects:						
Reviewer	YES	YES	YES	YES	YES	YES
Year	YES	YES	YES	YES	YES	YES
Submission Classification	YES	YES	YES	YES	YES	YES
Review Team Size	YES	YES	YES	YES	YES	YES
Geographic Division	YES	YES	YES	YES	YES	YES
# of Rejection		YES	YES		YES	YES

Notes: This table presents the estimation from equation (2) using the sample without reviewers who received internal promotion during the test period. This set of tests examines the different review performance FDA revolvers demonstrate towards firms located in different proximity to their first industry hirers. *ProximityApptoEdu(logged)* is a continuous variable measuring the proximity between the applicant firm and the reviewer's first U.S. post-secondary alma mater. Reviewer fixed effects are included in all columns. Standard errors are clustered by reviewer and geographic division and reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1

Table 15.1: Review Performance by Reviewer Seniority – No Internal Promotion Sample

	(1) *DirectApproval*	(2) *lgReviewTime*	(3) *lgAdvEvent*
Revolver	**-0.009**	**0.061*** **	**-0.095**
	(0.012)	**(0.019)**	**(0.073)**
Seniority	-0.014	-0.003	-0.194***
	(0.011)	(0.009)	(0.064)
Revolver X Seniority	**0.048**	**-0.057*** **	**0.230** **
	(0.033)	**(0.021)**	**(0.097)**
Drug Characteristics:	Yes	Yes	Yes
Reviewer Characteristics:	Yes	Yes	Yes
Constant	0.719***	6.015***	3.324***
	(0.065)	(0.055)	(0.350)
Sum of	0.040	0.004	0.135*
Revolver + Revolver x Seniority	(0.028)	(0.007)	(0.071)
Observations	4,052	4,052	4,052
Adj R2	0.519	0.813	0.741
Cluster	Firm, Reviewer	Firm, Reviewer	Firm, Reviewer
Fixed Effects:	Firm, Year, Sub. Class., Rev. Team Size, # of Rejection (model (2)&(3) only)		

Notes: This table presents the estimation from equation (3) using the sample without reviewers who received internal promotion during the test period. This set of tests examines the different review performance between FDA revolvers and non-revolvers based on their seniority towards new drug applications submitted by the same firm. *Seniority* is a binary variable which equals to 1 if a reviewer has "Chief," "Director," "Manager," "Team Lead," or "Supervisor" title. Firm fixed effects are included in all columns. Standard errors are clustered by firm and reviewer and reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1