REGULATORY CAPTURE OR ORGANIZATIONAL DEFERENCE?
THE EFFECT OF PRODUCER STATUS POSITIONS
ON FDA DRUG REVIEW 1990-2004

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ABSTRACT

In this study, I propose an alternative mechanism to interest-based accounts of regulatory capture: regulatory deference towards prominent actors in the institutional field. Using review times for 884 New Drug Applications (NDAs) approved by the Food and Drug Administration between 1990 and 2004, I find that firms with higher status in the knowledge domain receive faster approval for their drugs. The effect of status strengthened when the agency’s political legitimacy was threatened, while evidence suggests that observed status effects were not the direct result of quality differences. The findings contribute to understanding how states respond to legitimacy claims of firms.
Goldman, he thought, could help value the assets and syndicate the loans. “They’re freakin’ smart!” he liked to tell his staff.

-Timothy Geithner, President of the Federal Reserve Bank of New York, 2008

For whose benefit is regulation undertaken? Though protecting public interest is commonly viewed as the motivation for government intervention (Pigou, 1932), there is considerable evidence suggesting that policy and law advance the interests of a subset of actors at the expense of consumers and broader social welfare (e.g., Bernstein, 1955; Stigler, 1971; Djankov, La Porta, Lopez-De-Silanes, & Shleifer, 2002). For example, Stigler (1971) observed that regulation of inter-city truck hauls depended on the extent to which existing railroad interests are threatened by competition from the new form of transportation. Djankov et al. (2002), in a survey of entry-regulation in 75 countries, find that heavier entry-regulation is associated with higher profits for incumbent firms already affiliated with politicians. And studies of the textile (Viscusi, 1992), telecommunications (Crandall & Flam, 1989), and pharmaceutical (Grabowski & Vernon, 1977) industries have found that large and established firms enjoy relative advantages in regulatory outcomes over smaller and newer firms. For organizational scholars who view the state as an important legitimizing actor (e.g., Fligstein, 1990; Dobbin & Sutton, 1998; Marquis & Huang, 2009), the insight that regulatory actions differ depending on the identity of the regulated entity raises numerous questions of significance.

Despite the keen interest in identifying the winners and losers of regulation, there has been a surprising lack of attention towards clarifying the mechanisms that produce differential regulatory outcomes (Carpenter, 2004). Most studies implicitly view regulation as a set of

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1 From Aaron Ross Sorkin, “Too Big to Fail: The Inside Story of How Wall Street and Washington Fought to Save the Financial System—and Themselves”
transactions between producers, regulators, politicians, and consumers, with inequalities in regulation a natural result of the “supply” of regulation adjusting to the different levels of “demand” from external parties (Stigler, 1971; Peltzman, 1976). While it is certainly possible that regulatory actions are entirely determined by exogenous forces, there is strong anecdotal and theoretical reasons to believe that states exercise autonomy in choosing their agendas (Skocpol, 1985; Kalev, Shenhav, & Vries, 2008), and are boundedly rational actors subject to decision-making errors (Bazerman, Baron, & Shonk, 2001), rendering conclusions based exclusively on the economic interests of external actors incomplete or misleading.

In this paper, I propose an organizational mechanism—deference to prominent actors (Galaskiewicz & Burt, 1991; Podolny, 1993)—that allows one to view regulatory motivations that extend beyond the maximization of votes or social welfare. My argument is that certain producers are favored in regulation, not because they are acquired by dominant interests, but rather, due to uncertainty rendering producer positions in the institutional field more salient. The rapid infusion of scientific knowledge in industries, and the increasing complexity of interaction within and across innovations has put tremendous technical and political demands on regulators (Jasanoff, 1990). Decades of sociological and organizational work suggest that evaluators in uncertain contexts shift attention away from what is exchanged to the social structural positions of their potential exchange partners (Geertz, 1978; Gulati, 1995). I argue that status positions—accumulated acts of deference (Podolny & Lynn, 2009)—of regulated firms in the institutionalized knowledge domain have an impact on regulatory evaluation, which leads to more favorable outcomes for these prominent firms.

To test this proposition, I examine the role that firm status positions in the knowledge domain plays in explaining differences in new pharmaceutical drug approval times by the U.S.
Food and Drug Administration (FDA). The New Drug Application (NDA) review period, where the FDA assesses safety and efficacy data from clinical trials to determine whether a drug can be marketed to consumers, has significant strategic implications for firms due to the regulator’s power over entry into the market. In particular, the duration of regulatory evaluation for new drugs (i.e. how fast a drug is approved) is a closely watched outcome with real consequences for the financial performance of firms\(^2\) and the health of our society\(^3\). Given the difficulty of assessing the safety and efficacy of a new drug (Avorn, 2004), the status position of a sponsoring firm acts as a proxy for unobservable quality (Olson, 1997), expediting the review process for these drugs. But beyond acting as a heuristic for true quality, I argue that regulatory deference towards high status producers provides additional benefits in protecting the reputation of the agency, and as a result, produces a systemic bias towards prominent actors even when the position of the actor is inconsistent with the quality dimensions under evaluation.

Using data from review times of 884 New Drug Applications (NDAs) submitted to the FDA between 1990 and 2004, I find that firms with highly cited knowledge bases receive faster approval for their products, up and beyond what “capture” variables such as firm size or political donations would explain. The idea that the observed variance in review times is a result of uncertainty-driven deference behavior, and not that of capture, is further reinforced by the fact that status effects are greater when the product is entering a less competitive environment, and when product recalls threaten the political legitimacy of the agency. While firms with stronger knowledge positions may have an advantage in producing higher quality drugs leading to faster reviews, the data suggest that high status firms are no less likely to submit a drug that is a

\(^2\) For example, a 2001 Merrill Lynch research report estimates that a one-month delay in a drug’s approval results in $41.7 million in lost revenues

\(^3\) One estimate claims a one year delay of the introduction of a new drug costs between 32,000 and 76,000 additional deaths per year (Gieringer, 1985)
significant advance over existing drugs. Furthermore, I find that prominence in therapy
categories that are unrelated to the drug under review have a strong positive impact on review
speed, implying that the observed deference effects are not entirely quality driven.

The investigation of status effects in new drug review has a number of contributions for
organizational and management theory. First, by highlighting the importance of deference and
the institutional field in which regulators are embedded, the study makes a strong case for the
complementary role organizational theory can play in understanding how state policy is formed
and executed. Second, the paper adds to existing studies of the state in the neo-institutional
literature by painting a richer picture of the state as an actor. While most work in institutional
theory views the state as an exogenous force bestowing legitimacy on firms (Meyer & Rowan,
1977; DiMaggio & Powell, 1983), this paper frames state agencies as actors responding to
legitimacy claims endogenously generated by firms, depicting a more co-evolutionary dynamic
(Edelman & Suchman, 1997). Finally, the study contributes to the large body of research
documenting status and other network positions as a competitive asset (Podolny, 2005; Stuart,
Hoang, & Hybels, 1999) by adding non-market settings as an additional context to which status
can “leak”. But more importantly, this study builds upon and advances recent efforts to
emphasize the socially constructed nature of status (Washington & Zajac, 2005) by delving into
the content of status and exploring the potential for status-quality decoupling.

In the following section, I provide a theory of regulatory action that focuses on the role
deference in achieving and maintaining bureaucratic autonomy. I then put forth an account of the
FDA drug review process, and propose testable hypotheses related to my theory of regulatory
deference. After describing the data I collected, I present results from the empirical analysis, and
conclude with a discussion of the theoretical and practical implications of this work.
THEORY

Determinants of Regulatory Action: Interests, Autonomy, and Deference

Regulation is the use of a state’s coercive power for the purpose of restricting the decisions of economic agents (Viscusi, Vernon, & Harrington 2000). These limitations on individual and firm behavior are imposed to prevent market failures and to establish market order consistent with prevailing principles of fairness (Schneiberg & Bartley, 2001), which help the government achieve its ultimate goal of maximizing social welfare. From this perspective, regulatory actions are determined based on whether enhancements in consumer gains outweigh the costs associated with government intervention.

In practice, however, the drivers of regulatory behavior are more complex and diverse. Scholars have typically viewed states as “an arena within which economic interest groups or normative social movements contended or allied with one another to shape the making of public policy” (Skocpol, 1985 p. 4), and thus, understanding regulatory behavior involves analyzing the groups that stand to gain or lose the most through government intervention. Most prominent among theories in this vein is the so-called “capture-theory” (Bernstein, 1955; Stigler, 1971), which posits that producers prevail in regulation over consumers and smaller firms by using regulation to limit competition and control markets. Large firms with significant lobbying budgets and political clout dominate the regulatory process due to the lower marginal costs of political action, and regulatory action is “supplied” by the government based on the extent to which “demand” from dominant producers exist. Numerous studies from the pharmaceutical (Grabowski & Vernon, 1977), telecommunications (Crandall & Fleming, 1989), and transportation (Stigler, 1971) industries have documented with great consistency how dominant producers benefit from regulations that purportedly protect consumer interest.
Capture theory and its variants have gained significant traction in the economics and legal literatures (for a review, see Dal Bo, 2006), but it is often criticized for underplaying the role that non-producer groups play in influencing state behavior. Consumers and other non-industry groups are neither powerless nor disorganized (Vogel, 1996; Schneiberg & Bartley, 2001), and counterorganizing social movements to contest laws and policies governing corporate behavior are often effective in changing policies (Ingram & Rao, 2004). Parallel to market-based capture theories, incentives to organize and influence policy are thought to be important in understanding which interest groups actively seek influence, while group size and resources of the interest group are critical in determining the effectiveness in inducing change in policy (Fishback & Kantor, 1998).

More recently, some sociologists have challenged the view that interest groups or class interests alone determine state action, instead considering the state to be an autonomous actor that pursues its own agenda (Evans, Rueschemeyer, & Skocpol, 1985; Skocpol, 1985; Evans, 1995). Ties to industry do not act as a liability according to this perspective, but to the contrary, provide information and power to independently mediate and shape relationships between labor and capital (Evans, 1995). In the organizational literature, this “autonomous” view has allowed researchers to paint a richer picture of states’ interests and intentions (e.g. Kalev et al., 2008), and avoid treating states as an agent-less source of legal constraints (Ingram and Rao, 2004) or passive cultural outlets reflecting national culture (Dobbin, 1994) and norms of the world society (Meyer, Boli, Thomas, & Ramirez, 1997).

But if state agencies are truly autonomous, how can we account for the fact that certain producers have systematically favorable regulatory outcomes? To resolve this puzzle, it is important to understand how autonomy emerges for state agencies. Bureaucratic autonomy
prevails when bureaucracies are politically differentiated, have unique organizational capacities, and most critically, when agencies have political legitimacy grounded in an independent power base (Carpenter, 2001). That the foundation of autonomy is built upon an agency’s political legitimacy—“a reputation for expertise, efficiency, or moral protection” (Carpenter, 2001, p. 4)—suggests that actors and actions within institutional fields providing expertise, efficient practices, and moral authority have significant influence over regulatory behavior. Prominent actors in the institutional field receive disproportionate attention from regulators, not because they are acquired by the industry, but more so because they are salient to regulators protecting their reputations, and to the stakeholders in the institutional filed whose perceptions form the basis of the legitimacy. Put differently, the autonomy of a regulator, or the deference that elected officials, organized interests, and courts show towards the actions of the agency, is closely related to the extent to which the agency shows proper deference to key experts or sources of moral authority in institutional fields.

I argue that regulators express deference by looking toward status relationships in the institutional field when determining action. First, status positions proxy the underlying quality of a producer’s offerings (Podolny, 1993; Stuart et al., 1999), allowing the regulator to reliably identify higher quality producers and products. This has the direct effect of enhancing the agency’s reputation as an effective regulatory. But more critically, an agency’s reliance on status

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4 At this juncture, it is useful to distinguish the concepts of reputation, status, and prominence that have been mentioned throughout this paper. Following Fombrun and colleagues, I view reputation as the “public’s affective evaluation of a firm’s name” (Fombrun, 1996; Fombrun and Shanley, 1990), while status is the “prestige accorded to individuals because of the abstract positions they occupy rather than because of immediately observable behavior” (Gould, 2002). Status, cannot exist independently from other actors forming the social structure, while reputation is not contingent on some comparison to other actors. Prominence, as a statement of an actor’s structural position, will often lead to prestige and privileges, and thus, following Stuart et al. (1999), I use status and prominence interchangeably.
signals can provide political protection in the case that regulators’ judgments are incorrect or incomplete. Mistakes in regulatory judgment cause irreparable harm for bureaucratic reputation and the agency’s ability to function without constraint. However, as the often cited saying “Nobody ever got fired for buying IBM” illustrates, mistakes that result from deference to prominent actors are less costly from a political standpoint than when low status actors are involved. Prominence provides buffering for the evaluating agent, not necessarily because high status actors always have the highest quality, but due to the fact that key stakeholders also defer to high status actors under conditions of uncertainty.

In sum, while most assume a regulatory mechanism of capture when explaining the observed pattern of firm-based inequalities in regulatory outcomes, an alternative mechanism of deference to high status actors in the institutional field driven by legitimacy concerns can be an equally effective account, while offering a more nuanced view of regulatory behavior. In the following section, I explore these dynamics in the context of a specific regulatory agency, the U.S. Food and Drug Administration (FDA).

**FDA Drug Approval, Uncertainty, and Knowledge Status**

In the United States, the FDA is responsible for “protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices” (www.fda.gov), and any other product that may impact the health of society. Most importantly, the FDA interacts with firms in the development of new drugs, and reviews the clinical trial data submitted by firms to ensure that only safe and effective products reach consumers (Ng, 2004). This gatekeeping role has significant consequences for public interest, not to mention for the viability of firms seeking regulatory approval (Bosch & Lee, 1994). In
fact, the high stakes of new drug review have led many to suspect that firms influence regulation in ways that run counter to public interest. Consistent findings of regulatory advantages for large and established firms (Grabowski & Vernon, 1977; Thomas, 1990; Olson, 1997; Carpenter, 2002) have led many to conclude that the FDA is captured by industry interests.

Why would the FDA advantage already successful and powerful firms? While capture is a plausible explanation, the nature of the drug review task plays a significant role in firm-based differences in regulatory outcomes. The evaluation of a new drug is an inherently challenging task (Avorn, 2004), and decisions about product quality are mostly made without the benefit of full information. Although the FDA requires firms to conduct multiple stages of clinical trials to detect problems in advance, there is no guarantee that clinical trials will reveal all potential problems. Furthermore, even with comprehensive clinical trial data, the regulator may not have the capacity or time to process this information due to pressure from key stakeholders such as patient groups, Congress, or the media (Carpenter, 2002). Delaying approval to analyze and assess clinical trial data reduces the likelihood of errors of commission (i.e., approving unsafe and ineffective drugs), yet the social benefit of deliberation can decrease or turn negative as the regulator delays to reduce errors of omission (i.e., denying access to safe and effective drugs).

The challenges of drug quality evaluation compel the FDA to take on certain measures to manage uncertainty. First, similar to other regulatory agencies emphasizing science (Jasanoff, 1990), the agency turns towards the profession for relevant knowledge and expertise. Since the 1962 Kefauver-Harris amendments to the Food, Drug, and Cosmetic Act requiring companies to provide scientific evidence of safety and efficacy, science and scientists have played a major role in the agency’s review process (Hilts, 2003). Standard practices in science such as double-blind random assignments, and literature reviews of recent academic research are heavily emphasized.
by FDA management and scientists to maintain review integrity. External ties to the science profession are established through Advisory Committee meetings, and through alliances with scientific bodies such as the National Academy of Sciences and the National Health Institute to promote the flow of knowledge (Hawthorne, 2005). The close relationship to the knowledge community not only helps the agency maintain expertise in evaluating drugs, but it is also acts as an independent power base providing cultural authority (Starr, 1982) to maintain autonomy in light of competing interest groups (Carpenter, 2004).

Second, the agency can rely upon external markers of quality to come to conclusions about the unobservable quality of a candidate drug. In explaining why large and established firms receive faster approval for drugs even in the absence of capture, scholars have argued that the FDA is likely to take into consideration firm characteristics such as size (Olson, 1997) and firm experience (Carpenter, 2004) in their assessment of highly uncertain drugs. As noted in the previous section, under conditions of uncertainty, actors are likely to turn to the position of the producer for cues on the underlying quality of products. Larger and more experienced firms generally have greater access valuable resources and are more likely to possess the skills to produce high quality drugs. Hence, for the boundedly rational regulatory agency, relying upon signals correlated with quality can be a valuable tactic in allocating attention in an efficient manner.

While any signal related to quality should have an effect on FDA drug review behavior, given the agency’s embeddedness in the knowledge community, I argue that signals related to a firm’s status position in the knowledge domain will have a particularly strong influence over the FDA’s quality evaluation of a new drug. Firms with higher status in the knowledge domain inspire greater trust in their clinical trial data, which alleviates the FDA’s concern over the
technological and scientific integrity of a given product—a concern that is particularly salient for an organization striving for legitimacy and maintaining its reputation. Second, network theory suggests that central or prominent actors receive greater attention through visibility (Wasserman & Faust, 1994), implying that higher status actors in the knowledge domain will receive a more preferable allocation of the FDA’s limited attention. Finally, as the FDA is biased toward “doing no harm” (Bazerman et al., 2001), signals of quality that buffer the agency from criticism are particularly valuable for the agency. When harmful drugs are erroneously approved, the political damage is likely to be higher if the producer was an unknown entity, as opposed to a well-respected company with a long history of contributions to the knowledge community.

All in all, I expect the FDA to judge products from high knowledge status producers as being higher quality products than firms that do not occupy such positions. Given the need to expedite review, this should lead to faster approval speeds for candidate drugs sponsored by firms with high knowledge status positions.

*Hypothesis 1: The greater the status of a firm in the knowledge domain, the faster the rate at which the FDA reviews the products of the firm.*

**Conditions that Enhance Status Effects: Technical and Political Uncertainty**

To sum up the main proposition of this paper, I argued that the previously documented large-firm advantages in FDA regulatory review times (Olson, 1997; Carpenter, 2002) are the result of the agency relying on status signals in the relevant institutional field (i.e., knowledge domain) to resolve uncertainty, rather than dominant producer interests driving regulation. Larger firms no doubt have an advantage in establishing prominence in the knowledge domain,
but economic dominance does not guarantee prominence in the institutional field. If in fact, uncertainty and the regulator’s protection of reputation (and autonomy) are behind the salience of status positions, then conditions that increase uncertainty or threaten political legitimacy should lead to an even greater advantage for prominent firms. On the other hand, if large firm advantages are purely an outcome of producers controlling the regulatory process, then one should expect large (or high status) firm advantages to be consistent regardless of the context.

Broadly speaking, the drug review process is more uncertain when there are technical challenges to evaluating a drug (e.g., difficult to understand the mechanism of a drug), and politically threatening when key stakeholders are less likely to accept the judgments of the regulator to be legitimate. Building on this observation, I look at three conditions that enhance the technical and/or political uncertainties surrounding drug review: radical innovations, new market (i.e., disease) niches, and product recalls.

**Radical Innovation.** When a candidate drug is based on a highly novel compound never examined before, uncertainty is higher than when it is based on an existing compound. In general, breakthrough products developed from new components create high levels of uncertainty for both inventors and evaluators (March, 1991; Fleming, 2001). These radical innovations often provide sharp performance improvements over existing products that can shift the industry (Tushman & Anderson, 1986). At the same time, the organizational learning literature suggests that returns from this type of exploration (March, 1991) are less certain and, on average, less successful (Fleming, 2001). This nature of novel products has a number of implications for regulatory review: first, the regulator must develop new evaluation routines and schemas, which place additional cognitive burdens on the agency; second, the higher variance and lower mean success rate of radical innovations compels the regulator to scrutinize products
more intensely to prevent safety issues. Taken together, this implies that novel products that generate uncertainty should take longer to complete FDA review.

While developing a novel compound should be a regulatory liability on average, I propose that the extent of this effect will differ depending on the knowledge status position of a firm. Prior studies have demonstrated that increased uncertainty enhances the value of status (Podolny, 1994; Stuart et al., 1999). Higher status actors possess idiosyncratic credits that enable them to deviate from existing product categories (Blau, 1960; Phillips & Zuckerman, 2001) and elicit trust from other actors (Glaeser et al., 2000). As a result, I argue that high status firms can alleviate regulatory concerns over the quality of novel products, and mitigate the slowdown in review.

A firm’s knowledge status should be particularly valuable for innovative products, as novel compounds that constitute scientific advancement further enact the FDA’s institutional identity, reinforcing routines that focus the agency’s attention on knowledge signals. An example of how embedded routines can lead to science/knowledge becoming more prominent can be found in the codified review process of the FDA. In a set of “best practices” for New Drug Application review (www.fda.gov/cder/reviewer), the FDA suggests “if the drug is an NME [New Molecular Entity] look at the relevant published [academic] literature”, while “if the drug is established, limit search to the relevant stage and type of cancer”. Novel products push reviewers to pay attention to broad scientific debates within the academic community, while established products focus reviewers’ attention on narrow product (therapy) categories that do not invoke the institutional field. This implies that for novel and uncertain products, knowledge status should be particularly salient to reviewers. As a result, I hypothesize that the marginal effect that knowledge status has on regulatory approval times should be positive. Thus,
Hypothesis 2: The effect that knowledge status has on the rate at which the FDA reviews the products of the firm will be greater the more radical the underlying innovation is.

New Market Niches. Products targeted toward new disease niches can also be a source of uncertainty for the FDA. When a product does not fit existing categories, evaluators have difficulty evaluating the quality of the product (Urban, Weinberg, & Hauser, 1996). Specifically to pharmaceutical products, products targeted for diseases with no existing treatments make it harder for the FDA to identify the correct review division, or execute the review process efficiently. The lack of familiarity with disease-specific mechanisms can lead to delays similar to those expected with radical innovation.

While the technological challenges are significant, products for new disease niches also pose significant political risks to bureaucratic reputation. Advocacy groups organized around diseases are politically powerful stakeholders, and are particularly vocal when they perceive a lack of viable options for treatment, as was the case with HIV/AIDS (Vogel, 1989). The “untreatable” label for a disease also attracts significant attention from the media, and elected politicians, further heightening the damage any potential delay in approving a new treatment for a disease category. This suggests that new entrants into a disease niche will receive faster approval, as opposed to delayed approval (Carpenter, 2002).

Regardless of the net effect, the influence that a producer’s knowledge position has on FDA’s review speed should be larger when a product is addressing a new disease category than when products are addressing a crowded disease niche. Status alleviates the uncertainty associated with the new disease niche similar to what was hypothesized with radical innovations.
In addition, because the status positions of producers are salient to other key stakeholders such as disease groups and the media, the agency will be under greater pressure to accelerate drug approval for prominent actors when a product addresses a new disease. Delaying the approval of a drug from a high status producer is particularly costly if the disease receives widespread attention from the public. As a result, I hypothesize a positive interaction between newness and firm prominence.

**Hypothesis 3:** The effect that knowledge status has on the rate at which the FDA reviews the products of the firm will be greater the newer a product is to a particular disease niche.

**Product Recalls.** The recall of a product provides an external shock that influences both the firm that produced the defective product (Rhee & Haunschild, 2006; Milgrom & Roberts, 1992) and the evaluators that failed to foresee the potential problem. Economists view the enforcement of regulatory law regarding product defects as a breach of contract between producers and the government, which leads to penalties enforced by the regulator both directly related to the product (e.g., loss of the right to market the product, cost of collecting and destroying defective products, etc.), and indirectly related to a specific product (e.g., loss of overall sales, damage to firm’s reputation, etc.) (Milgrom & Roberts, 1992; Rhee & Haunschild, 2006). In the specific case of pharmaceutical regulation, the 2004 recall of the pharmaceutical drug Vioxx showed how the financial consequences to of a defective product can be devastating to the producing firm (Oberholzer-Gee & Inamdar, 2004), and also the agency responsible for approving the drug, the FDA (Topol, 2004).
Adverse events also have ramifications that extend beyond the specific defective product or producer. As producers in the same organizational field, practices that led to product defects for one producer are likely to have been shared by many firms within the industry, creating a broad distrust of all producer submissions. Key stakeholders are also more apt to investigate or revisit the existing processes at the agency, which leads the FDA to alter its regulatory behavior in a number of different ways. For one, the agency is likely to slow down review for all drugs from all producers regardless of their relationship to the tainted product. As an organization biased to “do no harm” (Bazerman et al., 2001), delaying approval of all candidate drugs to investigate quality is a risk averse strategy. This allows the agency to manage legitimacy in ways that admit that certain aspects of its operations were flawed and “act decisively and visibly to remedy those specific faults” (Suchman, 1995). This restructuring of behavior has both a functional aspect, in that it amends flaws and prevents future disasters, and a symbolic value, in that it signals contrition and may “persuade some constituents that they can safely resume pragmatic exchanges with the troubled organization” (Suchman, 1995, p. 598).

In addition to slowing down review, the threat to bureaucratic reputation following the occurrence of a product recall is likely to prompt the regulator to show even greater deference to producers with expertise. In times of crises, organizations are more likely to accept institutionalized and legitimized market orders (Meyer & Rowan, 1977), rendering existing reputation or status signals even more valuable. As crises induce a flight to quality, the favoring of prominent actors will reduce the risk of a subsequent scandal (assuming a positive correlation between status and quality), while simultaneously stabilizing market orders by reconfirming existing notions of hierarchy, Therefore, I argue that producers with high status in the knowledge
domain will suffer a smaller penalty when there is a recent drug recall, mitigating the industry-wide penalty levied upon all firms as a result of that negative event.

_Hypothesis 4_: The effect that knowledge domain status has on the rate at which the FDA reviews the products of the firm will be greater when there has been a recent product recall.

**Loose Linkages Between Status and Quality.** I have argued in this paper that observed patterns of regulatory favoritism, which at first blush suggest capture by the industry, can actually be the result of the regulators relying on status signals due to uncertainty surrounding the technical and political aspects of quality assessment. While the focus so far has been on distinguishing deference from the common presumption of capture, this leaves the contrasting view that regulators are competently approving the highest quality products without bias or capture unaccounted for. Given the intertwined nature of quality and status (Benjamin & Podolny, 1999), it is certainly plausible that the products of prominent firms receive favorable regulatory outcomes purely because of quality advantages, and not because the agency’s desire to pursue legitimacy.

Prior work on signals and FDA review (Olson, 1997; Carpenter, 2004) do not explicitly state a position on the “true” quality of the drugs being assessed, but as most economic models of signaling, implicitly assume that the actual distribution of a producer’s quality is equal to the distribution of quality audiences expect on the basis of the signal (Podolny, 1993). It is true that in the long run, all signals or market orderings must be consistent with quality if market equilibrium (Shapiro, 1983) and stability (White, 2002) are to be maintained. However, as
Podolny (1993) notes, presuming equality between signal and quality diverts attention from the factors that “may undercut this equality and engender only a loose linkage between a signal and that which it is supposed to represent” (p. 832). Not to mention, when signals are assumed to be perfectly aligned with quality, the regulator’s capacity and autonomy to make decisions are likely to be underestimated.

As status flows through interlinkages between individuals and groups (Goode, 1978), perceptions of quality are more robust and persistent to changes in quality than other attributes that can be directly observed. Thus, status positions emerge as a niche external to the producer itself—put differently, the status effects I propose should exist even when controlling for the underlying “true” quality of a candidate drug. Of course, due to the cost advantages associated with high status (Benjamin & Podolny, 1999), prominent producers’ products are generally higher quality, and disentangling advantages stemming from high quality and high status are often difficult (c.f. Washington & Zajac, 2005).

One way to examine the extent to which status signals decouple from actual quality is to delve into the content of the status signals. More specifically, I distinguish between status that is closely tied to the actual product under review, and status unrelated to the actual product. Firm status is a producer-level attribute that is the aggregate of perceptions regarding a firm’s portfolio of products. When expertise and skills that produce quality in one product segment correlate highly with other segments, a producer’s status in one domain is relevant to other areas of the product portfolio. However, if status in one set of products does not necessarily imply quality in other domains, a producer’s overall status may not reflect the quality of all parts of the firm’s product portfolio.
Prior research has shown that proximal technological and product market experience lead to more valuable products (Nerkar & Roberts, 2004), suggesting that the products from producers occupying high status positions in the product’s therapeutic domain will be of higher quality. This, in turn, suggests that regulators accurately evaluating quality will show faster approval for those prominent firms. On the other hand, if the value of firm positions is independent of actual product quality, then status in unrelated domains should also have a positive influence over institutional review times up and beyond the effects of therapy-specific status. Take, for example, a firm submitting a cardiovascular product for regulatory approval. It would not be surprising if the firm’s standing as a cardiovascular knowledge producer influenced regulatory review, as the firm’s status can be simply correlated with the product’s quality. However, if recognition of the firm’s contribution to the field of cancer—controlling for status in cardiovascular—has a tangible effect on regulatory treatment of the new cardiovascular product, this suggests that the regulator’s focus on status is driven by overall consideration of the producer’s position, as opposed to its competencies in narrow product categories. Given my argument that the FDA focuses on firm positions in the knowledge domain, I expect that a firm’s status in unrelated and basic knowledge domains has a significant effect on regulatory review times.

Hypothesis 5: The greater the status of a firm in the non-therapy domain of its product, the faster the rate at which the FDA reviews the products of the firm.
METHOD

Sample and Data: New Drug Application (NDA) Reviews

My sample frame includes all non-generic New Drug Applications (NDAs) submitted to the FDA from 1990 to 2004. For a new molecular entity (NME) to reach consumers, it must clear numerous scientific and regulatory hurdles (Ng, 2004). New drugs go through two distinct stages: drug discovery (Henderson & Cockburn, 1996) and drug development (Cockburn & Henderson, 2001). The drug discovery stage involves finding compounds that demonstrate some desirable effect in either an animal or chemical screen (Henderson & Cockburn, 1996). Scientific articles and patents usually appear at this stage. The drug development stage is largely about exploring the degree to which a particularly promising compound is safe and effective for humans by conducting three separate stages of clinical trials (Phase I, II, and III). Once a drug completes its clinical trials and the results demonstrate that the drug is safe and efficacious over existing treatment drugs, a New Drug Application (NDA) is filed to seek approval for marketing the drug. As I am interested in the regulatory agency’s evaluation of products, I focus exclusively on this final stage of drug development, as it isolates institutional evaluation from a firm’s ability to successfully run large-scale clinical trials.

The data I collected include 372 approved New Molecular Entities (NME) and 512 approved non-NMEs, or Incrementally Modified Drugs (IMDs) (new combinations, new formulations, etc). I exclude generic drugs as they are subject to different application rules (i.e., Abbreviated New Drug Application (ANDA)) and approval criteria (i.e., demonstration of bioequivalence as opposed to safety/efficacy). These 884 applications were submitted by roughly 300 pharmaceutical and biotechnology firms.
I collected the submission date and approval dates for NDAs from a variety of sources. First, Ed Hass from the FDA provided a dataset of all approved NMEs from 1964 to 2004. For non-NMEs approved during my sample frame, I collected New Drug Approval letters issued to sponsor pharmaceutical firms posted on the FDA electronic reading room (www.fda.gov) as part of the 1996 Freedom of Information Act (FOIA). The full range of approval letters are only available from 1998 to present, so I obtained the remaining non-NDAs not covered by this data from Daniel Carpenter at Harvard University. Other NDA relevant data such as the review priority of an NDA (priority or standard) or the chemical entity type (new molecular entity, new combination, etc.) were collected from the FDA electronic reading room and the Orange Book, an annual government publication listing all approved prescription drugs and over-the-counter (OTC) drugs currently on the market.

Data for independent and control variables were obtained from a variety of sources. Detailed project-level and firm-level data come from Pharmaprojects, a database which provides event-history data (time to failure/launch), related patents numbers, detailed therapeutic categorization, and the licensing status of drug development projects from 1980 to 2004. Patent data were collected from the United States Patent and Trademark Office, the NBER patent database (Hall, Jaffe, & Trajtenberg, 2001), and the National University of Singapore’s patent database (patents.nus.edu.sg). Compustat and Bioscan provided additional information regarding employment and subsidiaries of firms in my sample.

**Dependent Measure**

**NDA Review Times.** The dependent variable for the study is the approval time for New Drug Applications submitted to the FDA (Olson, 1997; Carpenter, 2002, 2004). As I frame the
hypotheses in terms of the speed of approval I use an event history approach (Allison, 1984; Tuma & Hannan, 1984) to investigate the effects on the institutional review times of new drugs. To allow variations in baseline hazard rates across different time periods, I employ a piecewise exponential model with the equation that I estimate taking the following specification:

\[ h(t) = h_0(t) \exp[XB + Y(t)S] \]

where \( h(t) \) is the hazard or transition of project success/failure, \( h_0(t) \) is an unspecified baseline rate for the hazard, \( X \) is a matrix of time-constant covariates, \( Y(t) \) is a matrix of time-varying covariates, and \( B \) and \( S \) are vectors of unknown regression parameters. Piecewise exponential models are preferable due to the fact that they do not require one to assume a functional form for time dependence. In addition to the piecewise models, I also estimated Cox Proportional Models (Cox 1972) and Log-Normal parametric models with a “frailty” to capture unobserved observation-specific effects (Gutierrez 2002) with identical results.

**Independent Measures**

**Status in the Knowledge Domain (H1).** Following prior work that takes an ecological perspective on knowledge and technology (Podolny & Stuart, 1995), I utilize patents and patent citation patterns as a tool to identify a firm’s relative position in the knowledge space. Patents are useful in identifying inventions of firms (Schmookler, 1966) and the citations of patents provide insight on the technological building blocks of an invention (Podolny & Stuart, 1995). Admittedly, patents only reflect knowledge that is easily codified and less of the tacit nature (Cowan, David, & Foray, 2000), making patents a less than perfect measure of a firm’s overall
knowledge base. In addition, patents encompass not only scientific knowledge based inventions, but also local search derived technologies (Fleming & Sorenson, 2004) that cause them to be somewhat of a noisy signal of a firm’s knowledge standing. Yet, for a number of reasons, I believe patents are equally suitable and even preferable to measures of firm knowledge such as scientific publications. First, although firm propensities to patent differ (Levin et al., 1987), this heterogeneity in policies is much more pronounced for publication of scientific articles by research staff (Henderson & Cockburn, 1996). Second, in the pharmaceutical and biotechnology domains where the distinction between science and technology are rapidly disappearing (Narin & Noma, 1985), patents usually come before publications due to concerns over spillover effects (Meyer, 2000), making patents a more up-to-date reflection of the firm’s knowledge base. Finally, it is more difficult to ensure a uniform standard of evaluation for scientific publications, which have a number of diverse outlets, than patents, which have a single entity—the United States Patent and Trade Office—judging all patent applications.

To obtain the status of firms in the technological domain, I use patent citation relationships as the manifestation of deference between two actors in the knowledge space (Podolny & Stuart, 1995). When a firm applies for a patent, it is required to list prior inventions that deal with similar issues to demonstrate how the current application differs. Because patent citations reflect technological building relationships, a direct tie (citation) from one organization to another signals an implicit acknowledgement of the importance of the citation-receiving organization, and suggests a certain deference by one organization to the other (Podolny & Stuart, 1995).

Not all citations are submitted by firms. Patent examiners at the USPTO also include relevant technologies or scientific references at their discretion. This makes it somewhat problematic to consider citations as a form of deference between firms. However, as Sampat (2004) shows, the medical and biotechnology domain of patents has by far the lowest level of examiner-inserted patents—20% at the citation-level and 45% at the patent-level—mitigating some concerns.
Thus, firms that receive more citations on their technological work are expected to enjoy a higher status in the technological domain than others. Therefore, I define status in the technology domain as:

\[ D_i = \frac{\sum_{j} \sum_{t} C_{j(i,t-5)}}{\sum_{j} \sum_{t} C_{j(i,t-5)}} \]

where \( D_i \) is the status of a firm \( i \) at time \( t \), and \( C_{j(i,t-5)} \) is coded 1 when a patent of firm \( j \) cites a patent of firm \( i \) during the preceding five years up to \( t \). In essence, status measures the proportion of citations a firm receives to all citations made to pharmaceutical firms in the sample five-year moving window.\(^6\)

**Innovativeness of a Product (H2).** I use the FDA’s classification system based on chemical type to determine the innovativeness of a new drug. The agency designates drugs based on compounds that have never been approved for the U.S. market as new molecular entities (NMEs) and assigns it to type 1 in the chemical entity classification. Drugs that include active ingredients that are new derivatives (type 2), new formulations (type 3), new combinations of existing compounds (type 4), or modified by new manufacturers (type 5) are collectively referred to as incrementally modified drugs (IMDs). For the purpose of this study, I do not distinguish between the various chemical types of IMDs, and instead create a dummy variable coding for NMEs (=1) and IMDs (=0).

Furthermore, I argue that examiners themselves are members of the ecology and thus reflect general perceptions of status in the knowledge space, rendering their deference patterns meaningful in the context of determining status.\(^6\) This measure is essentially a degree centrality measure of a firm’s position in the patent network. While other studies have utilized a Bonacich centrality measure, prior studies (Stuart, 1998) and my own analysis on a subset of firms in my sample suggest that the correlation between the two measures is usually above .90, so I used the more simple measure for this study.
**Order of Market Entry (H3).** To determine the “newness” of a market (i.e., disease) niche, I create a running count of the number of drugs that exist in a particular disease niche based on the therapeutic indication submitted for the NDA. Drug candidates that were early in the entry order are considered to be a pioneer of that market niche while those that have a high order of entry are viewed as less innovative. There were a total of 216 unique disease categories in my sample, and a list can be obtained from the author upon request.

**Product Recalls (H4).** Despite the frequently used term ‘recall’, the Food, Drug, and Cosmetic Act in fact does not generally authorize the FDA to order a manufacturer to recall a food, cosmetic, or supplement. Only in the specific case when a medical device, human tissue product, or infant formula pose a risk to human health does the law authorize the FDA to take direct action. The more common action taken by the FDA in regards to a drug that can cause harm to humans is to advise or request a voluntary withdrawal of the product from the marketplace by the manufacturer of the drug. I compiled a list of all the drug withdrawals that have occurred due to safety issues from 1980 to 2003, with detailed information on the sponsor of the drug and the date of withdrawal. There were a total of 18 events, ranging from McNeil’s withdrawal of Zomepirac in 1983 to the 2001 withdrawal of Bayer’s Cerivastatin. To examine whether a previous market recall influenced the review times of new drugs, I created a series of dummy variables coding whether any firm in the industry had products recalled in the preceding year.

**Therapy vs. Unrelated Status (H5).** I first create a ‘therapy category specific status’ measure by counting the proportion of citations a firm receives from all the citations made by patents in the therapy category of the particular product. To sort patents into specific therapy categories, I created a matching scheme similar to Nerkar & Roberts (2004), where subclasses of
the “514” main class were manually matched up to the 15 ATC categories. I then proceeded to label all patents that had “514/xxx” as a technology class with the matching therapy code and calculated a status measure within that code. I then calculate a ‘non-therapy category specific status’ measure that captures the proportion of citations a firm receives outside the therapy category of the product. This unrelated status not only accounts for patents from other therapy categories, but also includes more basic molecular biology or organic chemistry technologies that are not tied to one therapy category.

Control Variables

**Quality of a Drug.** The hypotheses developed above all explore the effects of market position *independent* of the actual quality of the product that is being evaluated. Due to the intertwined relationship of status and quality, it is often times difficult to tell apart the effects of actual quality and status signals (Podolny, 1993). In the case of drugs, the dimensions of quality are multiplex (e.g. efficacy, safety, cost, etc.) and ambiguous (Avorn, 2004). Therefore, disentangling quality and status is an exceptionally challenging task in this context. I attempt to control for the quality of a drug submitted in two ways: First, I include the *priority rating* (priority vs. standard) conferred upon the drug by the FDA as a way to distinguish between significant improvements over existing treatments and those that are moderate improvements. Second, I examine the time it took a drug to proceed through the development phase *prior to* NDA submission. Drugs that complete clinical trials in a more expeditious manner can be assumed to have fewer problems of efficacy or critical side-effects. Higher quality drugs are also assumed to receive greater organizational support, leading to more resources to complete the development phase quickly. Prior work (Dranove & Meltzer, 1994) show that development time
of a drug and its FDA review time are correlated, suggesting that the former may act as a proxy for the quality of the drug. Following Dranove & Meltzer (1994), I use the date of patent application for a drug’s core invention as the start of the clinical development phase and measure the duration of a drug’s development by subtracting this from the date at which a firm files an NDA application to the FDA for that drug.

**Firm-Level Controls.** To control for the differential resources available to firms, I include the size of the sponsoring firm as measured by the log of the firm’s employee count in the submitting year. A dummy variable indicating the firm’s public or private status, and a dummy variable coding whether the firm is headquartered in the United States or internationally was included. In addition, given the possibility of learning effects in frequent submissions or interpersonal relationship building as a result of frequent contact, I include an experience variable that counts the number of NDAs a firm has approved prior to submission of the focal product. The popular press and consumer advocacy groups often raise the possibility that regulatory outcomes are influenced by political pressure from firms via elected officials (Hilts, 2003; Hawthorne, 2005), so I use data collected from the Federal Election Commission (FEC) to measure the extent to which firms contribute to political candidates as a way to control for a firm’s political influence. I include a count of the number of political contributions made by the firm in the election cycle when the drug was submitted to the FDA as a measure of political clout. To control for the correlation across projects within firms, I estimate robust standard errors by clustering the drugs by sponsoring firm.

**Disease Category.** It is well established that drugs treating certain diseases are easier to develop and cause fewer safety problems in the future (DiMasi, 2001; Danzon, Nicholson, & Pereira, 2003). This heterogeneity across disease categories also carries over to FDA review
times as certain treatments are not only easier/harder to evaluate due to the relative complexity of
the treatment and target mechanisms, but also due to political factors such as the media or
disease support groups (e.g. AIDS) (Carpenter, 2002). To control for this correlation within
disease categories, I include a dummy variable for each of the 216 disease categories in the
regression, and estimate effects within a particular disease category.

**Other Controls.** I include *year dummies* to control for general shifts in FDA review times
that result from laws such as the Prescription Drug User Fee Act (PDUFA) of 1992, which
allows the FDA to collect fees from firms submitting NDAs to support increased staffing, and
escalating deregulation pressures and political influence from the Republican-controlled
executive and legislative branches during the sample frame (Hilts, 2003; Hawthorne, 2005). I
also include a variable indicating whether the candidate drug was originally developed by the
sponsoring firm or *licensed* later on in the development stage.

**RESULTS**

Table 1 reports the means and correlations for the major variables. Figure 1 shows the
Kaplan-Meier estimates of exiting FDA review (i.e., drug approval). As expected, the rate of
approval is low in the first few months, accelerates significantly in the 6 month to 1-year
window, and decelerates from year 1 to year 2, plateauing after more than 3 years under review.
This forms the basis for creating five time pieces in the piecewise constant models.

Results from the piecewise constant models of the hazard of completing FDA review are
shown in Table 2.

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Insert Figure 1, Table 1 and 2

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Baseline Model. The first model shows the baseline estimates with the control variables. Drugs that receive priority ratings from the FDA received significantly faster approval (p<.01). Consistent with prior work (Carpenter 2002, Olson 1997), larger firms receive faster approval for their drugs (p<.05), though the experience of the firm submitting NDAs to the FDA or firm political contributions did not have a statistically significant effect. The newness of a market niche (i.e., order of entry) had a significant effect (p<.01) on drug approval, with drugs that were treatments for underserved diseases receiving faster approval. The effect of New Molecular Entities, which I argued lead to greater technology uncertainty, had a coefficient in the expected direction, but was not significant at the .05 level. As expected, the effect of a product recall in the previous year led to a slowdown of review for all drugs submitted to the FDA (p<.01).

Status Effects (H1). Tests for the main effect of status are presented in Model 2. Supporting Hypothesis 1, the status of the firm in the knowledge domain has a strong and positive effect on the review times of its drugs (p<.01). According to the piecewise-hazard estimates, a one standard deviation increase in status leads to a 21% increase in the hazard of completing review. To translate hazard rates into review duration (i.e. days), I calculated the marginal effects of each variable with all other control variables at mean levels. For status, a firm in the top 15% of status will spend 218 fewer days in FDA review than the median status firm. These effects show strong support for the claim that status signals generated in the knowledge domain influence regulatory decision making. Also noteworthy is the change in the effect of firm size. With the inclusion of firm status in the model, the effect of firm size is reduced by more than half, and the coefficient is not statistically different from zero (p>.10).

\[ \text{The hazard of completing review is 1.212 (=exp(.192)) times the baseline hazard rate for each standard deviation increase in status} \]
Status and Uncertainty (H2, H3, H4). Model 3 includes the interaction effects of various measures of uncertainty. Contrary to Hypothesis 2, the uncertainty stemming from radical innovation does not seem alter the effect of status. On the other hand, there is evidence—though not at the .05 level—that as the order of entry increases, the effect of status diminishes (p<.10), providing partial support for Hypothesis 3. The interaction effect between the product recall variable and status is positive and significant (p<.05), confirming the hypothesis that regulatory deference is more likely when political uncertainty is heightened. Figure 3 depicts the relationship between status, recall, and review speed. It is interesting to note that for the most prominent actors (i.e., top 5% in status), product recall events are actually more beneficial in expediting review than non-crisis times. Taken together, the results from the interactions effects suggest that political uncertainty and the threats this poses to the FDA’s reputation is a main motivation for relying upon status signals.

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Insert Figure 3
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Therapy Status vs. Non-Therapy Status (H5). Model 4 shows estimates for the two components of a firm’s status position, status that is related to a particular product, and status in the broader domain of knowledge. The regression results show that a firm’s status in the product’s therapy category does not have a strong effect over the speed of approval (p>.10). On the other hand, unrelated status is significant with slightly smaller effects than the combined status position of a firm. Figure 4 plots the coefficients with confidence intervals for both models. While the difference between therapy and non-therapy status is not statistically significant at the .05 level, it strongly suggests that the observed status effects are driven to a
greater degree by the firm’s position in the overall knowledge space as opposed to domain-specific status positions.

**Revisiting Quality and Status.** The main effect of status, the interaction with uncertainty, and the effect of unrelated status together paint a compelling picture that a firm’s position in the knowledge domain, *independent* of the quality of the drug being reviewed, has an effect on the FDA’s review behavior. Yet, despite efforts to control for differences in quality, the difficulty of determining “true” quality, as noted in previous sections, makes entirely eliminating quality differences as a driver for different regulatory outcomes challenging. The alternative hypothesis that high status actors have faster approval because they produce higher quality products is both plausible and difficult to ignore.

Underlying this alternative explanation is the assumption that high status actors produce high quality products at a higher rate than low status actors. While by no means a direct measure of a drug’s quality, the priority rating of a drug provides a rough cut at distinguishing between high quality products and those that are regular products, and thus provides a window into examining the assumption of positive correlation between status and quality. According to the FDA, drugs that receive priority ratings are those that “are significant improvement over existing treatments” (FDA website). The FDA further specifies that priority drugs should exhibit one of the following characteristics: 1) increased efficacy 2) decreased toxicity 3) increased compliance or 4) effectiveness in new subpopulation. Treating this as a measure of quality, I estimated the likelihood that a drug candidate receives this priority rating. Table 4.2 below shows the estimates from a logit analysis.
New Molecular Entities are four times as likely to be deemed as a priority drug (p<.01). Not surprisingly, drugs that are early entrants into a disease category received priority ratings at a significantly higher rate (p<.01). Also, drugs that took longer to develop have a significantly lower chance of receiving a priority rating (p<.05). Interestingly, both firm size and political clout have a negative effect on priority ratings, though not statistically significant (p>.10). Of greatest interest is the effect of status on a product’s chances of receiving a priority rating. The results suggest (though not at a statistically significant level) that higher status actors have a lower rate of producing exceptionally high quality products. More specifically, when separating between therapy status and non-therapy status, the former has a positive effect on obtaining a priority rating (p<.10), which is consistent with the argument that therapy status is a good proxy for quality. On the other hand, the coefficients suggest that non-therapy status lowers the probability of producing a high quality product. The finding that large and high status firms are on average producing fewer drugs with great therapeutic potential is quite noteworthy, and I discuss possible explanations for this finding in the following section. All in all, the finding that prominent firms in the knowledge domain do not produce higher quality drugs consistently adds support to my argument that the demonstrated status effects go beyond a simple story of better quality drugs receiving faster approval.

**DISCUSSION**

The current study examines the duration of FDA new drug approval and how the identity of the sponsoring firm can expedite or delay regulatory reviews. Favorable regulatory outcomes enjoyed by established firms have traditionally been considered the result of political capture. Alternatively, some scholars have argued that a firm’s reputation signals product quality to the
regulator, which leads to better outcomes. My main argument in this paper is that deference by the regulatory agency toward prominent producers in the institutional (i.e., knowledge) fields can explain observed regulatory advantages. In the case of the FDA, firm positions in the knowledge domain are particularly valuable for regulatory review as they provide both technical and political buffering from uncertainty, and thus I hypothesized that status would be more valuable when innovations were radical and legitimacy threats were highest.

Results from an examination of 884 New Drug Approval (NDA) applications submitted to the FDA from 1990 to 2004 supported a number of the hypotheses. First, firms with higher status in the knowledge domain enjoyed faster review times for their drugs. A drug sponsored by a firm occupying a position in the top 15% of the knowledge hierarchy spends roughly two hundred days less in the regulatory review process compared with a drug from a median status firm. This advantage bestowed upon high status actors translates into significant revenue for the firm. Second, the evidence confirmed that knowledge status is more valuable when threats to the agency’s legitimacy was highest. The interaction effects imply that high status firms are rewarded for pursuing new market niches that enhance the bureaucratic reputation of the FDA, and enjoy a smaller penalty when the FDA slows down approval after a significant product recall event.

While these status effects can simply be the result of high status actors producing higher quality products, I find evidence that the regulatory advantages high status firms enjoy have less to do with the underlying quality of a specific product, and have more to do with the general identity of the firm in the broader knowledge domain. A firm’s status in the relevant therapeutic domain had a positive effect on review speed, but it was status accumulated in more basic scientific domains or unrelated therapy categories that had a larger effect on regulatory duration.
Furthermore, status did not exhibit a strong correlation with observable measures of quality such as priority rating, suggesting that these status effects occur independent of actual differences in quality.

The study, of course, is not without limitations. First, by examining just approved drugs without accounting for NDAs that were abandoned during the FDA review process, there is a possibility that my results are biased. Information on NDAs are treated as trade secrets prior to full approval by the FDA, and are unavailable if a drug fails to reach the market. Analysts suggest that roughly 10-20% of NDAs are deemed “Not Approvable”, and in my sample approximately 12.6% of NDAs received “Not Approvable” decisions in the first review cycle, but were subsequently approved after resubmission, implying that a majority of Not-Approvable drugs are eventually captured in my data. While this is consistent with FDA reviewer comments that the number of drugs that are abandoned post-FDA submission is very small, nonetheless, the potential for bias exists. Second, the current study fails to account for firm decisions on the timing of their submissions to the FDA. If firms adjust their submission strategy to maximize market reception, then review times can in fact be endogenous to events that alter the submission calculus. Failing to adequately model this is a limitation of this study. Finally, while the paper proposes that uncertainty resolution and legitimacy concerns are the mechanisms that drive the positive effects of status positions, the agents that are making decisions in light of this uncertainty are not the organization per se, but rather the individuals that comprise the review teams of the agency. The intra-organizational dynamics that determine the action of the FDA have not been explored in this paper to any extent. For example, social structures within the organization (such as the network composition of the review team) or micro identities of reviewers can potentially be factors that interact with firm characteristics to influence FDA
review time. This intersection of micro and macro dynamics of signal processing provides an intriguing research question that future studies will attempt to address.

Despite these limitations, I believe the study offers a number of important contributions to the organizational theory literature. First, the paper contributes by providing a richer view of regulation and the theory of capture. In the academic literature and popular press, evidence of regulatory bias is attributed to producers’ economic interests steering regulation in their favor. This paper presents an alternative mechanism to the profit or vote-driven views of regulatory capture by highlighting the role of deference towards expertise in resolving technical and political uncertainty. This does not mean that one should rule out corruption or political influence as an explanation, but rather, the study makes a strong case for considering multiple factors when understanding the determinants of regulatory behavior. In particular, emphasizing the organizational challenges and solutions to regulatory decision-making paints a more nuanced picture of the agency, which contrasts prior work viewing institutional actors as entirely determined by economic forces (e.g., capture theory) or as an exogenous mechanism that exists to align firms to existing cultural norms of market behavior (Fligstein, 2001; Schneiberg & Bartley, 2001). From this perspective, the paper adds to the neo-institutional perspective of states as an entity that legitimizes organizations (e.g., Dobbin & Sutton, 1998; Ingram & Simons, 2000) by offering an alternative image of states as actors that respond to the legitimacy and status claims generated by actors in the institutional field (Henisz & Zelner, 2005).

Second, the paper adds to the burgeoning work on status as a competitive asset in market settings (Podolny, 1993, 2005) by identifying an additional source of advantage: regulatory performance. Scholars have argued that prominence and prestige generate greater resource flows to the actors that occupy those positions (Burt, 1982; Podolny, 1993). While the mechanisms of
this resource flow have focused on direct consequences such as lower costs or higher revenues, this paper identifies institutional attention as an indirect route to obtaining strategic advantages. The study also delves deeper into the social construction of status signals (Washington & Zajac, 2005) by exploring the content (therapy vs. unrelated) and potential decoupling of status. While prior work focused on status as a signal of quality (Podolny, 1993; c.f. Washington & Zajac, 2005), this study raised the possibility that broader identity claims embedded in status signals are equally, if not more, important as a driver of status effects. This emphasis on social mechanisms of status expands the theoretical reach of the concept, while enriching our understanding of the process that leads to previously identified outcomes.

Third, the study opens a window into the dynamic interaction between gatekeepers and market organization. Third-party actors such as regulators, critics, and analysts play a critical role in market settings by evaluating or providing schemas that help other audiences evaluate offerings from firms (Zuckerman, 1999; Hsu, 2006). While the direct impact of gatekeeper evaluation on firm outcomes is somewhat obvious, the insight that the mediating actors themselves are subject to social influences (Rao, Greve, & Davis, 2001) renders the relationship between gatekeepers and firms more intriguing. For example, how can we explain the empirical observation that high knowledge status firms have a lower rate of products of exceptional quality? One potential explanation is that the lower costs enjoyed by high status actors (Podolny, 1993)—realized in the development stage (e.g., recruiting scientists, attracting partners, etc.) and projected in the regulatory stage (e.g., scrutiny from the FDA)—allow high status actors to pursue relatively less-promising products compared with lower status actors, while maintaining similar returns. The upshot of gatekeepers reacting to a firm’s social standing throughout the product development process is that the distribution of products—conditional on surviving to a
particular stage—will tilt towards a decoupling of status and quality. In other words, high status actors will have a higher proportion of low quality products compared with the initial baseline relationship that led to high status actors achieving prominence. In the FDA example, not only do high status actors have a lower propensity to submit exceptional quality drugs, but I find evidence (documented in another study) that candidate drugs sponsored by high status actors also have a higher propensity of causing significant adverse events such as major product withdrawals or severe warnings. These findings suggest that the social and organizational dynamics of the gatekeeper-firm interaction can lead to outcomes that are not predicted by existing theory.

The research also carries many strategic and practical implications for firms competing in the pharmaceutical space. While the FDA review period is just a piece in the whole drug development process, it is the final and most important stage to firms realizing revenue from their years of developmental efforts (Hawthorne, 2005). First, the results from this study provide tangible guidelines to firms choosing their product strategies. The fact that new markets and political uncertainty following product recalls render status an even more valuable asset implies that low status actors should sort into appropriate market niches (i.e., established disease niches) as a way to avoid incurring institutional penalties. This implication is somewhat ironic, given that the conventional wisdom holds that young (and thus, low status) biotechnology firms should pursue high-risk, high-return opportunities, when in fact, these are the firms that suffer the most from any delay in regulatory approval. A strategy that initially pursues easily developed and quickly approved drugs for faster revenue recognition provides more time to build technological reputation may be more ideal for these young and unproven firms.
Second, the finding that general signals of quality (as opposed to therapy-specific signals) were more important in expediting review has implications for R&D investment strategies of firms. While a firm’s status position in the knowledge domain, being the product of the perception of others, is not something over which firms have complete control, the long-term strategy implication for firms is that investment in basic science and other non-product specific capabilities can generate “halo effects” for future products even if the actual results from the investment return little in tangible results. In other words, a firm’s knowledge competency is not necessarily mediated by the actual products that embody this knowledge, and can influence external evaluators regardless of the presence or content of the products firms produce. This decoupling of research and product provides further evidence for building broad and deep knowledge bases regardless of the immediate benefits to firms.

Finally, this paper provides a broader understanding of the implicit reward system created by the regulators and their institutionalization. As a gatekeeper and evaluator, the FDA’s regulatory behavior provides strong incentives (and disincentives) for the firms it regulates (Thomas, 1990; Fligstein, 2001). For example, if the FDA unconsciously rewards firms that forgo innovative research and focus on outbidding other firms for promising drug candidates, then logic suggests that large firms possessing the resources to conduct cutting-edge resource will opt to utilize it in a less-innovative fashion. By taking a close look at the implicit incentives laid out by the FDA, this paper provides the public, the ultimate principals of all state regulators, a better understanding of the tradeoffs involved in protecting consumer interest through regulation and the counter-productive incentives that such an approach may incur.
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Piecewise Constant Models of Hazard of FDA Approval

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FIGURE 1
Kaplan-Meier Survival Estimates of FDA Approval

FIGURE 2
Hazard of Completing FDA Review and Interaction Effect Between Status and Recall
FIGURE 3
Hazard of Completing FDA Review by Therapy and Unrelated Status