Pushing for Speed or Scope? Pharmaceutical Lobbying and FDA Drug Review

ABSTRACT

We argue firms implementing political activities face a fundamental trade-off between the content and the speed of public officials' decisions. We show evidence of this trade-off looking at FDA drug approvals: lobbying for broader drugs leads to longer revisions, whereas lobbying to speed up the review process leads to narrower drugs. How do firms respond to this trade-off? We argue firms' lobbying strategies depend upon the level of IP protection behind their drugs. We predict that firms with high levels of IP protection will lobby for drug scope, whereas firms with low levels of IP protection will lobby for revision speed. We find support for our theory in a sample of 540 new drug applications to the FDA from 1998 to 2015.

"*[Company X] hired us to obtain financial support from the government. Once we started working on the project, we realized there were two options. We could lobby to get a standard subsidy quickly or we could be ambitious and lobby for a larger one. However, lobbying for the larger subsidy had a downside: it would significantly delay the process and the firm was facing strong competitive pressures. Ultimately, the final decision needed to be made by the board.*" – (Professional Lobbyist)

Governments' routinely make decisions that significantly impact corporations. This is why firms are active participants in the government's decision-making process (Hillman, Keim, and Schuler, 2004) and why firms undertake political activities to try to shape public officials' decisions in their favor (de Figueiredo and Richter 2014; Hillman et al., 2004). One aspect firms try to influence is the *content* of public officials' decisions. By using their political capital, firms can push public officials to pass the policy decision that best meets the firm's needs.[1] In addition to the content of the decision, firms can use their political influence to improve the *speed* with which decisions are made. Firms are frequently in situations where they need public authorization to implement their strategy.[2] Thus, undertaking political efforts to speed up such authorizations represents a valuable option. Overall, then, political capital provides an opportunity to influence both the content and the speed of governmental decisions.

However, as the lobbyist's quote suggests, these two objectives are typically incompatible. As firms try to adapt policy content to their preferences, the more complex the decision-making process becomes for public officials, which is likely to translate into longer evaluations (Choudhury and Haas, 2017; Marco, Sarnoff and deGrazia, 2016). Conversely, if firms want a quick decision, the way to accelerate public official's evaluation is to simplify the

[1] For example, firms seek to adapt a new regulation to their interests (Bonardi, Holburn, and Vanden Bergh, 2006; Haeder and Yackee, 2015), to lower corporate taxes (Richter, Samphantharak, and Timmons, 2009) or to secure larger federal contracts (Richter, Samphantharak, and Timmons, 2009).

[2] For example, firms need to wait for (a) the necessary certification to quickly enter a new market and gain first-mover advantages (Hawk, Pacheco-de-Almeida and Yeung, 2013), (b) product approval from the appropriate regulatory agency to rapidly introduce a new product into the market (James, Leiblein and Lu, 2013), (c) patent granting to start licensing a new technology before competitors (Dowell and Swaminathan, 2006), or (d) anti-trust agency's consent to merge with another firm in the fastest possible way (Homburg and Bucerius, 2006).

process by pushing for less tailored content. Therefore, political efforts to shape the content of governmental actions are likely to delay public officials' decisions; whereas efforts to speed up governmental decisions are likely to lead to policy content that is less adapted to the firm's needs. The question then becomes: when do firms use their political capital to speed up public officials' decisions at the expense of less customized content, and when do they push for more tailored content at the expense of speed?

Understanding how firms respond to this trade-off is key to the extent that this dilemma arises in very diverse situations. For instance, a firm waiting for the anti-trust agency's permission to merge with another company faces a trade-off between a quick decision (so they can start the merging process and reduce stock market uncertainty as soon as possible) and an advantageous decision (that the anti-trust agency does not require the divestiture of any of the acquired firm's assets). Similarly, firms applying for patent approval to the USPTO face a trade-off between a quick approval process (so they can start licensing their technology and gain network effects before competitors) and a broad patent (adding as many claims as possible as a way to increase the barriers to imitation of their new technology). This trade-off is also felt across a variety of industries. For example, a mining companies face a trade-off between obtaining the rights to extract minerals quickly (in order to increase profits immediately) and negotiating a deal with the government to lower royalties. Further, companies producing driverless cars also face the trade-off between being first to the market and crafting a regulatory environment that is tailored to their product.

In spite of its relevance and ubiquity, the question of how firms respond to this trade-off remains unexplored in the CPA literature. Extant work almost exclusively focuses on how political efforts influence policy content, overlooking the fact that firms may also use their

political capital to speed up public officials' decisions. Therefore, because prior studies do not even account for speed as a meaningful non-market outcome, they cannot inform us about how firms respond to this trade-off between content and speed. In this study, we account for the interdependencies between speed and content and show how firms resolve this trade-off. For this, we look at the political activities of pharmaceutical firms who submit drugs for approval to the Food and Drug Administration (FDA). We believe this is an ideal setting because (a) pharmaceutical firms are among the most active organizations in the political arena and (b) the trade-off between speed and content is highly salient in new drug applications.

For a new drug to enter the U.S. market, firms must file a New Drug Application (NDA) and get a positive review by the FDA. In these NDA reviews, the FDA decides two things firms care about: the patients for which the drug is approved (i.e., *drug scope*) and when the drug is allowed to enter the market (i.e., *review time*). We examine which of these two outcomes firms try to influence through a specific political tactic, lobbying. Obviously, firms want their drugs to be approved as quick as possible and with the greatest possible scope—i.e., for as many conditions/subpopulations and the least interactions/contra-indications as possible. Yet, regulatory agencies' reviews take longer the larger the number of issues they need to evaluate (Choudhury and Haas, 2017; Marco et al., 2016). This means firms that lobby to get the broadest possible drug are likely to experience longer reviews, whereas firms that lobby to get quicker reviews will probably obtain drugs with lower scope. Therefore, firms going through NDA reviews face the trade-off that motivates this study: do firms lobby to obtain broader drugs or quicker reviews?

To address this we combine CPA and innovation theories to develop a contingency model that predicts when firms will lobby for speed (quick reviews) or content (broader scope).

Specifically, we argue the market pressure a firm faces captures their urgency to enter the market, and thus whether the firm prefers a quick decision or a decision better tailored to its needs. For new product introductions, the biggest market pressure comes from potential imitators, which is determined by the intellectual property (IP) protection behind new products (Ceccagnoli, 2009; James et al., 2013; Teece, 1986). Firms whose products have weak IP protection are more vulnerable to imitation and therefore have a stronger urgency to introduce their products as quick as possible to start exploiting first-mover advantages (Leiponen and Byma, 2009; Sheng, Zhou, and Lessassy, 2013). Conversely, firms whose products enjoy strong IP protection face weaker imitation threats and thus are willing to take more time to better optimize their product to market demand (James et al., 2013; Teece, 1986). Based on this, we claim firms with strong IP protection behind their drugs are more likely to lobby for greater drug scope at the expense of longer reviews, whereas firms with weak IP protection behind their drugs are more likely to lobby for quicker reviews at the expense of narrower drug scope.

We test our predictions in a novel data set containing 540 NDAs between 1998 and 2015 and find support for our theory. When firms have strong IP protection lobbying the FDA leads to broader drugs at the expense of longer reviews. On the contrary, when firms have weak IP protection lobbying leads to faster revisions but narrower drugs. The magnitude of these effects is substantial. Among firms with weak IP protection, lobbying the FDA speeds up the approval process by about six months compared with firms that do not lobby the FDA, which represents a 44% reduction in revision time. Open-market estimates of the value of this time difference are upwards of $300 million (Ridley and Regnier, 2016). Likewise, for firms with strong IP protection, lobbying the FDA provides a 90% greater likelihood that their drugs are approved to treat multiple diseases which, according to experts, can more than double sales (Carroll, 2005).

Our paper makes several contributions to the CPA literature. First, we account for the multi-dimensionality of public officials' decisions. While prior studies exclusively examined the content of public officials' decisions, our study shows that there is another critical dimension—the speed with which public officials make their decisions—that firms may try to influence through their political activities. Second, by accounting for this multi-dimensionality, our study unveils a fundamental trade-off in non-market strategies: lobbying for customized content may imply a delay of public officials' decisions whereas lobbying for decision speed may require sacrificing policy content. Third, we show how firms respond to this trade-off by developing a contingency model around the logic that firms' non-market strategies are not isolated from the firms' market environment. We propose the pressures firms face in the market arena strongly determine how firms design their non-market strategies. This approach responds to calls to better understand how market and non-market dimensions are interrelated (e.g., Hillman et al., 2004). In addition, we believe our paper contributes to the innovation literature. This is one of the few studies that accounts for the regulatory stage in the innovation process. Our findings may help explain part of the variance in firms' success with their new product introduction strategies. It provides a plausible explanation for why certain firms that put a lot of R&D effort on identifying new uses for their products are not able to end up with a product with broader scope. It is important to account for the non-market stage in new product introductions as well: a broad or a quick introduction requires the appropriate non-market strategy.

EMPIRICAL CONTEXT: NEW DRUG APPLICATIONS

Our main proposition is that, when it comes to influencing public officials' decisions, firms can either push for quick decisions or tailored decisions but rarely both. Therefore, to explore our proposition we need a context where: (1) we can easily observe the time and content

of public officials' decisions and (2) both provide benefits to the firm. Based on these requirements we decided to look at the FDA approval process of new drug applications (NDAs). The NDA review is the last stage of the drug approval process in the U.S. Once a firm has undertaken the necessary clinical trials with a drug candidate and believes enough evidence exists to pass the FDA's requirements, it submits an NDA. In this NDA submission, the firm shares all the data and results obtained throughout the clinical studies, which are then reviewed by one of the FDA's scientific advisory committees (e.g., arthritis advisory committee).[3]

One might think that the main decision the advisory committee makes is whether to approve the drug for marketing or not. In practice, this is not the case since the FDA approves around 90% of the NDA applications (www.fdareview.org). Instead, the committee makes a series of decisions to determine how and when the drug enters the market. For each potential indication, the committee decides if (1) the drug is safe and effective enough and should be approved to treat such an indication, (2) the drug is not safe or effective enough and should *not* be approved to treat such indication, or (3) more evidence, thus revision time, is required in order to assess whether such an indication should be included in the drug's label. Thus, the committee determines the drug's *scope* (i.e., conditions/subpopulations and interactions/contraindications) and the drug's *revision time* (when is the drug allowed to enter the market).[4]

Therefore, this context is perfect for our study since it allows us to identify the speed and scope of public officials' decisions where both decisions are important for a firm—i.e., firms generate more profits the broader their drugs and the quicker they can introduce these drugs into the market. Moreover, this context provides some additional advantages. First, the FDA's decision for NDA reviews typically occurs in a relatively consistent timeframe: within the first

[3] See www.fda.gov/AdvisoryCommittees.
[4] Drugs cannot be advertised or prescribed for unapproved indications, so these decisions determine market size.

six months after NDA submission.[5] This consistency allows us to test the causal link between lobbying efforts and policy outcomes in a more reliable manner since we know when lobbying needs to occur for the firm to be able to influence the NDA process. Second, at this stage, firms have a clear understanding of the market environment that the new drug will face, so we can look at market pressures as a determinant of non-market decisions. Finally, the decision-making process in NDA reviews is relatively transparent and the FDA provides detailed information on how such decisions are made. This allows us to build a richer conceptual link between lobbying and agency outcomes that enhances the validity of our theoretical model.

THEORY AND HYPOTHESES

Lobbying the FDA in NDA reviews

Firms often need to wait for public authorization to implement their strategies (Bonardi et al., 2006; Hillman et al., 2004). In these situations, firms can either passively observe the process or proactively try to influence the decisions of public officials (Hillman et al., 2004). In our context, pharmaceutical firms need the authorization of the FDA to introduce a new drug into the market. The FDA decides the drug's scope and when can the drug enter the market, two outcomes that firms strongly care about. Then, consistent with prior research in the CPA literature, we argue firms may attempt to shape the agency's decisions on NDA reviews in their favor by undertaking political activities (Bonardi et al., 2006).

To understand how firms can influence the FDA in the context of NDA reviews it is critical to understand the motivations of the FDA officials making these decisions, namely, scientific advisory committee members (Bonardi et al., 2006). Such members that decide each drug's fate are appointed rather than elected, and are usually academics and health professionals

[5] FDA scientific advisory committees usually meet once a quarter.

without conflicts of interest.[6] This means that their motivation stems from gaining legitimacy and reputation rather than from politics (Bonardi et al., 2006; Carpenter, 2004). These officials gain legitimacy and reputation by adhering to existing rules and norms, as well as by making decisions uncontested by external audiences (Bonardi et al., 2006). When external audiences become suspicious about the FDA's decisions, the agency is subject to public scrutiny and pressures that put its reputation, credibility, and committee members' positions in danger. Thus, scientific committee members must ensure that their final decisions appear fair, coherent, and consistent (McCubbins, Noll, and Weingast, 1987). This makes the basis for committee members' activities during NDA revisions purely informational (Bonardi et al., 2006). They need to substantiate their final decisions with as much evidence as possible.

The problem is that, while the members of the scientific advisory committee are academics and health professionals, they are not experts on every aspect of every drug. Therefore, they need to rely on external sources of information to interpret and make sense of the clinical data provided by the firm, and thus be able to present their final decision in a way that looks reliable and convincing enough. For this reason, they rely upon expert witnesses during committee hearings before making final decisions. Such expert witnesses, who are invited by the FDA or the applying firm, are usually doctors, scientists from research organizations, or patient advocacy representatives.

We argue these external speakers provide a viable channel through which firms can influence scientific advisory committees' decisions (Bonardi et al., 2006). By designing and coordinating these external speakers' interventions, a firm can implement an information provision strategy that can shape the committee's decision in its favor. While a firm could directly convey its message through its own employees speaking in committee hearings, external

[6] Terms last 4 years, although members can be replaced if doubts about their independence arise (CDER, 1998).

speakers provide a channel that is richer (i.e., firms can leverage speakers' expertise), more effective (i.e. they are more influential), and more legitimate (i.e., by putting their reputations at stake, speakers are thus a more credible source of information) (Carpenter, 2004).[7] The fact that firms are building closer relationships with advocacy group representatives and other influential speakers provides evidence that firms think of these agents as powerful allies to influence public officials' decisions in committee hearings (McCoy et al., 2017).

This information provision strategy through external speakers is actually a clearly defined political tactic, i.e., *corporate lobbying* (Hillman and Hitt, 1999; Hillman et al., 2004). The Lobbying Disclosure Act (2 U.S.C. § 1601) defines lobbying as the provision of information to policy makers and agencies by individuals representing the firm interests. In the words of one of the professional lobbyists with experience in the U.S. pharmaceutical industry we interviewed, "*collecting and preparing the information that will be communicated in public hearings is maybe our most important function*". Thus, all corporate expenditures used to design and coordinate external speakers' interventions in scientific advisory committee hearings will fall under the lobbying activities category. Lobbying activities targeted at this issue, then, should increase the firm's ability to influence scientific advisory committee's decisions with respect to NDA reviews. The question is: how do firms use this ability to influence committee's decisions? What specific outcome of NDA reviews do firms try to influence through their lobbying efforts?

Lobbying the FDA in NDA reviews: Push for Speed or Scope?

There are two main outcomes scientific advisory committees decide upon: the drug's scope and revision time. Ideally, firms that can influence the committee's decisions would prefer

[7] While committee members with a potential conflict of interest are preempted from participating in NDA reviews, this is not the case for external speakers. When one of these speakers has a conflict of interest, such as the applying firm supporting his/her research or the applying firm collaborating with a speaker's consumer advocacy group, the speaker is asked to acknowledge it before the presentation but can still participate in the hearings.

to have the broadest drug and the quickest review possible, since drug scope and speed to market are two of the most critical determinants of how much pharma firms profit from new drugs. However, we argue achieving both non-market outcomes simultaneously is extremely difficult.

Trying to convince committee members to approve the drug for multiple indications and demographic subpopulations, and with the least possible interactions/contra-indications, will necessarily come at the expense of longer revisions. The larger the number of indications and demographic subpopulations under review, the more clinical evidence needs to be evaluated, which should require more revision time. Moreover, an increase in indications also means an increase in the number and relevance of possible side effects due to potential interactions with other drugs. Because drug approval requires both efficacy *and* safety to be assured, more review time is necessary to assure that the minimum safety requirements are met in these cases. Thus, as with other agencies, the more issues under review the longer it takes for public officials to make their decisions (Choudhury and Haas, 2017; Marco et al., 2016). Analogously, we argue that trying to convince committee members to accelerate drug approval will necessarily come at the expense of narrower drugs. The only way to have these committee members make quicker decisions is by reducing the amount of evidence they need to evaluate.

It is true that if the FDA and scientific advisory committees had unlimited resources, a trade-off between scope and speed may not exist. More resources could be assigned to the revision of broader drugs (e.g., multiple indications) and review time should not be affected. However, many complain the FDA is very resource-constrained, so this does not seem to be the case (Carpenter et al., 2012, Psaty and Burke, 2006).

Lobbying for Speed or Scope? Non-market strategy determined by market pressures

Since there is a trade-off between drug scope and review time, the natural question is: what specific non-market outcome do firms try to influence through their lobbying activities? We propose firms will lobby for drug scope or review speed depending on the magnitude of the pressures they face in the market environment. In the context of innovation, prior research shows that these pressures take the form of imitators that may hamper the firm's ability to generate profits with their new product (Leiponen and Byma, 2009; Sheng et al., 2013). The threat from imitators, as suggested in the literature, is strongly determined by the level of intellectual property (IP) protection behind the firm's new product, in that IP rights are a powerful mechanism to prevent the entry of similar products (Ceccagnoli, 2009; James et al., 2013; Teece, 1986). Thus, we explore how the level of IP protection firms enjoy in the drugs reviewed by the FDA explains their non-market strategies: do they lobby for drug scope or review speed?

When a firm has weak IP protection, it has little legal power to prevent competitors from developing similar products. Without protection, firms can only exploit what the literature has defined as Schumpeterian or entrepreneurial rents (Keyhani, Lévesque and Madhok, 2015; Rumelt, 1987). For such firms, the best strategy to make above-average returns is to build first-mover advantages before competitors (Lieberman and Montgomery, 1988; Kessler and Chakrabarti, 1996). When it comes to pharmaceutical drugs, first-mover advantages can be quite significant in that early entrants can build consumers' loyalty, exploit economies of scale in manufacturing, and develop relationships with prescribing doctors before competitors (Budish, Roin, and Williams, 2015). Recent estimates suggest that the order of entry in this industry has a significant and long lasting impact on drugs' market share: the difference in market share between the first and the second entrant 10 years after entry is around 17.5 percentage points, with this difference being larger for later entrants (McKinsey, 2014). Thus, lobbying to reduce

review time can provide significant benefits, even if it comes at the expense of a narrow drug. Lobbying for a greater scope with a product that has weak IP protection is unlikely to pay off. Although the firm would be able to target multiple niches, this may not translate into greater profits because it might not be able to exploit first-mover advantages before competitors in any of these niches (Fang, 2008; Kessler and Chakrabarti, 1996; Lukas and Menon, 2004). For all these reasons, we claim that firms with weak IP protection will be more likely to lobby for *review speed* at the expense of drug scope.

Conversely, strong IP protection means a firm can employ legal barriers against competitors attempting to introduce products that are too similar to its own. Strong IP protection allows firms to generate what scholars have defined as Ricardian or monopoly rents (Mathews, 2006). With strong IP protection, firms do not face the urgency to be the first to enter the market because competitors can be kept away through legal mechanisms. With this safety net, firms are willing to spend more efforts in broadening the scope of the new product so that it will appeal to the broadest possible range of consumers (Leiponen and Byma, 2009; Sheng et al., 2013). The case of Invokana, Johnson & Johnson's diabetes drug that enjoyed strong IP protection, provides a good example: the company fought intensively to deter the inclusion of a warning in the drug's label indicating a high risk of leg and foot amputation to the extent that such warning significantly threatened the drug's marketability. Therefore, in cases like this, firms enjoying high levels of IP protection are better off lobbying to increase drug scope even if this comes at the expense of a delay in product introduction (Budish et al., 2015). The opportunity cost associated with a delay in market entry will be compensated with the profits from a larger market. Lobbying to reduce revision time has little benefit when firms have strong IP protection, as the legal protection against competition means the firm is likely to be the first mover even if

the revision takes longer due to the firm's efforts to obtain a broader drug (James et al., 2013; Leiponen and Byma, 2009; Sheng et al., 2013). Therefore, we expect that firms with strong IP protection behind their drugs will lobby for *drug scope* at the expense of longer reviews.

In sum, we argue that firms are more likely to lobby the FDA to reduce revision time at the expense of drug scope for high levels of IP Protection; yet, they will lobby the FDA to increase drug scope at the expense of revision speed for low levels of IP Protection:

Hypothesis 1: Lobbying activities will decrease a drug's revision time under low levels of IP protection, and will increase a drug's revision time under high levels of IP protection.

Hypothesis 2: Lobbying activities will increase a drug's scope under high levels of IP protection, and will decrease a drug's scope under low levels of IP protection.

METHODS

Data

To test our theory we combine data from various sources. First, we rely on the FDA's repository of files to obtain data on NDA revision time. This database gives access to NDA approval letters in which both submission and approval dates are provided, enabling us to calculate the exact time each NDA was under revision by the FDA. Second, we obtain data on drug scope from the U.S. National Library of Medicine's RxClass database. This database provides information on the clinical and chemical profile of every drug approved by the FDA.

Third, we use data on firms' lobbying activities from the Center for Responsive Politics' OpenSecrets database (see www.opensecrets.org). This center tracks lobbying activities and money donated to candidates' PACs. We focus on lobbying data, which the OpenSecrets database provides from government-mandated reports by registered lobbyists regarding their

lobbying activities. In accordance with the Lobbying Disclosure Act (2 U.S.C. § 1601), all lobbyists, whether internal or external to the firm, are required to file quarterly reports about their activities. These reports include the name of the client/employer, expenses for lobbying on behalf of such client/employer in a given quarter, which agency/agencies were lobbied, and the particular issue being lobbied. The database covers lobbying activities for the 1998–2015 period.

Fourth, to capture each drug's IP protection we identify the patents behind the drug from the FDA's Orange Book Patents Database. The patents associated with a given drug are incorporated into each NDA submission. Finally, we rely on the FDA's Orange Book Products Database to gather information on firms' prior drug introductions.

Sample

Out of all the NDAs whose approval letters were available in the FDA's files, we select our final sample based on the following criteria. First, we exclude all generic drug applications—i.e., those under the Abbreviated New Drug Application (ANDA) system. The review process for generics is very different both in terms of patent protection and administrative process, and our proposed conceptual logic does not directly apply to these cases.[8] Second, we eliminate drugs with a priority revision. For some types of drugs, like those that treat orphan diseases, the FDA commits to a faster revision process (CDER, 2014). Therefore, we remove all priority revision NDAs in order to have a sample of comparable observations. Third, since the OpenSecrets database only covers the 1998–2015 period, we restrict our final sample to those NDAs submitted after January 1, 1998. After applying these filters, we have a final sample of 540

[8] In generic drug applications (ANDAs), a trade-off between speed and scope does not exist. Firms only care about speed for two main reasons: (1) IP Protection is null and (2) drug scope is already fixed by the outcome in the NDA review of the original branded drug the generic imitates. Therefore, for generics, our theory predicts that lobbying will just reduce revision time. We found support for this looking into a sample of generics (available upon request).

observations (i.e., unique drug applications) for the 1998–2015 period. These 540 NDAs were submitted by as many as 228 distinct firms.[9]

Measures

Revision time. Our first dependent variable is the time it took the FDA to complete the NDA revision process. It is important to note that our measure represents the opposite to review speed. We operationalize revision time by calculating the number of days between the submission date and the approval date and then taking the natural logarithm. The median time it took the FDA to approve NDAs in our sampled period was just over one year (366 days), although a lot of variation exists. At its fastest, the FDA approved drugs in about three months; at its slowest, the FDA took a little over eight years.

Drug scope. We define a drug's scope by the number of diseases it can treat.[10] To identify the diseases a drug is approved to treat we look at the pharmacological classes the drug is assigned to by the FDA in the revision process. A pharmacologic class represents a category of drugs that is associated with certain indications (CDER, 2013). For instance, "Antihistamines" is a pharmacological class for drugs that treat allergic reactions. Drugs can be assigned to more than one class and the number of assigned classes determines the range of diseases the drug is allowed to treat. Therefore, the more pharmacological classes a drug is assigned to, the more approved diseases for the drug.[11] Consequently, to capture a drug's scope we looked at the number of pharmacological classes to which each drug was assigned. The majority of drugs in our sample were assigned to either one or two pharmacological classes—only a few NDAs were

[9] For our estimations with our second-dependent variable (drug scope), due to missing data, we end up with 457 NDAs submitted by 197 firms.
[10] We also use an alternative measure of scope consisting in the presence of contra-indications. Specifically, we create a dummy variable takes the value of 1 if the drug is contra-indicated when patients are simultaneously using other medications and 0 otherwise. We find similar support for our theory (results available upon request).
[11] The number of classes to which a drug is assigned to is not the same across the drugs that belong to the same class. The only requirement to be assigned to a given class is that the drug achieves the intended function in an effective and safe manner (e.g., suppressing histamine-induced responses for antihistamines).

assigned to more than two classes. Therefore, we relied on a binary variable that took the value of 1 if the drug was assigned to multiple classes and 0 if it was assigned to one single class.[12]

FDA Lobbying. We use the OpenSecrets database to create a measure of FDA lobbying in the following way. First, we gather all lobbying activities for public and private pharmaceutical firms that submitted an NDA application. Second, we only account for lobbying that targets the FDA, since it matters what government agencies firms lobby (Ridge et al., 2016). We do not expect, for example, that lobbying the Department of Defense or the Department of Transportation to help with FDA approvals. Third, because the FDA is responsible for many issues other than NDA reviews, we try to capture only those lobbying activities intended to influence drug approval decisions. For that, we use the information provided in the OpenSecrets database on the issue firms are lobbying for (e.g., medical research, budget, taxes, torts, advertising).[13] Specifically, we choose the issue that we believe is most likely to capture efforts to influence NDA reviews. To identify this issue, we look at the information that companies provide where they describe the purpose of their lobbying activities.[14] We searched in these short descriptions for the terms "FDA" and "approval" and found that the issue that was most likely to include these terms was "medical research", for which we found descriptions such as "*FDA issues. Seeking accelerated approval for breakthrough medical treatments to treat Duchenne Muscular Dystrophy*" or "*Work on FDA approval for Cancer treatment*". Therefore, we only account for lobbying activities in which the reported issue was "medical research." Finally, to ensure we capture lobbying activities during the NDA revision, we only look at lobbying in a

[12] We also tried looking at the number of classes and the results provided similar support (available upon request).
[13] The list of all the reported issues can be found in www.opensecrets.org and is available upon request.
[14] In addition to information on the issue firms are lobbying for, firms may also report a short description with more detailed information of what was really the purpose of their lobbying activities. We cannot use this information to create our measure since it was not widely available until 2008. Yet, it provides some insights into the actual purpose of firms' lobbying activities, which allows to identify what issue captures the lobbying we are interested in.

very specific timeframe. In our theory we argue that firms try to influence the scientific advisory boards, and since those boards typically meet within the first six months after NDA submission, we focus on lobbying conducted in the quarter the NDA was filed and in the following two quarters.[15] Accordingly, our final measure was constructed by adding all lobbying expenditures on medical research to the FDA across these nine months to create our main independent variable: *FDA lobbying*. We calculated the natural logarithm of this measure to account for its skewed distribution. In addition, we constructed a binary variable that took a value of 1 when lobbying expenditures were greater than $0, and 0 otherwise.

IP Protection. To capture a drug's IP protection we use the number of patents behind each drug in the FDA's Orange Book. Although patents are not the only mechanism through which firms can protect their IP, it is one of the strongest mechanisms for firms in the pharmaceutical industry (Katila and Mang, 2003; Ouellette, 2010). A single patent, however, does not provide full protection to a firm's IP behind a given drug (Lanjouw and Schankerman, 2001). Competitors can often innovate around a firm's patent without infringing on the firm's IP; in addition, it is not uncommon that a firm's patent is deemed invalid after a competitor's challenge (Marco, 2005; Ouellette, 2010). Therefore, the IP behind a new drug is usually more protected the more patents the firm has on that specific drug.

In the pharmaceutical industry drugs are often protected by more than one patent. Prior studies have shown that among those drugs with patent protection, over 60% had more than one patent (Ouellette, 2010). Drugs composed of several chemical entities can hold more than one patent since firms can protect each entity with a different patent. However, there is not a one-to-one correspondence between the number of chemical entities and the number of patents

[15] The following two alternative measures provided similar support to our theory: (1) lobbying in the quarter *before* NDA submission and the following three quarters, and (2) lobbying in the quarter of NDA submission and the quarter before (available upon request).

(Ouellette, 2010). Drugs composed of a single chemical entity can also hold multiple patents. In addition to patents protecting new chemical entities, firms can add formulation patents (protecting the composition or method of application), process patents (protecting the method of producing the drug), patents on the products into which drugs are transformed in a patient's body, or patents on intermediate products used in producing drugs (Ouellette, 2010). These patents are complementary, and the larger the number of patents, the more protected the drug is from competition. Therefore, to create our measure of *IP protection*, we looked at the natural logarithm of the total number of patents behind a given drug plus one.

Controls. We add the following controls in our tests. First, firms whose drugs have several chemical entities might be more likely to hold multiple patents than single-entity drugs, and having more such entities could be positively correlated with the drug's scope. Extant evidence suggests that there is not a one-to-one correspondence between chemical entities and patents, since even drugs with one single entity frequently hold more than one patent. However, we control for a drug's number of chemical entities to ensure that this factor is not driving the relationship between the number of patents and drug scope. Using the data provided in the RxClass data set, we created a measure of the *number of chemical entities* calculated as the natural logarithm of the total number of chemical entities in each single drug.

Second, experienced firms are more likely to have a better understanding of the NDA revision process. This could influence both the revision time and the drug's scope. For this reason, we control for the firm's *development experience* by using the natural logarithm of the number of drugs the firm has had approved in the previous ten years. Third, some firms may have a greater ability in assuring the safety of their drugs, which should be a critical factor determining both drug scope and revision time. To capture the presence of safety competences

we use the natural logarithm of the number of safety alerts received in the previous five years for marketed drugs (*prior safety alerts*). Data on firms' safety alerts was obtained from the FDA's MedWatch database. The presence of past safety crises with FDA-approved drugs may signal the presence of safety weaknesses in the firm's drug development process, which could lead to the agency giving special attention to safety issues in the current NDA.

Fourth, to control for the firm's *prior FDA lobbying* with the FDA, we look at the natural logarithm of the firm's lobbying expenditures to the FDA the year before the NDA was submitted. This accounts for the possibility that the success of lobbying during the NDA revision varies depending on whether the firm had previously lobbied the FDA. Fifth, to control for the firm's overall lobbying activities (*non-FDA lobbying*) we include the natural logarithm of lobbying expenditures to agencies other than the FDA during the same nine months in which our main lobby measure was constructed. This helps to rule out the possibility that our main independent variable is simply capturing whether firms are politically active in general. Finally, we added a dummy that captured whether the firm was public or private (*public*), to account for the possibility that public firms approach lobbying in a different manner due to their visibility.

Analysis

We use ordinary least squares (OLS) to estimate the effect of lobbying the FDA on *revision time* and logistic regressions for *drug scope* given its binary nature. Several drugs in our sample were submitted by the same firm, which means that the error terms across observations belonging to the same firm might not be independent (Greene, 2003). To address this potential dependence, our models include clustered standard errors at the firm level. In addition, we include therapeutic area fixed effects to account for the fact that the main therapeutic area to which the drug belongs (e.g., dermatology or cardiology) is likely to influence the NDA revision

outcome to the extent that each therapeutic area has a different committee. Finally, we include approval year fixed-effects to control for temporal dynamics in the revision process.

We acknowledge our analyses may be subject to endogeneity bias. Firms might bring very different drugs into the NDA review process, with some of these drugs being broader than others, which may explain part of the variance of our main dependent variables *revision time* and *drug scope*. If our key independent variables—*FDA Lobbying* and *IP Protection*—are somehow correlated with this unobserved heterogeneity, our results could be subject to a self-selection bias. To address this, in addition to adding controls to capture the drug's breath in our main analyses (e.g., *number of chemical entities*), we implemented a series of Heckman two-steps analyses to address this potential endogeneity (see robustness tests section below).

RESULTS

Table 1 reports descriptive statistics and correlations for all the variables in our final sample. This table shows that some correlations exist above the 60% level (e.g., *prior safety alerts* and *development experience*). To rule out potential problems of multicollinearity we looked at the variance inflation factors (VIFs) and found that all main and interaction terms had a VIF lower than 3, significantly below the threshold of 10 that is indicative of the presence of multicollinearity problems (Belsley, Kuh, and Welch, 1980).

[Insert Table 1 about here]

In Table 2 we report our estimations for both *revision time* and *drug scope*. Models 1 through 6 provide the estimations for *revision time* in which the first three models use continuous measures for all lobbying variables and the last three use binary measures. In Models 1 and 4 we provide the estimations with just the control variables. In Models 2 and 5 we add our main independent variable, *FDA Lobbying*, and find it has a negative but insignificant effect on

revision time (β = -0.019, p = 0.161 and β = -0.207, p = 0.161 respectively). In Models 3 and 6 we add the interaction between our two main independent variables, *FDA Lobbying* and *IP Protection*, and find that the coefficient is positive and significant in both cases (β = 0.043, p = 0.001 and β = 0.477, p = 0.001 respectively). Once we add the interaction term, the main effect of *FDA Lobbying* becomes negative and significant (β = -0.060, p = 0.001 and β = -0.689, p = 0.001 respectively). This suggests that in the absence of *IP Protection*, *FDA Lobbying* shortens the revision process, whereas for high levels of *IP Protection*, *FDA Lobbying* leads to slower revisions. These results support Hypothesis 1.

The results are not only significant, but substantial. Looking at the size of effects using Model 6 we find that for low levels of *IP Protection* (one standard deviation below the mean), lobbying firms should expect *revision time* of about 245 days, whereas non-lobbying firms should expect revision time of about 435 days. Thus, under low *IP Protection*, lobbying shortens revision time by 190 days (a 44% reduction). For high levels of IP Protection (one standard deviation above the mean), lobbying firms had a revision time of about 500 days, compared to 410 days for non-lobbying firms. This implies that lobbying increased revision time by 90 days (a 22% increase).

[Insert Table 2 about here]

In Models 7 through 12 we show our estimations with *drug scope* in which the first three models use continuous measures for all lobbying variables and the last three use binary measures. Models 7 and 10 provide the estimations where we only include the control variables. In Models 8 and 11 we include the main effect of *FDA Lobbying* and find this measure has a positive but not significant effect on *drug scope* (β = 0.026, p = 0.681 and β = 0.341, p = 0.638 respectively). In Models 9 and 12 we add the interaction between *FDA Lobbying* and *IP*

Protection and find that the coefficient is positive and significant in both cases (β = 0.262, p = 0.001 and β = 2.773, p = 0.001 respectively). As with *revision time*, the main effect of *FDA Lobbying* becomes negative and significant once the interaction is added (β = -0.314, p = 0.018 and β = -3.417, p = 0.036 respectively), suggesting that *FDA Lobbying* leads to greater scope when *IP Protection* is high, but less scope for low *IP Protection*. This supports Hypothesis 2.

The results in Model 12 suggest that, for high levels of *IP Protection* (one standard deviation above the mean), lobbying increased the probability to get a drug approved for multiple indications from 20% to 38% (a 90% increase). However, for low levels of *IP Protection* (one standard deviation below the mean), lobbying reduced the probability of getting drugs approved for multiple indications from 14% to 6% (a 57% decrease). Overall, the size of the effects suggested by our estimations appear to be quite significant.

Graphical analysis

We also interpret our results through a graphical analysis. The fact that the estimations with *drug scope* are nonlinear implies that the graphical interpretation of the size and significance of our effects is especially necessary (Ai and Norton, 2003; Hoetker, 2007). For this, we use a simulation-based approach developed by King, Tomz, and Wittenberg (2000), which was introduced into the management literature by Zelner (2009). We analyze the main and interaction effects of both dependent variables by taking 100,000 post-estimated draws from a multivariate normal distribution using the coefficients and variance co-variance matrices from the estimations in Models 3 and 9. We then multiply the coefficients obtained in each draw with the real values of the underlying data, but for different values of the interacted variables: *FDA Lobbying* and *IP Protection* (Zelner, 2009). These analyses are provided in Figures 1a and 1b.

[Insert Figures 1a and 1b about here]

Figure 1a shows the effect of *FDA Lobbying* on *revision time* for different levels of *IP Protection* (one standard deviation above and below the mean). This graph shows how increases in *FDA Lobbying* lead to decreases in *revision time* for low levels of *IP Protection* but to increases in *revision time* for high levels of *IP Protection*. These effects are consistent with our prediction in Hypothesis 1. Figure 1b shows the effect of *FDA Lobbying* on *drug scope* for different levels of *IP Protection*. This graph shows, as predicted in Hypothesis 2, how increases in *FDA Lobbying* lead to increases in *drug scope* for high levels of *IP Protection*, but to decreases in *drug scope* for low levels of *IP Protection*.

Robustness tests

The decision to lobby might not be exogenous to our main outcomes. Firms could decide whether to lobby or not as a function of the characteristics of the drug they are submitting for review, and thus contingent on the expected outcomes in the revision process instead of the other way around (de Figueiredo and Richter, 2014; Richter et al., 2009). To address this potential self-selection bias, we reran our analysis using a two-step estimation technique (Heckman, 1979). In the first step we regress the control variables on the dummy variable of *FDA Lobbying* using a Probit estimation. In the second step, we re-estimate both *revision time* and *drug scope* and include the inverse Mills ratio calculated from the first step (Hamilton and Nickerson, 2003).[16] The firm's donations to political campaigns, in the quarter when the NDA was applied for and the two subsequent quarters, were used as an instrument in the first step. We argue that this is a valid instrument for a few reasons. First, political donations are correlated with the possibly endogenous variable, *FDA Lobbying,* since firms that are politically active in one dimension are likely to be politically active in other dimensions (Hillman et al., 2004; Ridge et

[16] The inverse Mills ratio, λ, was calculated as $\lambda_1=(\phi(\beta X))/(\Phi(\beta X))$ for those firms that lobbied the FDA and $\lambda_0=-\phi(\beta X)/([1-\Phi(\beta X)])$ for those firms that didn't lobby the FDA.

al., 2016). Second, donations meet the exclusion restriction, because supporting political candidates is unlikely to impact FDA decisions about a particular NDA since the FDA's scientific committees are relatively insulated from the political process.[17] The results of these two-step estimations are shown in the first three columns of Table 3. As expected, the proposed instrument, *campaign donations*, has a positive and significant effect on the probability of lobbying the FDA. After including the inverse Mills ratio in the second-step estimations, the interaction and main effect coefficients have the same sign as previously shown and remain statistically significant.

[Insert Table 3 about here]

In addition, although patents are generally applied for several years before firms submit NDA applications (i.e., around six years before), one concern is that this decision is not completely exogenous to NDA outcomes. Maybe firms that obtained patents bring drugs into NDA reviews that have broader applicability and thus have a greater chance of obtaining larger scope. To rule out this potential endogeneity we estimate a two-step Heckman analysis. In this case, in the first step we regress the control variables on a dummy variable capturing whether the drug has at least one patent (i.e., *IP Protection* greater than zero) using a Probit estimation. We use the number of patents behind the other drugs the firm had developed in the previous five years as the instrument in this first stage. We expect this instrument to capture the general ability of the firm to obtain patents and thus to be correlated with the probability that the firm will get patents for the current drug candidate, but not be correlated with the outcomes of the current

[17] We replicate this Heckman analysis using two alternative instruments: (1) donations in political campaigns to losing candidates (to make sure these donations are not providing any influence on FDA reviews) and (2) the amount of lobbying expenditures done by competitors in the same period. The results with these two alternative instruments provide similar support to our theory (available upon request).

NDA application.[18] In the second step, we re-estimate both *revision time* and *drug scope* and include the inverse Mills ratio calculated from the first step (Hamilton and Nickerson, 2003). The results are provided in the last three columns of Table 3 and support our theoretical predictions.

Moreover, we implement a robustness test where we include firm fixed-effects in all of our estimations. It is important to note that this is a rather conservative specification in that it looks into variance within each firm, i.e., how differences in IP Protection and lobbying activities across different drugs of the same firm explain differences in revision time and drug scope. The results of these tests are shown in Table 4 and provide support to our theory.

[Insert Table 4 about here]

Finally, we test our theory with an alternative measure for *IP Protection* to account for the possibility that our measure looking at the number of patents behind a given drug may have certain limitations. Having multiple patents on a drug might not provide much protection if the patents are about to expire. Thus, we replicate our main results with an alternative measure of *IP Protection* consisting of the number of remaining days until the latest expiration date among all the patents of a given drug at the moment of the NDA submission. The results with this measure are shown in the last four columns of Table 4 and continue to provide support for our theory.

Mechanism

Our theory proposes that firms will lobby to achieve different outcomes (speed or scope), yet, we cannot see these different lobbying strategies in place. We tried to compile qualitative data from different sources to provide some evidence in support of our mechanism. First, we interviewed professional lobbyists with experience in a broad range of industries, including the U.S. pharmaceutical market. These lobbyists recognized that, in many contexts, "*time is*

[18] We also tried an alternative instrument consisting on the amount of patents behind competitors' drugs. The results with this alternative instrument provides similar support to our theory (available upon request).

essential", so they frequently face a trade-off between speed and content. Given the presence of this trade-off, we asked them how they design their strategies in the context of public hearings accordingly. These lobbyists acknowledged that "*not all firms have the same objectives*" and that the objectives depend on "*[firms'] competitive environment*". For this reason, *"firms use lobbying to achieve different outcomes*" and therefore "*design different strategies depending on the outcome they want to achieve*". The elements they consider when designing these strategies include: "*the number and type of speakers you bring to the hearings*", "*the order in which these speakers participate*", "*the kind of message you try to convey*", and "*the choice of the tone of the message: more technical appealing to reason or more personal appealing to emotions*". The selection of these speakers is based on "*who will convey the most credible message based on his/her experience*" and "*will appear more neutral and legitimate*" in the eyes of evaluators.

Using these insights, we decided to look into a series of examples (see Table 5) to illustrate how firms use different non-market strategies to influence scientific advisory committees' decisions on revision time and drug scope.[19] These examples show how firms' messages to the scientific committee members (conveyed through invited speakers) are aligned with their non-market objective. Firms with low IP Protection trying to speed up drug approval relied on speakers to convey a message of urgency by appealing to either the suffering of patients or the lack of alternative solutions for the disease at stake. On the other hand, speakers of those firms with high IP Protection pushed for a greater drug scope by (1) stressing all the different conditions for which the drug can be used, (2) highlighting the effectiveness of the drug for multiple subpopulations, or (3) underscoring the lack of side-effects and contra-indications of the

[19] This documentation was obtained from the FDA's Dockets Management. The FDA's Dockets Management serves as the official repository for administrative proceedings and rule-making documents for the FDA.

drug under evaluation. It is important to highlight that the majority of the speakers included in these examples acknowledged that they had a financial relationship with the applying company.

[Insert Table 5 about here]

DISCUSSION

We explore how firms resolve a fundamental trade-off: attempting to shape the content of public officials' decisions runs the risk of longer decision-making processes, whereas pushing for quicker decisions increases the chance to get decisions not perfectly tailored to their needs. We examine this within the specific context of NDA revisions, showing how lobbying efforts allow firms to influence both: drug scope and review time. We argue that firms' non-market preferences will be determined by the market pressures they face, which we capture by looking at the level of IP protection behind their new products. Building on this logic, we claim that firms whose drugs enjoy strong IP protection face little pressures and therefore lobby the FDA to get their drugs approved for more indications and less contra-indications. Conversely, we argue firms with weak IP protection behind their drugs are likely to face stronger pressures and therefore lobby for faster approval rather than greater scope as a way to exploit first-mover advantages before competitors. Our quantitative analysis supported this contingency model.

Contributions and managerial implications

We believe our study provides several contributions to the corporate political activities (CPA) literature. Our first main contribution consists in unveiling a fundamental trade-off in non-market strategies: in certain contexts lobbying for customized content implies a delay of public officials' decisions, while lobbying for quick decisions leads to content that is not tailored to the firm's preferences. While this trade-off is not present in every non-market context, we believe there is a broad range of situations where firms implementing political activities are

likely to face this dilemma—e.g., obtaining a patent to license a new technology, getting approval to market a new product, or gaining permission to undertake a merger. Speed is critical in all these cases, which means that firms lobbying regulatory agencies such as the U.S. Patent and Trademark Office (USPTO), the FDA, or the antitrust division of the U.S. Federal Trade Commission (FTC) are likely to face this trade-off between speed and scope. The presence of this trade-off reveals a fundamental conceptual dilemma faced by firms undertaking non-market efforts: should they push for speed or content? Moreover, it suggests that designing a firm's non-market strategy implies making complex decisions that require a quite sophisticated understanding about how political efforts will affect different non-market outcomes.

To reveal this trade-off we took several substantial departures from the set of implicit assumptions used in prior CPA research, and outlined a more complex logic to analyze non-market strategies. First, while prior research has almost unanimously focused on the content of public officials' decisions, in our study we underscore the importance of the speed with which such decisions are made. Given the importance of speed in the *market* literature, it is surprising how little attention the role of speed has received in *non-market* research. Second, we depart from extant CPA theories by acknowledging the multidimensionality nature of public officials' decisions. Prior CPA research has largely analyzed government decisions in a unidimensional way, typically focusing on a single public policy outcome and, therefore, assuming that a firm's only preference is to influence that specific outcome. However, in many settings, public officials decide upon several issues simultaneously. Thus, it is not until we acknowledge the existence of multiple non-market outcomes that we realize that some of these outcomes, like drug scope and revision speed, may actually be incompatible and therefore lead to a critical dilemma.

The benefits of our more complex and richer picture of non-market outcomes become clear if we look at how extant CPA theories are unable to explain some cases we found in our data. Many firms in our sample lobbied the FDA and obtained, what appear to be, worse non-market outcomes: their drugs were approved for less conditions and with more contraindications than the drugs of firms that did not lobby the FDA. Through the lens of extant CPA theories, these cases would be interpreted as evidence against the effectiveness of lobbying. Our multi-dimensional perspective on non-market outcomes considering scope *and* speed simultaneously provides a plausible explanation that is contrary to the conclusion that lobbying efforts were ineffective. We show these lobbying efforts were successful at achieving shorter reviews and thus quicker access to the market, but this came at the expense of narrower drugs. Thus, our more nuanced model of non-market outcomes enhances our understanding about what to look at in order to evaluate the success of firms' non-market efforts. This provides useful insights to the stream of research looking at whether political activities indeed help firms achieve their objectives and thus improve their performance (e.g., Bonardi, Hillman, and Keim, 2005; Hadani and Schuler, 2013; Shaffer, Quasney, and Grimm, 2000).

Our second main contribution to CPA research consists in developing a contingency model that allows us to understand how firms resolve the trade-off between speed and content. We respond to recent calls to examine how market and non-market strategies are interconnected (Baron, 1999; Hillman et al., 2004). Similar to Holburn and Bergh (2014), who explore how firms' market strategies explain *when* firms lobby, we investigate how firms' market environment help us understand *what* specific non-market outcome firms will firms lobby for. Specifically, we argue that firms' market pressures will determine whether they lobby for speed or scope. For this, we draw from innovation theories on new product development (James et al.,

2013; Kessler and Chakrabarti, 1996; Leiponen and Byma, 2009) and look at the level of IP protection behind the firms' new drugs to capture the magnitude of market pressures.

To develop this model we again had to depart from some of the implicit assumptions made in prior CPA studies. Prior non-market theories looked at firms as homogenous entities, assuming all had the objective to influence the specific non-market outcome explored in each particular study. Under this assumption, we are unable to explain why firm A will push for non-market outcome X while firm B will push for non-market outcome Y. In our study we relax this assumption and assume firm heterogeneity with respect to their market environment, which will translate into different non-market preferences. Therefore, once we account for the fact that firms will undertake non-market efforts for different purposes, we are able to explain which non-market outcome firms are more likely to push for in the presence of trade-offs such as the one between revision speed and drug scope illustrated in our study.

In addition, we believe our study also contributes to the innovation literature on new product development (NPD). Prior studies have mainly looked at the research and development aspects of a firm's NPD strategy to understand innovation outcomes such as product scope and time to market, while the non-market aspects of NPD have received less attention. Yet, this non-market dimension is also important in explaining such innovation outcomes. The characteristics of the institutional context where a firm operates, such as the political/legal environment, strongly determines the success of its strategy (Aldrich and Pfeffer, 1976; Dacin, Ventresca, and Beal, 1999; Scott and Meyer, 1994). In the case of NPD strategies, this is especially true. Prior research has provided evidence that several aspects of the political/legal environment, such as patent and copyright law, are highly influential in determining firms' innovation success (Heller and Eisenberg, 1998; Hirsh, 1975; James et al., 2013). In our study, we focus on an unexplored

non-market stage: the regulatory approval of a new product. Our paper is the first study, up to our knowledge, to show evidence of the importance of the regulatory approval stage for firms' innovation strategies.

We believe our study also has important implications for managers. Our findings outline a potential reason why NPD strategies may fail in some instances. A firm with a NPD strategy aimed at increasing product scope may put a lot of R&D effort on identifying new uses for its product but still fail to achieve its objective if the regulator does not approve those product uses. Our study shows how adopting a proactive rather than reactive non-market approach increases substantially the probability that a firm will achieve its NPD goals. In addition, our study suggests that managers using political efforts to achieve a more tailored content may need to account for the negative consequences of such political activities, i.e., that the policy outcome will take longer. Understanding the nature of the trade-off between speed and scope in non-market activities is critical for firms entering the political arena.

Limitations and future research

We acknowledge that our paper has certain limitations. First, with the objective of providing a richer and finer-grained analysis of our trade-off we were restricted to a particular context—NDA revisions by the FDA. Therefore, a logical question is whether our story also applies to other contexts. We believe that our theoretical model and conclusions may have broad applicability in contexts where there is a regulatory agency, e.g. product approvals, patent grants, or merger authorizations. In all these cases firms care about both the content and speed of the decision. In each of them, the contingency variable determining market pressures and, therefore, explaining preferences for speed or content will be context-specific. Moreover, we believe our story may also apply beyond this type of non-market actors. When governmental actors such as

congress decide on policy, they are deciding on both the content of the policy and the speed of the decision. Therefore, in those cases where firms wish to have governmental issues resolved quickly and policies that are favorable to them, a trade-off between decision speed and decision content will also be present. However, the trade-off we examine may not exist in all contexts. When it comes to policy change, for instance, some firms may actually prefer a slow decision-making, so the trade-off between speed and content is unlikely to apply in these cases. Thus, a better understanding about the presence of trade-offs across different types of non-market contexts provide a fruitful direction for future research.

A second limitation is that while prior work in the CPA literature examines a broad range of political activities (lobbying, donations to political candidates, directors with prior public service, etc.) we focused on only one: lobbying. It might be the case that firms combine different political activities to maximize their impact. In our context, we believe this is unlikely since advisory committee decisions are temporarily and structurally insulated from political elections—as it happens with many decision-makers in regulatory agencies. This leads us to believe that other political activities, such as candidate donations, might not be effective in influencing NDA revisions. This, however, raises an additional concern with respect to the generalizability of our conclusions to other non-market contexts where firms face very different types of public officials. Governmental actors such as politicians have very different motivations than regulators, the key actors in our study. This means that the lobbying strategies suggested in our study may not work for politicians, for which campaign donations may be more successful.

A final limitation is that we are unable to observe the mechanism driving our predictions. For obvious reasons we cannot directly see lobbying firms' specific actions and how/whether public officials are affected by such actions. Although this is a limitation in almost every CPA

study, we believe it is still necessary to acknowledge it. We have tried to minimize this limitation as much as possible through interviews with lobbying professionals and by examining examples of how external speakers may influence FDA advisory committee decisions, and thus provide a plausible explanation of how the proposed mechanism works in practice.

In sum, we believe that our contingency perspective on public officials' decisions and firms' political activities provides a richer and broader view of the reasons why firms approach the political arena. We hope that future research will further explore this view as a way to theoretically enrich our understanding of how firms benefit from being politically active.

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Table 1 Descriptive Statistics and Correlations [a]

	N = 540	Mean	s.d.	1	2	3	4	5	6	7	8	9	10
1	Revision Time	6.15	0.54	1.00									
2	Drug Scope	0.21	0.41	-0.05	1.00								
3	FDA Lobbying	0.31	1.86	-0.01	-0.02	1.00							
4	IP Protection	1.05	0.82	-0.08	0.07	-0.01	1.00						
5	Non-FDA Lobbying	4.37	6.33	0.05	0.07	0.27	0.10	1.00					
6	Prior FDA Lobbying	0.37	0.89	-0.02	0.03	0.36	0.16	0.56	1.00				
7	Number of Chemical Entities	0.72	0.50	-0.01	0.32	-0.03	-0.26	-0.08	-0.09	1.00			
8	Development Experience	1.80	1.33	0.01	0.10	0.14	0.09	0.52	0.37	-0.15	1.00		
9	Prior Safety Alerts	0.36	0.48	0.03	0.13	0.12	0.21	0.44	0.36	-0.16	0.67	1.00	
10	Public Firm	0.54	0.50	0.12	0.01	0.10	0.09	0.34	0.20	-0.10	0.41	0.29	1.00

[a] Descriptive statistics and correlations with Drug Scope are calculated on a sample of 457 observations .

Table 2 Main Results [a]

Dependent Variable	Revision Time						Drug Scope					
FDA Lobbying Variable	Continuous			Binary			Continuous			Binary		
Model	OLS (1)	OLS (2)	OLS (3)	OLS (4)	OLS (5)	OLS (6)	Logit (7)	Logit (8)	Logit (9)	Logit (10)	Logit (11)	Logit (12)
FDA Lobbying	-	-0.019 (0.131)	-0.060 (0.001)	-	-0.207 (0.163)	-0.689 (0.001)	-	0.026 (0.681)	-0.314 (0.018)	-	0.341 (0.638)	-3.417 (0.036)
IP Protection	-	-0.020 (0.529)	-0.032 (0.311)	-	-0.020 (0.537)	-0.033 (0.307)	-	0.336 (0.080)	0.281 (0.156)	-	0.337 (0.079)	0.282 (0.155)
FDA Lobbying x IP Protection	-	-	0.043 (0.001)	-	-	0.477 (0.001)	-	-	0.262 (0.001)	-	-	2.773 (0.001)
Non-FDA Lobbying	0.009 (0.090)	0.009 (0.077)	0.010 (0.062)	0.009 (0.090)	0.009 (0.078)	0.010 (0.062)	0.014 (0.676)	0.015 (0.651)	0.017 (0.622)	0.014 (0.676)	0.015 (0.655)	0.017 (0.622)
Prior FDA Lobbying	-0.018 (0.649)	-0.003 (0.936)	-0.008 (0.841)	-0.018 (0.649)	-0.003 (0.926)	-0.007 (0.850)	-0.326 (0.124)	-0.373 (0.087)	-0.391 (0.082)	-0.326 (0.124)	-0.376 (0.083)	-0.388 (0.083)
Number of Chemical Entities	-0.042 (0.406)	-0.048 (0.342)	-0.051 (0.316)	-0.042 (0.406)	-0.048 (0.345)	-0.051 (0.316)	2.392 (0.001)	2.544 (0.001)	2.552 (0.001)	2.392 (0.001)	2.546 (0.001)	2.550 (0.001)
Development Experience	-0.071 (0.006)	-0.074 (0.004)	-0.075 (0.004)	-0.071 (0.006)	-0.074 (0.004)	-0.075 (0.004)	0.282 (0.133)	0.281 (0.131)	0.285 (0.131)	0.282 (0.133)	0.282 (0.131)	0.284 (0.131)
Prior Safety Alerts	0.071 (0.232)	0.078 (0.188)	0.074 (0.209)	0.071 (0.232)	0.078 (0.184)	0.075 (0.200)	0.607 (0.137)	0.555 (0.170)	0.567 (0.163)	0.607 (0.137)	0.553 (0.171)	0.569 (0.161)
Public Firm	0.093 (0.070)	0.097 (0.060)	0.099 (0.059)	0.093 (0.070)	0.097 (0.060)	0.097 (0.059)	0.305 (0.403)	0.278 (0.437)	0.269 (0.466)	0.305 (0.403)	0.278 (0.437)	0.268 (0.465)
Observations	540	540	540	540	540	540	457	457	457	457	457	457
Number of Firms	228	228	228	228	228	228	197	197	197	197	197	197
(Pseudo) R^2	0.176	0.180	0.192	0.176	0.180	0.193	0.287	0.293	0.302	0.287	0.293	0.302

[a] All models include approval year and therapeutic area fixed-effects. P-values in parentheses.

Table 3 Robustness tests: Heckman estimations [a]

Robustness test	Heckman 2-Steps: FDA Lobbying					Heckman 2-Steps: IP Protection				
Dependent Variable	FDA Lobbying	Revision Time		Drug Scope		IP Protection	Revision Time		Drug Scope	
FDA Lobbying Variable	-	Continuous	Binary	Continuous	Binary	-	Continuous	Binary	Continuous	Binary
FDA Lobbying	-	-0.060 (0.001)	-0.696 (0.001)	-0.308 (0.046)	-3.402 (0.117)	-0.043 (0.247)	-0.059 (0.001)	-0.675 (0.001)	-0.314 (0.012)	-3.421 (0.026)
IP Protection	-0.263 (0.194)	-0.032 (0.318)	-0.032 (0.314)	0.278 (0.164)	0.281 (0.157)	-	-0.054 (0.140)	-0.055 (0.138)	0.507 (0.050)	0.507 (0.050)
FDA Lobbying x IP Protection	-	0.043 (0.002)	0.475 (0.001)	0.271 (0.001)	2.782 (0.001)	-	0.043 (0.001)	0.474 (0.001)	0.261 (0.001)	2.749 (0.001)
Non-FDA Lobbying	-	0.010 (0.063)	0.010 (0.065)	0.018 (0.612)	0.017 (0.623)	-0.001 (0.989)	0.009 (0.068)	0.009 (0.069)	0.017 (0.630)	0.017 (0.631)
Prior FDA Lobbying	0.666 (0.001)	-0.007 (0.847)	-0.008 (0.834)	-0.376 (0.132)	-0.386 (0.128)	0.136 (0.183)	-0.008 (0.821)	-0.008 (0.829)	-0.348 (0.126)	-0.344 (0.129)
Number of Chemical Entities	-0.046 (0.859)	-0.051 (0.315)	-0.051 (0.316)	2.552 (0.001)	2.550 (0.001)	-0.628 (0.001)	-0.048 (0.353)	-0.048 (0.354)	2.591 (0.001)	2.588 (0.001)
Development Experience	-0.056 (0.691)	-0.075 (0.004)	-0.075 (0.004)	0.284 (0.132)	0.284 (0.132)	-0.208 (0.005)	-0.075 (0.004)	-0.075 (0.004)	0.298 (0.103)	0.297 (0.103)
Prior Safety Alerts	-0.334 (0.433)	0.074 (0.209)	0.074 (0.201)	0.567 (0.164)	0.569 (0.161)	0.164 (0.344)	0.067 (0.267)	0.069 (0.257)	0.615 (0.131)	0.618 (0.129)
Public Firm	0.368 (0.339)	0.097 (0.059)	0.097 (0.060)	0.270 (0.460)	0.268 (0.462)	0.052 (0.687)	0.098 (0.059)	0.098 (0.059)	0.263 (0.463)	0.263 (0.462)
Campaign Donations	0.091 (0.017)	-	-	-	-	-	-	-	-	-
Prior Drugs with Patents	-	-	-	-	-	0.092 (0.001)	-	-	-	-
Inverse Mills Ratio	-	0.003 (0.983)	-0.010 (0.949)	0.161 (0.893)	0.021 (0.988)	-	0.073 (0.351)	0.073 (0.352)	-0.864 (0.141)	-0.864 (0.141)
Observations	540	540	540	457	457	540	540	540	457	457
Number of Firms	228	228	228	197	197	228	228	228	197	197
(Pseudo) R^2	0.432	0.193	0.193	0.303	0.302	0.096	0.194	0.195	0.303	0.307

[a] All models (except the 1st stages) include approval year and therapeutic area fixed-effects. P-values in parentheses.

Table 4 Robustness tests: Firm Fixed-effects and Time-to-expiration [a]

Robustness test	Firm Fixed-effects				IP Protection: Time-to-expiration			
Dependent Variable	Revision Time		Drug Scope		Revision Time		Drug Scope	
FDA Lobbying Variable	Continuous	Binary	Continuous	Binary	Continuous	Binary	Continuous	Binary
Model	OLS	OLS	Logit	Logit	OLS	OLS	Logit	Logit
FDA Lobbying	-0.038 (0.041)	-0.452 (0.017)	-1.699 (0.024)	-19.74 (0.036)	-0.056 (0.001)	-0.628 (0.001)	-6.803 (0.018)	-83.45 (0.017)
IP Protection	-0.062 (0.238)	-0.063 (0.234)	-1.579 (0.342)	-1.580 (0.343)	-0.009 (0.219)	-0.009 (0.216)	0.061 (0.228)	0.061 (0.230)
FDA Lobbying x IP Protection	0.035 (0.029)	0.396 (0.018)	2.037 (0.001)	24.27 (0.001)	0.005 (0.030)	0.064 (0.019)	0.778 (0.017)	9.552 (0.016)
Non-FDA Lobbying	0.017 (0.033)	0.017 (0.033)	-0.128 (0.698)	-0.128 (0.397)	0.010 (0.061)	0.010 (0.062)	0.015 (0.650)	0.015 (0.654)
Prior FDA Lobbying	-0.011 (0.860)	-0.010 (0.876)	-2.395 (0.125)	-2.413 (0.122)	-0.008 (0.838)	-0.008 (0.824)	-0.383 (0.076)	-0.387 (0.071)
Number of Chemical Entities	-0.059 (0.560)	-0.059 (0.555)	14.19 (0.045)	14.21 (0.044)	-0.056 (0.280)	-0.055 (0.282)	2.514 (0.001)	2.516 (0.001)
Development Experience	-0.080 (0.376)	-0.078 (0.390)	-7.386 (0.027)	-7.380 (0.028)	-0.075 (0.004)	-0.075 (0.004)	0.286 (0.137)	0.287 (0.136)
Prior Safety Alerts	0.093 (0.385)	0.095 (0.374)	-11.64 (0.006)	-11.61 (0.006)	0.083 (0.164)	0.084 (0.159)	0.608 (0.138)	0.607 (0.138)
Public Firm	0.169 (0.122)	0.168 (0.116)	13.36 (0.007)	12.63 (0.005)	0.100 (0.055)	0.100 (0.054)	0.289 (0.434)	0.291 (0.433)
Observations Number of Firms	413 101	413 101	196 37	196 37	540 228	540 228	457 197	457 197

[a] All models include approval year and therapeutic area fixed-effects. P-values in parentheses.

Table 5 Examples of *Speed* and *Scope* Non-market Strategies in Scientific Advisory Committee Hearings [a]

Drug (NDA)	Gestiva (21945)	Northera (203202)	Zelnorm (21200)	Farxiga (202293)	Orkambi (206038)	Afrezza (22472)
Committee	Reproductive Health (2006)	Cardiovascular and Renal (2012)	Gastrointestinal (2000)	Endocrinologic and Metabolic (2011)	Pulmonary-Allergy (2015)	Endocrinologic and Metabolic (2014)
FDA concerns during review	Clinical studies included only a certain population. Without more studies, if approved the drug will have narrow applicability.	Clinical studies are too narrow and short. Evidence of effectiveness is unclear. Considering the need for more studies	Effectiveness in certain subpopulations is not demonstrated due to clinical studies' narrow design.	Clinical studies are broad and examine the use of Farxiga for multiple types of diabetes. Effectiveness compared to narrower drugs is unclear.	Clinical studies include many subpopulations. Concerns about the effectiveness across all subpopulations.	Clinical studies show that Afrezza has some side-effects that similar drugs don't have but lacks side-effects other drugs have.
Quotes by FDA Reviewers	"*We are concerned that these findings may not be applicable to other populations*"	"*If we were to have one that had a longer placebo-controlled period we would be able to establish the durability of efficacy*"	"*Efficacy in males is not established […]The lack of differentiation from placebo may be due to inadequate sample size*"	"*Phase 3 studies show that [Farxiga] is efficacious […] however, we need to be concerned about the actual effect size*"	"*The studies were highly powered with a large number of subjects to analyze data for gender, baseline age group, and disease severity*"	"*Afrezza subjects showed weight loss while Aspart subjects showed weight gain […] Hypoglycemia was lower for Afrezza*"
IP Protection	Low	Low	Low	High	High	High
Non-market strategy	Speed: Stress urgency by pointing out at the suffering from patients	Speed: Stress urgency by highlighting the absence of alternatives	Speed: Stress urgency by pointing out at the suffering from patients	Scope: Stress benefits compared to narrower existing drugs.	Scope: Effectiveness across subpopulations (e.g., age)	Scope: Stress lack of side effects compared to other drugs.
Quotes by speakers	State Senator and Vice Chair of Women in Government: "*On behalf of my colleagues across the country, I urge the Advisory Committee to ensure access to life-saving technologies, such as [Gestiva]*" Co-Director of the Yale Blood Center for Women and Children: "*I urge the committee to consider seriously approving this drug for the prevention of preterm delivery*"	Nurse and co-president of a support group for patients: "*No other medication options were available at that time, and round-the-clock nursing care became a necessity*" Patient: "*Currently I'm taking a combination of other drugs to address my symptoms. Effectiveness is inconsistent. I urge you to approve the solution as soon as possible*"	Founder of the Functional Bowel Disease Foundation: "*If these drugs are found to be safe and effective, I would urge you to make them available to the patients who desperately need them. The toll of IBS [irritable bowel symptom] is on the individuals quality of life and discomfort, affecting almost every aspect of their life*"	Firm employee: "*We have over a dozen different types of diabetes medications on the market. Farxiga is effective in a broad spectrum of patients*" Editor in chief of three diabetes and obesity publications: "*Many agents are using combinations regimens. Simpler drugs are easier for patients to take and for doctors to prescribe*"	16-year-old patient: "*To not approve it for so many that have suffered will not only be confusing but cruel. On behalf of the thousands of children and adults with [cystic fibrosis] like myself, thank you so much*". Firm employee: "*[The improvement] was consistent across all subpopulations regardless of the age of the patient*"	Patient: "*My current treatment put me in danger of dying, especially in my sleep. In contrast, I could take Afrezza as late as 11 p.m., and I knew I was safe*" Patient: "*Another thing this medication did for me was help me get my diabetes under control so I could carry a healthy pregnancy*"

[a] Source: FDA's Dockets Management.

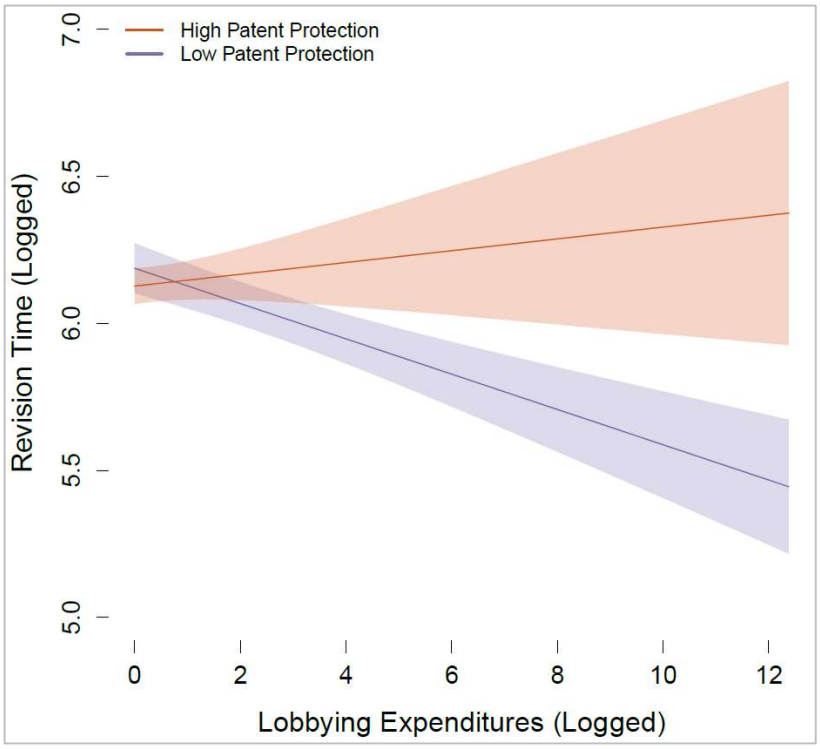

Figure 1a. The effect of *FDA Lobbying* on *Revision Time* for different levels of *IP Protection*.

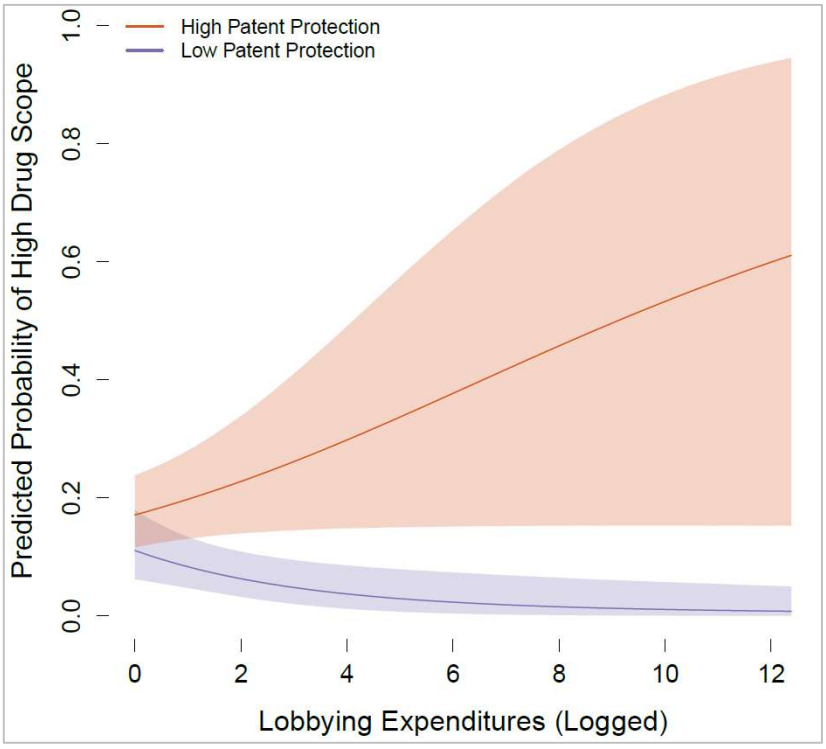

Figure 1b. The effect of *FDA Lobbying* on *Drug Scope* for different levels of *IP Protection*.