

# A THEORY OF APPROVAL REGULATION<sup>1</sup>

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## Abstract

Approval regulation – in which a firm seeking market entry must demonstrate an empirical case to a discretionary regulator with sole authority to grant legal market entry – is empirically ubiquitous. Such arrangements govern markets ranging from pharmaceuticals to environmental permits. Yet these arrangements have not been studied in a game-theoretic environment. We develop a simple theory of regulatory approval with endogenous product submissions. In the model, a firm and a regulator are both incompletely informed about the quality of a product, but the firm has better priors than the regulator. The firm may choose the scope of experimentation for a product before submitting it for approval or withdrawing it from consideration. Experiments are costly and provide information on product quality to both players. Upon submission the regulator must approve or reject the product. Among other findings, the model predicts that: (i) pre-acceptance R&D costs are non-monotonic in prior assessments of product quality, (ii) products from large or experienced firms will generally fare better in the regulatory process (even without capture), but that small-firm products will be accepted at a higher rate after lengthy R&D, (iii) regulators benefit from high experimentation and submission costs but, surprisingly, from relatively low product standards, and (iv) large (small) firms will be more likely to produce Type I (II) errors.

## 1. Introduction

Governments attempting to regulate economic activity ineluctably confront private actors who are better informed. The set of facts better known by firms is, moreover, usually of consequence to policy outcomes that interest the state. Compared to the entity that governs them, regulated firms better know their own costs, better know expected consumer demand, and better know the social costs and hazards associated with their products. This fact has led numerous theorists to consider how state regulators deal with these information asymmetries. The customary strategy adopted by theoretical regulators in response to information asymmetries is an audit (Baron and Besanko 1984), an expensive examination of firm costs that can serve to inform society and deter excessively high pricing or excessive production of an externality. Alternatively, the regulator can bound or set prices, thus directly constraining the firm’s behavior (Baron and Myerson 1982, Lewis and Sappington 1988).

In this essay we consider a different institution by which regulators respond to information asymmetries: regulation of product development and market entry. We call this *approval regulation*. Approval regulation exists when government entities exercise discretion over whether the firm or product can enter the market, such that firms must provide an empirical case for admission that the regulator must accept if legal market entry is to be granted.<sup>1</sup> In approval regulation the state acts as a discretionary market gatekeeper and potential entrants provide not a fee but a proof of quality or necessity. Consider the following examples where firms must successfully prove a case to a discretionary regulator in order to gain market entry.

*Regulation of pharmaceuticals, medical devices, and foods.* Nowhere is approval regulation more developed than in the complex governance of the pharmaceutical industry (*e.g.*, Quirk 1980, Heimann 1997, Olson 1997, Carpenter 2002). In most countries, no firm can introduce a pharmaceutical product to the prescription market without *ex ante* approval from a domestic regulator. Regulation of entry into the pharmaceutical marketplace is a function of state that remains predominantly nationalized.<sup>2</sup> Firms develop their products using procedures that are regulated, monitored, and in many cases dictated to them by the state entity regulating the market they seek to enter. After a sufficient degree of experimentation, a subset of developed

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<sup>1</sup>These two aspects of approval regulation – regulator discretion and a “proof requirement” – differentiate it from “regulation of entry” (*e.g.*, Djankov *et al* 2002, Breyer 1982). Entry regulation usually posits a screen, or procedural hurdles, such as entry fees and administrative licensing which, once met by the entrepreneur, are usually sufficient to gain market entry.

<sup>2</sup>The recent merger of European Union regulatory authorities marks a significant exception to the nationalization of approval regulation. EU pharmaceutical regulation is nonetheless amenable to analysis in terms of our model, as firms still confront a quasi-state regulatory entity.

chemical entities are submitted to this regulator for approval. In a process that can consume years of time and can add materially to firms' pre-market expenditure, the regulator then decides whether or not to approve the product. In many nations, a similar arrangement governs medical devices and genetically modified foods.

*Licensing.* In other cases, firms or individuals must develop a product or plan or demonstrate a special competence in order to persuade a licensing regulator to allow market entry (*e.g.*, Leland 1979, Lott 1987). Cases include the licensing of food or alcohol establishments (in many jurisdictions, the applicant must show need or expected profit, or the absence of community harm, before a license will be awarded); commercial fishing operations; broadcast frequencies (Levin 1964, Gormley 1979); and professional services, including physicians, accountants and barbers (Thornton and Weintraub 1979).

*Permitting.* States engage in permitting when they approve market entry for a particular activity. An architecture or construction firm might need a license to engage in building design generally, but a specific permit to building a particular structure on a particular site (*e.g.*, wetlands permitting by environmental agencies). Alternatively, a regulator may issue permits for productive activity even where no special competence is required (*e.g.*, grazing permits issued by the Bureau of Land Management or the Forest Service in the United States), but where the entrant must demonstrate minimal environmental impact.

Despite its ubiquity, approval regulation has received little theoretical study. There are perhaps two reasons for this. First, very few models of regulation address the issue of product quality, let alone endogenize the research and development (R&D) process. As Laffont and Tirole (1999: 233) summarize, “[w]hile there exists a vast literature on the provision of quality by an unregulated monopoly, surprisingly little research has been devoted to this issue in a regulated environment.”<sup>3</sup> However, in approval regulation firm R&D strategies are intrinsically important. For example, two of the most controversial aspects of drug regulation—approval and pricing—are affected greatly by the actions taken by pharmaceutical companies. The firms fund and direct the development and pre-approval clinical testing of proposed drugs (albeit under the supervision of the FDA). After clinical trials, they also propose labels for their products. All of these activities may affect approval times and impose costs. Moreover, because firms have almost complete control over pricing, these activities ultimately affect social welfare as well.

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<sup>3</sup>Leland (1979) studies the welfare effects of imposing quality requirements on a market, but in the absence of a strategic regulator.

Second, existing models of R&D in regulatory environments are almost exclusively decision-theoretic (*e.g.*, optimal stopping models). In earlier work, Carpenter (2002, 2003) develops a decision-theoretic model in which a regulatory agency balances the benefit of waiting for more information against the political cost of delay. This learning process induces even a risk-neutral agency that has not been captured to favor larger firms (*i.e.*, by reviewing their products more quickly), and thus exhibit characteristics of captured agency. While models such as these permit the examination of highly complex learning environments, their predictions rest on some non-trivial assumptions about either firm or regulator strategies, so a formal model of them would improve the specification of empirical tests.

Thus, we are aware of no *strategic* model of firm-regulator interaction in an approval regulation setting. That is, we are unaware of models in which firm experimentation (R&D) anticipates a regulatory response, and a regulator concerned with product quality faces an endogenous distribution of applications submitted by a strategic firm.

The model presented here therefore links optimal stopping theories of R&D with a regulatory approval stage. It also incorporates three other features that are common to approval regulation settings. First, the principal R&D effort is expended *before* market entry, whereas most auditing models consider an established firm with observable output and price. Second, approval regulation shifts the costs of information revelation directly to the regulated entity (for example, by requiring pre-market product experimentation and then disclosure of the results). Put differently, in approval regulation, the state often reorders and exploits strategic product development, both to gain information and to induce a pattern of firm behavior that it finds superior to unregulated behavior. Finally, *ex ante* uncertainty is two-sided and asymmetric. The firm does not fully know the quality or hazards of its product, but is better informed than the regulator. Thus the firm itself needs experimentation to determine the product's viability, and the regulator has an incentive to discourage the development of *ex ante* "bad" products.

Specifically, our game begins with a product development phase, in each period of which a firm may submit an application, perform an experiment to gather more information, or abandon the product. Each experiment is costly and takes the form of a Bernoulli trial that is publicly observable. If the firm submits, the regulator then chooses whether to accept or reject the proposal. The firm has private information about the quality of the product, and thus conditions its strategy on both it and its endogenously acquired experimental information. Thus experiments serve two purposes. As in standard "burned money" games, they are costly signals of private information. But they also provide public information that is used by both players in determining whether a product is approved, or even submitted.

In equilibrium, firms with the most favorable private information and initial experimental results submit tend to submit earliest. Those with less favorable results may continue experimenting in the hopes of improving their record, or perhaps withdraw. The equilibrium logic of the game is therefore exactly the reverse of that of standard costly signaling games: “high” types signal the least, while lower types must perform more costly experiments in order to put themselves in the position to submit. Interestingly, the quality of approved products is constant over time. This happens because the regulator can only rarely separate between those types that meet its requirements and those that do not. The optimal probability of acceptance deters the “worst” products from being submitted, but cannot screen out products that are just below standard.

The model generates some interesting predictions of both the regulator’s behavior and her preferences over regulatory policy. The results imply that many observed regularities in product approval regulation—the advantage of large firms, regulators’ preference for restricted entry—hold in a world where no rent-seeking prevails. Other findings are less intuitive, however, and we mention three here. First, because of Type II errors, the regulator typically benefits in equilibrium from having low acceptance thresholds. Second, under certain conditions where would-be entrants must delay submission until after a large amount of experimentation has been reached, small firms may enjoy an advantage in acceptance probabilities because their submissions are more credible. Finally, contrary to the logic of rent-seeking firms, the regulator’s preferred entry costs are increasing in the *divergence* of its interests from those of the industry.

Our results are also relevant to theories of administrative error (*e.g.*, Bendor 1985, Heimann 1997). The model predicts that large and small firms will be more likely to commit Type I and Type II errors, respectively. Additionally, Type II errors can be reduced by reducing experimental costs but raising submission costs, while the reverse is true for Type I errors. More broadly, the results suggest that analysts of administrative error should examine not only administrative arrangements, but also the shaping of the regulator’s induced “agenda.”

Finally, our analysis also offers some implications for the study of economic R&D in a regulatory setting where the firm must prove its case to a state agency that can veto entry. The model suggests that the standard summary statistics which are sufficient for characterizing optimal strategies in decision-theoretic R&D models are not sufficient for characterizing R&D strategies in a regulatory setting. Thus, the predictions of a large literature employing decision-theoretic models of R&D (*e.g.*, Dixit and Pindyck 1994) may be at odds with those from game-theoretic models.

The pharmaceutical marketplace is, of course, just one example of a larger set of industries that engage in knowledge production, information processing (Radner 1993), or problem solving (Hong and Page 2001). While audit and price regulation models remain useful tools for analyzing

regulation of these industries (witness Microsoft or AT&T), many are characterized by explicit regulation of market entry and implicit or explicit regulation of the R&D process. A theoretical examination of approval regulation, therefore, may have the advantage of shedding light upon the growing future of economic regulation as well as its present and past.

We proceed as follows. The next section presents the basic approval regulation model. Section 3 derives the two equilibria of the game. Section 4 examines a number of testable predictions and implications for regulatory policy. Section 5 discusses the results and concludes.

## 2. The Model

### 2.1 Game Structure

*Environment and Players.* There are two players: a (F)irm and a (R)egulator. Both are imperfectly informed about a parameter  $x$  of a product, which may be thought of as the revenue expected from bringing the product to market. We assume that  $x \sim \beta(\theta, n)$ , where  $\theta, n \in \mathbf{Z}_+$  and  $1 < \theta < n$ . The first parameter of the distribution,  $\theta \in \{m, m-1\}$ , is F's private information, while  $n$  is common knowledge. Let  $p$  represent R's prior belief of the "high" type ( $\theta = m$ ).

The Beta distribution of firm priors has two attractive features for our purposes. First, it admits a natural interpretation as a set of  $n$  Bernoulli trials, of which  $\theta$  resulted in success and  $n-\theta$  in failure.<sup>4</sup> Given  $\theta$  and  $n$ , the Beta distribution implies a prior mean  $\theta/n$  and prior variance  $\theta(n-\theta)/(n(n+1))$ . The uncertainty over  $x$  can be resolved partially through observable experiments. Second, it is flexible enough to accommodate a wide variety of "shapes" of the density function, as determined by  $\theta$  and  $n$ .

*Sequence.* The game has up to four periods, divided into a *development* phase with up to three periods and possibly a *regulatory* phase of one period. Periods are denoted by subscripts, and generic periods are denoted  $t$ . The phases are distinguished by the mover: only F moves in the development phase, and only R moves in the regulatory phase.

The game begins in the development phase. In it, F chooses an action  $f_t \in \{S, W, E\}$  at  $t = 1, 2$ .  $S$  denotes a submission for approval, which ends the development phase and commences the regulatory phase the next period.  $W$  denotes a withdrawal from consideration, ending the game. Finally,  $E$  denotes an experiment performed to gather more data. An experiment is a single simultaneous Bernoulli trials, which produces a publicly observable result  $e_t \in \{0, 1\}$  corresponding to failure or success, respectively. We adopt the convention that  $e_0 = 0$ . If  $f_t = E$ , then the development phase continues. F cannot experiment past the second period and thus  $f_3 \in \{S, W\}$ .

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<sup>4</sup>See the two-period models of Calvert (1987) and Alt, Calvert and Humes (1988) for a similar technology in the context of a reputation game.

At the beginning of the regulatory phase, R knows F's actions and experimental results (but not  $x$  or  $\theta$ ). Based on this, she makes a review decision  $r \in \{A, R\}$ , where  $A$  and  $R$  denote acceptance and rejection, respectively.

*Information.* Without experimentation, the model reduces to a simple signaling game (with F as the sender). With experimentation, both players update their expectations of  $\theta$ . The assumption of Beta-distributed priors makes the calculation of posterior beliefs very simple. For example, beginning with a prior of  $\beta(m, n)$ , two experiments producing  $e_1 + e_2$  successes generate a posterior on  $\theta$  that is distributed according to  $\beta(m + e_1 + e_2, n + 2)$ . Accordingly,  $E[x \mid e_1, e_2] = \frac{m + e_1 + e_2}{n + 2}$  and  $Var[x \mid e_1, e_2] = \frac{(m + e_1 + e_2)(n + 2 - m - e_1 - e_2)}{(n + 2)(n + 3)}$ .

*Utilities.* F receives  $x$  if the product is approved, and zero for rejection. Each experiment costs

$$c_e \in \left(0, \frac{m(m-1)}{(n+1)(n+2)(n+m-1)}\right], \quad (1)$$

while submission costs

$$c_s \in \left(0, \frac{m}{n+2}\right]. \quad (2)$$

These assumptions ensure that costs do not deter the low type from experimentation or submission (though they may choose not to do so in equilibrium). They also substantially simplify the analysis by eliminating some trivial equilibria.

To rule out a number of trivial cases, we assume that the regulator's quality standard  $k$  satisfies:

$$\frac{m+1}{n+2} > k > \frac{m}{n}. \quad (3)$$

The first part of (3) ensures that a high type may become acceptable to R after one round of experimentation, thus eliminating the dominant strategy of rejecting all "early" (*i.e.*, period 2) submissions. It also guarantees that the low type may become acceptable to R after two successful experiments, so that R's problem is not merely one of "separating" the two types. The second part states that  $k$  is higher than both types' *ex ante* expected product quality, thus ensuring that neither will submit and be accepted in period 1. These payoffs capture the notions that some experimentation is necessary to generate a product satisfactory to the regulator, but that the two players can disagree over the desirability of marginal products.

## 2.2 Equilibrium

We characterize Perfect Bayesian Equilibria (PBE) of this game that satisfy one additional refinement. Let  $H_t$  represent the set of experimental histories prior to time  $t$ ; thus,  $H_1 \equiv \emptyset$ ,  $H_2 \equiv \{0, 1\}$ , and  $H_3 \equiv \{0, 1\} \times \{0, 1\}$ . We use  $h_t$  to denote generic elements of  $H_t$ . The equilibrium has three elements.



1. F's strategy is a set  $\{\phi_t\}_{t=1}^3$ , where  $\phi_t : \{m-1, m\} \times H_t \rightarrow \Delta(\{S, W, E\})$  for  $t = 1, 2$ , and  $\phi_3 : \{m-1, m\} \times H_3 \rightarrow \Delta(\{S, W\})$  map types and experimental histories to probability distributions over submitting, withdrawing, and experimenting (where feasible).
2. R's strategy is the mapping  $\rho : \bigcup_t H_t \rightarrow [0, 1]$  from experimental histories, conditional upon a submission, into a probability of rejection.
3. R has beliefs  $\mu : \bigcup_t H_t \times \{\emptyset, S\} \rightarrow [0, 1]$  mapping the experimental and submission history into a probability of being type  $m$ . These beliefs must be consistent with Bayes' Rule along the equilibrium path of play.<sup>5</sup>

Our analysis will utilize two other pieces of notation. First, we decompose  $\phi_t(\theta, h_t)$  into probabilities of submitting,  $\sigma(\theta, h_t)$ , withdrawing,  $\omega(\theta, h_t)$ , and experimenting,  $\eta(\theta, h_t)$ . Letting  $\eta(\theta, h_3) = 0$ , it is clear that  $\sigma(\theta, h_t) + \omega(\theta, h_t) + \eta(\theta, h_t) = 1$  for all  $t$ .

Second, denote the expected quality of a period- $t$  submission (given beliefs  $\mu(\cdot)$ ) by:

$$\bar{x}(h_t) = E[x \mid h_t, f_t = S] = \frac{\mu(h_t, S) + m - 1 + \sum_{i=1}^t e_{i-1}}{n + t - 1}. \quad (4)$$

In some cases, it will be possible for submissions to occur out of equilibrium. To complete the PBE, we assume that in these cases, R's beliefs about  $\theta$  are given by  $\mu(\emptyset, \emptyset)$ . This is equivalent to R ignoring the experimental history of these submissions. By (3), this implies that  $\bar{x}(h_t) < k$  for all such  $h_t$ , and thus R rejects the submission.<sup>6</sup> These beliefs are relatively innocuous. To see why, suppose instead that R's beliefs were "optimistic," in the sense that  $\bar{x}(h_t) > k$ . R's subsequent acceptance of all submissions would then induce all types to submit. It is easily shown that no equilibrium can be sustained in this manner.

As the subsequent development shows, the PBE concept does not always isolate a unique equilibrium. We therefore refine the set of equilibria with the following *submission equilibrium* criterion: where possible, we select the equilibrium in which submissions occur with positive probability at  $t = 2$ . Note that because no submissions may occur at  $t = 1$ , we are thereby restricting attention to equilibria with "early" submissions. This refinement rules out equilibria in which R does not accept submissions at  $t = 2$ , and F therefore does not submit. This restriction is sensible in the context of our objectives, as the ruled-out equilibria have submissions only in the final period and therefore lack many of the interesting dynamics of the retained equilibria.

### 2.3 Two Benchmarks

<sup>5</sup> Along with  $h_t$ , this posterior distribution in turn induces a distribution over possible values of  $x$ .

<sup>6</sup> Any "pessimistic" beliefs that induce  $\bar{x}(h_t) < k$  would have the same effect. Thus, more complex beliefs that condition on  $h_t$  would support the same equilibrium behavior as that identified here.

*R & D in a Decision-Theoretic Environment.* A useful benchmark for the subsequent sections will be a decision-theoretic version of the problem featuring only a regulator. Suppose that instead of dealing with a firm, the regulator knows  $\theta$  and could conduct experiments herself. That is, R has access to the same experimentation technology that F has in the general model, but can approve or reject products without any submission process. The model is therefore an analog of the "optimal stopping" theories of R&D.

R will accept products if and only if  $E[x | h_t] \geq k$ . Note that in the first period, if (3) is violated (so that  $E[x | \emptyset] = [pm + (1-p)(m-1)]/n \geq k$ ), then the regulator accepts the product without conducting experimentation. In the following discussion we assume both (3) and  $k < (m+1)/(n+2)$ , so that type  $\theta = m$  (respectively,  $m-1$ ) requires at least one (two) success(es) to become suitable for acceptance.

Let  $v_d(\theta, h_t)$  represent the continuation value from experimentation given  $h_t$ . Consider first the case of type  $m$ . Then the first-period continuation value is:

$$\begin{aligned} v_d(m, \emptyset) &= \Pr\{e_1 = 1 | \theta = m\}E[x | e_1 = 1, \theta = m] \\ &\quad + \Pr\{e_1 = 0 | \theta = m\} \max\{0, v_d(m, 0)\} - c_e \\ &= \frac{m}{n} \left( \frac{m+1}{n+1} \right) + \frac{n-m}{n} \max\{0, v_d(m, 0)\} - c_e. \end{aligned}$$

If a failure is observed in period one, then:

$$\begin{aligned} v_d(m, 0) &= \Pr\{e_2 = 1 | \theta = m, h_1 = 0\}E[x | e_2 = 1, \theta = m, h_1 = 0] \\ &= \frac{m}{n+1} \left( \frac{m+1}{n+2} \right) - c_e \end{aligned} \tag{5}$$

The initially unsuccessful regulator therefore experiments iff (5) is positive, which is assured by (1). Substituting into  $v_d(m, \emptyset)$ , the regulator experiments at  $t = 1$  if:

$$\frac{m(m+1)(2n-m+1)}{n(n+1)^2} - \left(2 - \frac{m}{n}\right) c_e > 0, \tag{6}$$

which also holds by (1). Thus, because of the low experimentation costs assumed in (1), the regulator continues experimenting until a success is obtained.<sup>7</sup>

Now consider the case of type  $m-1$ . Here, R needs two successes before an acceptable product may be produced. This clearly implies that  $v_d(m-1, 0) = 0$ . Carrying out the analogous exercise to the previous case,

$$\begin{aligned} v_d(m-1, \emptyset) &= \frac{m-1}{n} \max\{0, v_d(m-1, 1)\} - c_e \\ v_d(m-1, 1) &= \frac{m}{n+1} \left( \frac{m+1}{n+2} \right) - c_e. \end{aligned}$$

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<sup>7</sup>If  $c_e$  were allowed to be high enough that (5) is negative but (6) positive, then R would withdraw after the first failure.

Note that if  $v_d(m-1, 1) < 0$ , then  $v_d(m-1, \emptyset) < 0$  and no experimentation occurs. Substituting and simplifying, R will experiment at  $t = 1$  if:

$$\frac{(m-1)m(m+1)}{(n+1)(n+2)} - (n+m-1)c_e > 0. \quad (7)$$

By (1), this holds trivially. Thus, the regulator experiments with a type  $m-1$  product in period 1, continues if the experiment is successful, and abandons the product otherwise.

This example shares a feature common to optimal stopping models of experimentation. Because optimal sequential experimentation is characterized by  $v_d(\cdot)$ , we can describe the regulator's strategies in terms of sufficient statistics in the following sense.

**Comment 1** *The dual  $[\sum e_t, t]$  constitutes a sufficient statistic for R's optimal stopping strategy.*

**Proof** All proofs are provided in the Appendix. ■

The information in  $[\sum e_t, t]$  is sufficient in the sense that (i) the regulator knowing  $[\sum e_t, t]$  has welfare equivalent to that it would enjoy were it to know the entire history  $h_t$ , and (ii) given fixed parameters and knowledge of type, observation of  $[\sum e_t, t]$  uniquely and monotonically determines optimal experimentation strategies at each  $t$ . This is a standard (though not uniform) result that greatly simplifies the analysis of models of sequential decisions upon Markov processes.

*R & D in a Short Approval Regulation Game.* Now consider the game-theoretic model with only a single possible period of experimentation. By assumption, no acceptances can take place unless F experiments successfully, and so it is clear that  $\rho^*(\emptyset) = 1$ ,  $\rho^*(0) = 1$  and  $\sigma^*(\theta, \emptyset) = 0 \forall \theta$ .

There are two cases, which depend on whether R is willing to accept a product with one successful experimental result outright. It will therefore be useful to define:

$$\begin{aligned} \tilde{x} &= \frac{p \frac{m}{n} \frac{m+1}{n+1} + (1-p) \frac{m-1}{n} \frac{m}{n+1}}{p \frac{m}{n} + (1-p) \frac{m-1}{n}} \\ &= \frac{m}{n+1} \left( 1 + \frac{p}{m-1+p} \right) \end{aligned} \quad (8)$$

as the expected period 2 quality conditional upon a single experimental success, given that both types experiment in period 1.

In the first case,  $k \leq \tilde{x}$ . This implies that if both types experiment at  $t = 1$ , and all successful experimenters submitted at  $t = 2$ , then  $\bar{x}(h_t) > k$  and R must accept the submissions ( $\rho^*(1) = 0$ ).

Under these conditions, F will clearly submit at  $t = 2$  ( $\sigma^*(\theta, 1) = 1 \forall \theta$ ) if it experiments successfully, and withdraw otherwise ( $\omega^*(\theta, 0) = 1 \forall \theta$ ). It is also easily verified that both types will experiment in period 1:  $\eta^*(\theta, \emptyset) = 1 \forall \theta$ .

In the second case,  $k > \tilde{x}$ . In this case, R would reject period 2 submissions if both types experimented and submitted if successful. Note however that if only high types submit, then  $\bar{x}(1) > k$  and R's best response is  $\rho^*(1) = 0$ . This induces all types to submit, which causes  $\bar{x}(1) < k$  and creates an obvious contradiction.

Since there cannot exist an equilibrium in which  $\rho^*(1) = 0$ , R must mix between accepting and rejecting submissions. This requires R to be indifferent between acceptance and rejection, and is possible if the low type does not experiment or submit with probability one. (The high type must experiment and submit if successful with probability one, since it receives strictly higher utility from a submission than the low type.) Hence,

$$p \frac{m}{n} \frac{m+1}{n+1} + (1-p) \frac{m-1}{n} \frac{m}{n+1} \eta^*(m-1, \emptyset) \sigma^*(m-1, 1) = k \quad (9)$$

Note, however, that an interior value of  $\sigma^*(m-1, 1)$  would imply that the low type cannot receive a positive payoff at  $t = 2$ , and thus does not experiment at  $t = 1$ . Thus,  $\sigma^*(m-1, 1) = 1$  and  $\eta^*(m-1, \emptyset) = \frac{n(n+1)k - pm(m+1)}{(1-p)m(m-1)}$ .

To determine  $\rho^*(1)$ , note that  $\eta^*(m-1, \emptyset)$  implies that the low type firm is indifferent between experimentation and withdrawal. This implies that they are indifferent between submission and withdrawal, and thus:

$$\frac{m-1}{n} \left[ (1-\rho^*(1)) \frac{m}{n+1} - c_s \right] - c_e = 0, \quad (10)$$

which yields  $\rho^*(1) = 1 - \frac{n+1}{m} \left[ \frac{n}{m-1} c_e + c_s \right]$ . Note that this rejection probability is consistent with the claimed experimentation and submission strategies of the high type.

*Discussion.* The two examples show an important difference between "optimal stopping" and game-theoretic models of approval regulation. In both, the regulator's decision problem produces well-defined withdrawal, experimentation, and submission regions in the state (history) space. However, in the decision-theoretic version, the regulator does not make any errors (for any given value of  $\theta$ ). In the game-theoretic version, the inability of the regulator to experiment or observe types results in an under-provision of experimentation. It also induces mixed acceptance decisions, which introduces Type I errors and Type II errors that can hurt both players.

The game-theoretic example also has two noteworthy features that will be explored further in the following section. First is the two-step nature of signaling, which distinguishes our model from standard costly signaling models. Here experimentation and submission are both signals of type, but it also endogenously generates additional information. This information, in addition to type, determines submission strategies. Second, because acceptance with certainty will induce all types to submit, the expected quality of submitted and accepted products will often be exactly R's reservation value of  $k$ . R thereby benefits from its gatekeeping power, as  $k > \frac{m}{n}$  by assumption.

Despite the errors introduced by incomplete information, approval regulation in effect allows R to "skim" the best products from the set of types, even when a product is *ex ante* unacceptable.

### 3. Main Results

We now turn to the repeated-experimentation model. Two types of equilibria are possible, depending on how players react to success in a period 1 experiment. We begin by deriving each equilibrium, and then apply the submission equilibrium refinement (where necessary) to choose between them.

Throughout the game, each player's actions can be stated in the following general terms. R's decision problem occurs when F submits. Clearly, R accepts a submission if its expected quality is greater than  $k$ , rejects if it is less, and is indifferent otherwise. Thus:

$$\rho^*(h_t) = \begin{cases} 0 & \text{if } \bar{x}(h_t) > k \quad \text{(i)} \\ \in [0, 1] & \text{if } \bar{x}(h_t) = k \quad \text{(ii)} \\ 1 & \text{if } \bar{x}(h_t) < k \quad \text{(iii)}. \end{cases} \quad (11)$$

F's choice will depend on his assessment of the value of experimentation. Let  $v(\theta, h_t)$  denote type- $\theta$ 's continuation value from experimentation, conditional upon experimental history  $h_t$ . Clearly,  $v(\theta, h_3) = 0 \forall \theta$ . He prefers submission over experimentation in period  $t$  if:

$$(1 - \rho^*(h_t)) \left[ \frac{\theta + \sum_{i=1}^t e_{i-1}}{n + t - 1} \right] - c_s > v(\theta, h_t). \quad (12)$$

Finally, F prefers submission or experimentation over withdrawal in period  $t$  if the expected payoff from either is non-negative.

The derivation of equilibrium strategies is simplified greatly by the fact that the following are dominant strategies for R:

$$\begin{aligned} \rho^*(\emptyset) &= 1, \\ \rho^*(0) &= 1, \\ \rho^*(0, 0) &= 1, \\ \rho^*(1, 1) &= 0. \end{aligned}$$

That is, when the experimental record  $h_t$  contains no successes, the expected product quality must be below  $k$ , and is thus rejected. This implies that  $\sigma^*(\theta, h_t) = 0$  for all such  $h_t$ . At  $t = 3$ , the inability to continue experimentation therefore requires that  $\omega^*(\theta, (0, 0)) = 1$ . Likewise, when  $h_t$

has two successes, both types have expected quality exceeding  $k$ , and are thus accepted. Hence,  $\sigma^*(\theta, (1, 1)) = 1$ .

This leaves three possible experimental histories to consider:  $h_1 = 1$ ,  $h_2 = (0, 1)$ , and  $h_2 = (1, 0)$ . In the following discussion, we restrict attention to these histories.

### 3.1 Early Submission Equilibrium

The first type of equilibrium is the *Early Submission Equilibrium* (ESE). In it, F submits "early" (*i.e.*, in period 2) with positive probability. Since  $(m + 1)/(n + 1) > k > m/(n + 1)$ , R wishes to accept only "high" types in period 2.

As with the single-period benchmark in Section 2.3, there are two cases, which depend on whether P is willing to accept a product with expected quality implied by a single successful experiment. Recall that  $\tilde{x} = \frac{m}{n+1} \left(1 + \frac{p}{m-1+p}\right)$  is the expected period 2 quality conditional upon a single experimental success, given that both types experiment in period 1. If  $k \leq \tilde{x}$ , then R is willing in expectation to accept the set of all successful first-period experimenters. Since additional experiments are costly and do not improve product quality in expectation, F therefore submits if  $h_2 = 1$ .

When  $k > \tilde{x}$ , the existence of an ESE depends on another condition, which ensures that an initially successful high type prefers submission to continued experimentation. We label this the *Early Submission* (ES) condition:

$$c_s - c_e > \frac{m(m + 1)}{(n + 1)(n + 2)}. \quad (13)$$

This expression is counter-intuitive because it suggests that F has less incentive to delay submission when submission costs are high and experimental costs are low. Under these conditions, it might be expected that F would have a greater incentive to wait for a (possibly) better product to submit. However, this incentive is reversed by the fact that the probability of acceptance is increasing in  $c_s$  and decreasing in  $c_e$  in equilibrium. This reflects the credibility of submissions when  $c_s$  is high (which encourages high quality submissions) and  $c_e$  low (which encourages information acquisition).

Equilibrium play also depends on  $c_s$  and  $c_e$  in another way. When both cost parameters are sufficiently high, then it is possible that upon a single failure, the low type will prefer withdrawal to continued experimentation. This is summarized by the following condition, which we label the *Early Withdrawal* (EW):

$$\frac{m - 1}{n + 1} \left( \frac{m}{n + 2} - c_s \right) - c_e \leq 0. \quad (14)$$

When EW is true, R correctly believes that only a high type would remain in the game after a failure, and thus has the same estimate of  $x$  as F. Note that under assumptions (1) and (2), EW implies ES.

The first result derives the ESE strategies over the set of game histories that do not have dominant strategies.

**Proposition 1** (*Early Submission Equilibrium*) *If  $k \leq \tilde{x}$  or ES holds, then there exists a PBE in which equilibrium path strategies are as follows.*

$$\begin{aligned}
& \text{For } F \text{ (type } m\text{): } \eta^*(m, \emptyset) = \eta^*(m, 0) = 1, \sigma^*(m, 1) = 1, \sigma^*(m, (0, 1)) = 1. \\
& \text{For } F \text{ (type } m-1\text{): } \eta^*(m-1, \emptyset) = 1, \sigma^*(m-1, 1) = \begin{cases} 1 & \text{if } k \leq \tilde{x} \\ \frac{n(n+1)k - pm(m+1)}{(1-p)m(m-1)} & \text{if } k > \tilde{x}, \end{cases} \eta^*(m-1, 1) = 1 - \sigma^*(m-1, 1), \\
& \eta^*(m-1, 0) = \begin{cases} 0 & \text{if EW holds} \\ \frac{kn(n+1)(n+2) - p(n-m)m(m+1)}{(1-p)(n-m+1)(m-1)m} & \text{otherwise,} \end{cases} \omega^*(m-1, 0) = 1 - \eta^*(m-1, 0), \\
& \omega^*(m-1, (1, 0)) = 1, \sigma^*(m-1, (0, 1)) = 1. \\
& \text{For } R: \rho^*(1) = \begin{cases} 0 & \text{if } k \leq \tilde{x} \\ \frac{n-m+1}{n+2} + \frac{n+1}{m}c_e - \frac{n+1-m}{m}c_s & \text{if } k > \tilde{x}, \end{cases} \rho^*(1, 0) = 1, \\
& \rho^*(0, 1) = \begin{cases} 0 & \text{if EW holds} \\ 1 - \frac{n+2}{m} \left( \frac{n+1}{m-1}c_e + c_s \right) & \text{otherwise.} \end{cases} \blacksquare
\end{aligned}$$

It is useful to trace two sample game histories in the ESE. First, suppose that costs are not high (so that EW is violated), and consider the path of a high type firm whose first experiment fails. F cannot submit, but is sufficiently confident to conduct another experiment. With probability  $m/(n+1)$ , he succeeds and submits. But because the low type would also experiment with positive probability and submit if successful, R mixes between acceptance and rejection. Second, suppose that  $k > \tilde{x}$ , F is of the low type, and  $e_1 = 1$ . Because  $k$  is high, R does not accept all period 2 submissions and instead mixes. This makes F indifferent between submission and further experimentation. Because all high types would submit, R infers that F is of the low type if he experiments. Thus a further experimental success ( $e_2 = 1$ ) results in submission and acceptance, while a failure results in withdrawal because  $k > m/(n+2)$ .

### 3.2 Late Submission Equilibrium

The second equilibrium type is the Late Submission Equilibrium (LSE). Here there are no submissions at  $t = 2$ , either because the expected quality of successful experimenters at  $t = 2$  does not warrant acceptance ( $k > \tilde{x}$ ). It is guaranteed to exist when the ESE does not, and additionally does not impose any requirements on  $c_s$  or  $c_e$  (as in ES). As with the ESE, however, the equilibrium path of play depends EW, with some low types withdrawing from play endogenously upon receiving negative experimental information.

Analogously to Proposition 1, the next result derives the LSE strategies over the set of histories without dominant strategies.

**Proposition 2** (*Late Submission Equilibrium*) *If  $k > \tilde{x}$ , then there exists a PBE in which equilibrium path strategies are as follows.*

*For F (type  $m$ ):  $\eta^*(m, \emptyset) = \eta^*(m, 0) = \eta^*(m, 1) = 1$ ,  $\sigma^*(m, (0, 1)) = \sigma^*(m, (1, 0)) = 1$ .*

*For F (type  $m-1$ ):  $\eta^*(m-1, \emptyset) = \eta^*(m-1, 1) = 1$ ,  $\eta^*(m-1, 0) = \begin{cases} 0 & \text{if EW holds} \\ \frac{kn(n+1)(n+2)-p(n-m)m(m+1)}{(1-p)(n-m+1)(m-1)m} & \text{otherwise,} \end{cases}$   
 $\omega^*(m-1, 0) = 1 - \eta^*(m-1, 0)$ ,  $\sigma^*(m-1, (1, 0)) = \frac{kn(n+1)(n+2)-pm(n-m)(m+1)}{(1-p)(m-1)(n-m+1)m}$ ,  $\sigma^*(m-1, (0, 1)) = 1$ .*

*For R:  $\rho^*(1) = 1$ ,  $\rho^*(1, 0) = 1 - \frac{n+2}{m}c_s$ ,  $\rho^*(0, 1) = \begin{cases} 0 & \text{if EW holds} \\ 1 - \frac{n+2}{m} \left( \frac{n+1}{m-1}c_e + c_s \right) & \text{otherwise.} \end{cases}$  ■*

It will again be instructive to trace two example game histories in the LSE. First, consider the path of a high type firm whose first experiment succeeds. R does not accept submissions at  $t = 2$ , so F experiments again. He submits regardless of the outcome. If  $e_2 = 1$ , then R accepts. If  $e_2 = 0$ , then the F's submission is still acceptable to R, but the low type's submission has an expected quality below  $k$ . Thus, R mixes between acceptance and rejection. Second, suppose that F is of the low type, EW holds, and  $e_1 = 0$ . Even though R does would accept a submission if  $e_2 = 1$ , the costs of experimentation and submission, as well as F's reduced assessment of the product's quality, induce him to withdraw.

### 3.3 Equilibrium Selection

Propositions 1 and 2 establish the existence of equilibria under two sets of parametric conditions. The ESE requires that either  $k \leq \tilde{x}$  or ES hold, while the LSE requires only that  $k > \tilde{x}$ . Thus when  $k \leq \tilde{x}$  (respectively,  $k > \tilde{x}$  and ES does not hold), the model uniquely predicts the ESE (respectively, the LSE). If  $k > \tilde{x}$  and ES holds, then both equilibria exist. Here the submission equilibrium refinement selects the ESE.<sup>8</sup>

The following table lists the submission equilibrium rejection probabilities as a function of the experimental history. We include only non-trivial histories, in which rejection and acceptance are not dominant strategies.

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<sup>8</sup>Because EW implies ES, the refinement therefore implies that the LSE strategies that depend on EW (see Proposition 2) are never used.



<b>Table 1</b>	
<b>Rejection Probabilities</b>	
History	Rejection Probability
1	$\begin{cases} 0 & \text{if } k \leq \tilde{x} \\ \frac{n-m+1}{n+2} + \frac{n+1}{m}c_e - \frac{n+1-m}{m}c_s & \text{if } k > \tilde{x} \text{ and ES holds} \\ 1 & \text{otherwise.} \end{cases}$
1,0	$\begin{cases} 1 & \text{if } k \leq \tilde{x} \text{ or ES holds} \\ 1 - \frac{n+2}{m}c_s & \text{otherwise.} \end{cases}$
0,1	$\begin{cases} 0 & \text{if EW holds} \\ 1 - \frac{n+2}{m} \left( \frac{n+1}{m-1}c_e + c_s \right) & \text{otherwise.} \end{cases}$

## 4. Regulatory Implications

We now examine a number of the model's testable implications for regulatory decision-making.

### 4.1 Firm Size and Experience

One intuitive way to think of  $c_e$  is as a proxy for the size or experience of the firm. Larger firms should face lower experimentation costs, in part because they have (probably) already developed products with similar R&D processes in the past. In our model firm size can affect both the timing of submissions and acceptance probabilities.

In equilibrium,  $c_e$  may affect the timing of submissions only if  $k > \tilde{x}$ . Under these conditions, the average quality of products is low and type separation may occur throughout the equilibrium. Sufficiently large (*i.e.*,  $c_e < c_s - \frac{m(m+1)}{(n+1)(n+2)}$ ) firms submit in period 2 with positive probability. Firms not satisfying this cutoff cannot submit early because ES is not satisfied and the Early Submission Equilibrium does not exist.

There are two effects on submission probabilities. First, submissions from smaller firms do better in "late" submissions. When experimentation has reached its last period, the model predicts that acceptance probabilities are weakly decreasing in firm size. For  $h_3 = (0, 1)$  and  $c_e < \frac{m-1}{n+1} \left( \frac{m}{n+2} - c_s \right)$  (*i.e.*, EW is violated), the relationship is strict. For other two-experiment histories and parameter values, the acceptance probability is constant in  $c_e$ .<sup>9</sup> This reflects a straightforward logic of signaling games: at  $t = 2$ , experimental costs can serve as a signal of  $\theta$ . Thus, increasing  $c_e$  increases the regulator's assessment of the quality of submissions.

<sup>9</sup>Off the equilibrium path, acceptance probabilities are also all constant in  $c_e$ .

Second, submissions from larger firms do better in “early” submissions. No submissions can occur if  $h_2 = 0$ , but if  $h_2 = 1$  and  $k > \tilde{x}$ , then the acceptance probability decreases linearly over  $c_e$  for  $c_e < c_s - \frac{m(m+1)}{(n+1)(n+2)}$ , and is zero otherwise.<sup>10</sup> The standard logic of costly signaling does not hold here because high experimental costs give the firm an incentive to cut short the R&D process. At the end of period 3, this incentive is removed, and experimental costs behave in the intuitive manner.

It is important to note that despite the higher late acceptance rates for small firms, large firms will receive higher payoffs in equilibrium. This is because the first-order effect of smaller values of  $c_e$  is a reduction in direct experimental costs, so firm utility is decreasing in  $c_e$ . Thus, our results resemble those of Carpenter (2003) in that large-firm advantage exists even when there is no “capture” (that is, the firm has no political clout or contributions that may influence the regulator’s welfare). The main difference is a small-firm advantage that results from the signaling value of high experimental costs, conditional upon a lengthy experimentation period and initial failure.

#### *4.2 Submission Cost as a Credibility Device*

Submission costs also play a role in the timing of submissions and acceptance probabilities. Consistent with standard costly signaling arguments, these effects generally reflect the greater credibility of submissions when  $c_s$  is high.

As with experimentation costs,  $c_s$  influences the timing of submissions through the possibility of period 2 submissions only if  $k > \tilde{x}$ . If  $c_s > c_e + \frac{m(m+1)}{(n+1)(n+2)}$ , then ES holds and the Early Submission Equilibrium exists. Therefore, the model predicts that higher values of  $c_s$  will cause submissions to occur earlier.

The effect of  $c_s$  on acceptance probabilities is straightforward. In all cases, equilibrium acceptance probabilities are weakly increasing in  $c_s$  (alternately, rejection probabilities are decreasing in  $c_s$ ). The only case in which the acceptance probability is constant for all  $c_s$  is for early ( $t = 2$ ) submissions when  $k \leq \tilde{x}$ .

What features of the regulatory process might  $c_s$  capture? One tempting possibility is to consider necessary or firmly expected aspects of the regulatory process as a sort of submission cost. For instance, regulators frequently impose stringent procedural and administrative requirements upon a submission, mandating aggregation and presentation of results in a particular format and with considerable elaboration. The FDA, for instance, imposes hundreds of stylistic and procedural requirements upon new drug applications, and if the agency judges that a firm has not met these

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<sup>10</sup>If  $k \leq \tilde{x}$ , then the out of equilibrium acceptance probability is one.

requirements, it can issue a "refusal-to-file" (RTF) judgment. One testable implication is that, where these requirements become more stringent, empirically observed acceptance probabilities will rise, *ceteris paribus*. In a similar vein, Olson (2000) has suggested that the user-fee provisions of the 1992 Prescription Drug User Fee Act (PDUFA), which requires firms to submit a user fee with each new drug application to the FDA, may also have this effect. As the real dollar value of these user fees rises, then, we might expect higher acceptance probabilities. Yet compared to the expected and fully capitalized revenue that pharmaceutical firms enjoy upon regulatory approval of their products, these fees are currently quite low (in FY 2004, \$573,500 for a new drug application requiring analysis of clinical data; *Federal Register* Vol. 68, No. 148 (August 1, 2003), pp. 45249-45252). Hence the observed distribution of  $c_s$  as measured by user fees may not lie in the range in which it become theoretically relevant to firm and regulatory strategies in the model. A final possibility is to consider expected administrative or regulatory delay as a cost of submission. Here a testable prediction is that as expected delay becomes greater, approval probabilities will rise. The problem here, of course, is that regulatory delay is highly variable and difficult to forecast (Carpenter 2002), and uncertainty over this variable complicates testing the model (which assumes  $c_s$  fixed and known).

### 4.3 Regulatory Policy

Another natural question that our model can address is the optimal level of experimentation and submission costs. While administrators do not have the ability to determine  $c_e$  and  $c_s$  completely, we may ask how, given R's payoffs, a regulator would choose the experimentation regime.<sup>11</sup>

Suppose that  $k \leq \tilde{x}$ , so that only the ESE exists. With probability  $pm/n + (1-p)(m-1)/n$ ,  $e_1 = 1$  and R receives  $\tilde{x} - k$ . If  $e_1 = 0$ , then there are two cases. First, if EW does not hold, then all equilibrium game histories end with withdrawal by F, or indifference by R over acceptance and rejection. R therefore receives 0 if  $e_1 = 0$ , and her overall expected utility is  $(m-1+p)(\tilde{x}-k)/n$ . Second, if EW is true, then R strictly prefers acceptance to rejection if  $h_3 = (0, 1)$ , because only the high type submits. R's expected utility conditional on  $e_1 = 0$  is then  $\frac{pm}{n+1} \left( \frac{m+1}{n+2} - k \right) > 0$ .

Now suppose that  $k > \tilde{x}$ . There are now three cases; first, if ES does not hold, then EW also does not hold and the submission equilibrium is a LSE. In this case all game histories result in withdrawal or indifference by R. Thus, R receives 0. Second, if ES is true but EW is not, then the equilibrium is an ESE. Again, all game histories result in withdrawal or indifference by R, and R receives 0. Finally, if ES and EW are both true, then R may receive positive utility in the ESE if

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<sup>11</sup>Historically, politicians and administrators have tended to take measures that increase both experimentation and submission costs simultaneously, for example, by imposing more stringent requirements upon both regulatory processes and clinical experimentation in reforms of the early 1960s, or by relaxing the stringency of both in the 1990s.

$h_3 = (0, 1)$ . This requires that F be of the high type, and thus R receives  $\frac{p(n-m)m}{n(n+1)} \left( \frac{m+1}{n+2} - k \right)$ .

The following table lists R's utility in each of the possible subgames.

<b>Table 2</b>			
<b>Regulator Expected Utility</b>			
$k$	ES	EW	Expected Utility
$k \leq \tilde{x}$	N/A	false	$\frac{(m-1+p)(\tilde{x}-k)}{n}$
$k \leq \tilde{x}$	N/A	true	$\frac{(m-1+p)(\tilde{x}-k)}{n} + \frac{p(n-m)m}{n(n+1)} \left( \frac{m+1}{n+2} - k \right)$
$k > \tilde{x}$	false	false	0
$k > \tilde{x}$	true	false	0
$k > \tilde{x}$	true	true	$\frac{p(n-m)m}{n(n+1)} \left( \frac{m+1}{n+2} - k \right)$

As the table makes clear, R would wish to set both experimental and submission costs high enough to satisfy EW; that is, so that  $\frac{m-1}{n+1} \left( \frac{m}{n+2} - c_s \right) \leq c_e$ . Interestingly, R also does best when  $k \leq \tilde{x}$ , which allows ESE to exist. Low product standards help R because they help to prevent the rejection of *ex post* good products. While the regulator may not typically be in a position to choose  $k$ , the result suggests that exogenously raising quality thresholds might not improve social welfare.

The induced regulatory preference for higher experimentation and submission costs may appear straightforward, but its endogeneity to our model stands in sharp contrast to standard rent-seeking theories of regulation, for instance Stigler (1971). Capture theory suggests that because the regulated industry has acquired the regulatory process, the regulator will restrict entry.<sup>12</sup> Our model predicts entry restrictions without capture (or even an "incumbent" firm) and where the regulator's preferences diverge from those of the industry. Indeed, our model implies a result opposite to that predicted by rent-seeking theories of regulation: *the greater the divergence of regulatory preferences from those of the firm ( $k$ ), the more the regulator prefers higher entry costs*. It is worth noting, in the interest of appropriate circumspection, that our model does not currently consider competitive dynamics among two firms.

#### 4.4 Regulatory Error

<sup>12</sup>For a more recent example of this logic, see Djankov *et al* (2002).

A related normative question is how regulatory policy (as determined by  $k$ ,  $c_e$  and  $c_s$ ) affects the frequency of Type I and Type II errors. The regulator can commit a Type I error by approving a product with expected quality below  $k$ , or a Type II error by rejecting a product with expected quality above  $k$ . Both kinds of error may occur at any node of the game in which submissions are pooled, because R cannot distinguish between types and mixes between acceptance and rejection in these cases.

Before proceeding, we note two reasons for examining regulatory error. First, while the model incorporates the regulator's tradeoff between both types of error, there are players outside the model whose payoffs are also of interest. For example, disease advocacy groups may care directly about Type II errors, while consumer safety groups may care directly about Type I errors.

Second, Type I and Type II errors can have drastic economic and policy consequences in many approval regulation settings. The most publicized cases have occurred when a pharmaceutical entry regulator has approved bad products, as when European regulators approved the sedative *Kevadon* (thalidomide). Thalidomide induced tens of thousands of birth deformities in Europe, and the role of the FDA in keeping it from the U.S. market was widely celebrated as a regulatory success.<sup>13</sup> In recent years, critics of the FDA have focused upon its rejection or delay of valuable products, pointing to the costs of procedural conservatism in holding up everything from therapies for AIDS to beta-blockers for heart disease. A growing literature in political science and political economy grapples with the frequency of Type I and Type II errors in administrative and regulatory settings. In classic treatments, Landau (1969) and Bendor (1985) argue that bureaucratic redundancy (*e.g.*, adding extra regulators whose decisions are procedurally independent of existing agents' choices) can reduce error probabilities.<sup>14</sup> Bendor and Kumar (2004) analyze an "adaptive" model of redundancy in which pharmaceutical regulation is the motivating example. Other decision-theoretic analyses of this question have been undertaken by Heimann (1997) and by Carpenter (2003), whose optimal stopping model of regulatory approval predicts no Type II errors (asymptotically). It is noteworthy that all formal analyses of Type I and Type II error in policy settings have taken the agenda of the policymaker as exogenous, implying that the set of products or ideas audited by the policymaker is fixed and unaffected by administrative decisions. Yet some of the most important influences upon Type I and II error may come in the manner in which the policymaker induces "applicants" – those submitting "ideas," proposals or products – to advance their idea or abandon it before the policymaker must weigh in.

Here we consider the probability of each type of error for each history in which F submits

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<sup>13</sup>For an overview see Quirk (1980).

<sup>14</sup>Most recently, Ting (2003) presents a strategic model in which the benefits of redundancy may be attenuated by intra-organizational shirking, as agents might free-ride off the efforts of others.

with positive probability. While this approach is analytically tractable and yields some testable implications, it has several limitations. For example, we examine errors from the standpoint of the regulator's preferences ( $k$ ) only, and thus cannot consider whether her "values" are optimal.<sup>15</sup> A further limitation is that we do not consider the *ex ante* (*i.e.*, weighted by the probability of reaching each history) probabilities of each kind of error. Finally, because we focus on errors conditional upon submission, we do not address the matter of Type II errors from abandoned products. All of these questions are highly relevant for the design of regulatory policy, but are left for future work.

Let  $\psi^I(h_t)$  and  $\psi^{II}(h_t)$  denote the equilibrium probabilities of Type I and Type II errors given  $h_t$  and a submission, respectively. The probability of a Type I error is then  $\psi^I(h_t) = (1 - \rho^*(h_t))(1 - \mu(h_t, S))$ , and likewise  $\psi^{II}(h_t) = \rho^*(h_t)\mu(h_t, S)$ . Calculating  $\mu(h_t, S)$  is facilitated by the fact that  $\bar{x}(h_t) = k$  whenever the rejection probability is interior. In these cases, we may use (4) to obtain:

$$\mu(h_t, S) = k(n + t - 1) - m + 1 - \sum_{i=1}^t e_{i-1}.$$

There are four histories for which submissions occur with positive probability. In the case of  $h_3 = (1, 1)$ , there are no errors because only "good" types have submitted. For the other histories, we may use Table 1 to calculate the error probabilities conditional upon submission for each.

<b>Table 3</b> <b>Error Probabilities</b>	
$\psi^I(1) = \begin{cases} 1 + m - k(n + 1) & \text{if } k \leq \tilde{x} \\ \left(\frac{m+1}{n+2} - \frac{n+1}{m}c_e + \frac{n+1-m}{m}c_s\right) (1 + m - k(n + 1)) & \text{if } k > \tilde{x} \text{ and ES holds.} \end{cases}$ $\psi^{II}(1) = \begin{cases} 0 & \text{if } k \leq \tilde{x} \\ \left(\frac{n-m+1}{n+2} + \frac{n+1}{m}c_e - \frac{n+1-m}{m}c_s\right) (k(n + 1) - m) & \text{if } k > \tilde{x} \text{ and ES holds.} \end{cases}$	
$\psi^I(1, 0) = \frac{n+2}{m}c_s(1 + m - k(n + 2))$ $\psi^{II}(1, 0) = \left(1 - \frac{n+2}{m}c_s\right)(k(n + 2) - m)$	
$\psi^I(0, 1) = \begin{cases} 1 + m - k(n + 2) & \text{if EW holds} \\ \frac{n+2}{m} \left(\frac{n+1}{m-1}c_e + c_s\right) (1 + m - k(n + 2)) & \text{otherwise.} \end{cases}$ $\psi^{II}(0, 1) = \begin{cases} 0 & \text{if EW holds} \\ \left[1 - \frac{n+2}{m} \left(\frac{n+1}{m-1}c_e + c_s\right)\right] (k(n + 2) - m) & \text{otherwise.} \end{cases}$	
$\psi^I(1, 1) = 0$ $\psi^{II}(1, 1) = 0$	

<sup>15</sup>Peltzman (1973, 1976) considers the question of optimal regulatory standards.

Two comparative statics are immediately obvious from Table 3. First, in most cases, error probabilities respond to  $k$  in the intuitive manner: raising  $k$  reduces Type I errors and increases Type II errors. Thus, no value of  $k$  can be dominated in the sense of reducing both types of error.

Second, in many cases error probabilities respond to  $c_e$  and  $c_s$ . The signs of these comparative statics are more subtle. Type I errors are weakly decreasing in  $c_e$  and increasing in  $c_s$ , because  $c_e$  reduces the incentive of low types to experiment, while  $c_s$  increases acceptance probabilities (due to the better information conveyed by a high submission cost). The reverse is true for Type II errors. Our model would therefore predict that disease advocates, who might place more weight on Type II errors, would support reducing experimentation requirements but increasing submission hurdles. Likewise, consumer advocates might support increasing experimentation requirements by reducing submission hurdles.

#### 4.5 Product Quality

In most situations, F's submission strategies make R indifferent between rejection and acceptance. Thus, the average product quality of submitted and accepted products is typically  $k$ .

There are two exceptions. First, when the average quality following a single experimental success is high (*i.e.*,  $k < \tilde{x}$ ), then submissions at  $t = 2$  will have higher quality than  $k$ . The prior distribution of firms or technologies therefore affects the quality of early submissions. Second, when  $c_s$  and  $c_e$  are high so that EW holds, low types will withdraw from experimentation if  $h_2 = 0$ . Hence submissions made when  $h_3 = (0, 1)$  will be of higher quality. Borrowing the interpretation of  $c_e$  and  $c_s$  from the previous subsections, this implies that smaller firms and high submission hurdles might contribute to increased expected product quality.

#### 4.6 Insufficiency of Summary Statistics for Firm Strategies

It is, finally, useful to compare firm strategies in our model versus those that are predicted by the "optimal stopping" benchmark considered in Section 2.3. Inspection of the results in Section 3 suggests some striking departures from optimal stopping models of experimentation by the firm.

**Comment 2** *The dual  $[\sum e_t, t]$  does not constitute a sufficient statistic for F's strategy.*

Even though  $[\sum e_t, t]$  remains sufficient for F's inference about  $E[x | h_t]$ , this information is insufficient for formation of optimal experimentation strategies in both early and late submission equilibria. Specifically, it does not provide sufficient information to characterize (12). The reason is that, in a strategic context, the history of experimentation matters. Under the LSE, late successes are more valuable than early ones, and even histories that conclude with failure may result in submission.

The result suggests the need for more caution in the application of standard models of R&D to investment settings characterized by approval regulation. Dixit and Pindyck (1994: 46, 345) and Moscarini and Smith (2001), among many others, characterize pharmaceutical development as amenable to analysis by decision-theoretic R&D models, and in both models, summary statistics are sufficient for optimization. By contrast, our results imply that measures of “early” or “late” experimental success should influence experimentation and submission probabilities, controlling for the (observed and summary) quality of the product.

## 5. Discussion

Approval regulation is a global pattern of market gatekeeping common to numerous industries, but has received little in the way of theoretical analysis. Our model of dynamic product development with a regulatory veto helps to explain several empirical regularities in approval regulation, and also points to proper specification of empirical tests.

The crucial difference between our theory and standard signaling models of information transmission is the incorporation of a partially observable development phase. Strategies therefore depend not only on the prior information of the firm, but on the experimental history preceding submission. Additionally, the firm may stop the game without the regulator ever acting. As a result, some of the most dramatic and durable effects of approval regulation occur (though are rarely observed) before the regulator ever weighs in. The dynamic of strategic product abandonment and submission generates many predictions that are of interest to students of political economy, including possible advantages for large firms, regulator and interest group preferences over different components of regulatory policy, a greater propensity of Type I (Type II) errors for products developed by large (small) firms, and the impact of approval regulation on product quality.

One of the most salient contrasts with previous models of regulation (which invoke the logic of costly signaling games) lies in the rationale for costly firm effort. As with a signaling game, a high-type firm can credibly convey its information by exerting costly effort through the submission process. But this logic does not hold from a dynamic perspective that includes the role of the experimentation process in generating firm information. Because experimentation is separate from product submission, and the regulator’s acceptance strategy requires a firm to get “close enough” to her threshold before a submission becomes worthwhile, experimentation costs are non-monotonic over the range of product quality. High types often undertake the least effort, choosing instead to submit early. Types with less favorable information typically incur the highest costs by lengthening experimentation. Finally, low types with unfavorable experimental histories will decide that its product will never be accepted and abandon the product.



There remain some unsatisfying features of this framework. First, the fact that much of the significant "action" in our model occurs at the development phase follows from the highly simplified regulatory review phase. Accordingly, the development of a dynamic regulatory phase would be useful. This may take several forms, including a regulatory audit, requests for additional testing, or *ex post* reviews of previously approved drugs. Second, the development phase itself may better reflect empirical reality, by incorporating a mandated minimum duration of experimentation before submission (*e.g.*, Phase I and Phase II clinical trials, which may usefully serve as a screening mechanism), or "fast track" procedures. More broadly, the regulator should play a role in designing the testing regime under which firms submit proposals.

As it stands, however, the model provides a tractable foundation for studying regulatory strategy in an environment with endogenous firm product development (R&D). We conclude by noting some of the substantively important extensions that the model can be expanded to address. These include:

*Competition.* Product applications to agencies such as the FDA are not independent; firms are well-apprised of market demand and as a result their research efforts overlap. The implications for competitive strategy, information revelation, and consumer welfare are of tremendous interest. In our next paper we plan to introduce a second firm that can experiment and submit simultaneously for the market in question.

*Lobbying.* There is no process in our model whereby the firm or outside groups can lobby, either in the sense of sending signals outside the regulatory process or providing contributions (or penalties) to regulators for certain decisions.<sup>16</sup> It seems reasonable to conjecture that lobbying cannot be done exclusively by low types, as it would then be construed as a signal of low product quality and would result in rejection. Beyond this, such an analysis could help to explain whether lobbying may, for example, help large firms.

*Pricing.* Approval regulators such as the FDA do not regulate pricing, but their activities have consequences for market prices and consumer welfare. One issue in this area might be the welfare effects of giving firms monopoly protection.

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<sup>16</sup>In advanced industrial countries, direct contributions to the regulator are usually illegal and are quite rare. In the United States, however, some firms have begun recently to enlist patient lobbies in the FDA approval process, as the consumers of certain drugs may form an identifiable and easily organizable group (*e.g.*, AIDS patients). Yet while plausibly *exogenous* political support from patient lobbies seems to enhance regulatory success (Carpenter 2002), the FDA reacts very cautiously to patient lobbying that appears to be influenced by submitting firms. As one pharmaceutical regulatory director told us in a recent interview, "There's a saying in regulatory circles these days that 'The louder the patient lobby, the less efficacious the product'." (Interview with Alison Lawton, Vice President for Regulatory Affairs, Genzyme, and President, Regulatory Affairs Professional Society (RAPS), July 15, 2003, in Cambridge, Massachusetts).

## APPENDIX

**Proof of Comment 1.** Let  $\mathfrak{F}_t$  be the *filtration*, or the set of non-decreasing  $\sigma$ -fields generated by experimentation. By construction, any  $H_t$  constitutes a filtration. The claim that  $[\sum e_t, t]$  is a sufficient statistic is equivalent to the claim that the field  $G = \sigma^{field}(\sum e_t, t)$  is a *sufficient subfield* for the family  $[P_\theta : \theta \in \Theta | \mathfrak{F}_t]$  in the context of the optimal stopping problem. If  $[P_\theta : \theta \in \Theta | \mathfrak{F}_t]$  is dominated by a  $\sigma$ -finite measure  $\nu$ , then (Billingsley 1995, Theorem 34.6) a necessary and sufficient condition for  $G$  to be a sufficient subfield is that the density  $f_\theta$  of  $P_\theta$  with respect to  $\nu$  can be written as  $f_\theta = g_\theta z$ , for a  $g_\theta$  that is measurable  $G$  and for  $z$  strictly non-negative.

Letting  $\mathfrak{F}_t = \{H_t\}$  as before, our claim is that  $G(\sum e_t, t)$  is sufficient for  $[P_\theta : \theta \in \Theta | \mathfrak{F}_t]$ . Then define the following:

$$f_{\theta t} = \Pr \left[ \{h_t\} : \sum_{t=0}^T e_t = q \mid \mathfrak{F}_t \right] \quad (15)$$

$$g_{\theta t} = \Pr \left[ \sum_{t=0}^T e_t = q \mid G_t \right] \quad (16)$$

Then we may interpret  $\mathfrak{F}_t$  as the countable set of histories  $\{e_t\}$ , which we can index by  $\sum_{t=0}^T e_t = q$ , and  $G$  is the countable set of  $\sum e_t$ , also indexable by  $q$ . Notice that  $G_t \subseteq \mathfrak{F}_t \forall t$  but not vice versa, hence  $G_t$  is a proper subfield. Then for any  $\theta$ , we can write  $f_{\theta t} = z g_{\theta t}$ , where  $z$  is now any inverse function of the number of histories such that  $\sum e_t = q$ . By (6) and (7),  $g_\theta$  as given in (4) and constructed from  $[\sum e_t, t]$ , uniquely determines optimal experimentation strategies, and all such strategies are strictly monotonic in  $[\sum e_t, t]$ . ■

**Proof of Proposition 1.** We derive the result in three steps. First, we consider histories where  $e_1 = 1$ , then histories where  $e_1 = 0$ . Finally, we establish parametric conditions on existence of the equilibrium.

*Histories Beginning with  $e_1 = 1$ .* There are two cases. First, if  $k \leq \tilde{x}$ , then if  $\eta(\theta, \emptyset) = 1 \forall \theta$ , and  $\sigma(\theta, 1) = 1 \forall \theta$  (i.e., both types experiment and submit if successful), then  $\bar{x}(h_t) > k$  and R accepts the submissions. Since  $E[E[x \mid h_3] \mid h_2 = 1] = E[x \mid h_2 = 1]$ , R can do no better by conducting another costly experiment.<sup>17</sup> Thus,  $\sigma^*(\theta, 1) = 1 \forall \theta$  and  $\rho^*(1) = 0$ .

In the second case,  $k > \tilde{x}$ . In this case, at  $t = 2$  P would reject submissions if  $\eta(\theta, \emptyset) = 1 \forall \theta$  and  $\sigma^*(\theta, 1) = 1 \forall \theta$ . Note however that if only high types submit, then  $\bar{x}(h_t) > k$  and  $\rho^*(h_t) = 0$ . This induces both types to submit, which forces  $\bar{x}(h_t) < k$  and creates an obvious contradiction.

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<sup>17</sup>R's out of equilibrium beliefs about F's type in the event that it continues experimenting are therefore inconsequential.

Thus, the low type with  $h_2 = 1$  must submit with some interior probability. Since this implies indifference between submission and continued experimentation, we have:

$$(1 - \rho^*(1)) \frac{m}{n+1} - c_s = v(m-1, 1), \quad (17)$$

which after manipulation yields the equilibrium rejection probability:

$$\rho^*(1) = 1 - \frac{n+1}{m} (v(m-1, 1) + c_s). \quad (18)$$

For R to choose an interior probability of rejection, it must be indifferent between acceptance and rejection. As a candidate for an equilibrium, suppose that  $\sigma^*(m, 1) = 1$  and  $\eta^*(\theta, \emptyset) = 1 \forall \theta$ . Then indifference by R at  $t = 2$  implies:

$$p \frac{m}{n} \frac{m+1}{n+1} + (1-p) \frac{m-1}{n} \frac{m}{n+1} \sigma^*(m-1, 1) = k. \quad (19)$$

and thus:

$$\sigma^*(m-1, 1) = \frac{n(n+1)k - pm(m+1)}{(1-p)m(m-1)}. \quad (20)$$

Now note that because  $\sigma^*(m, 1) = 1$ , the history  $h_3 = (1, 0)$  implies that  $\theta = m-1$ . Because  $k > \frac{m}{n+2}$ , this implies  $\rho^*(1, 0) = 1$  and  $\omega^*(m-1, (1, 0)) = 1$ . It is then straightforward to derive  $v(m-1, 1)$ :

$$v(m-1, 1) = \frac{m}{n+1} \left( \frac{m+1}{n+2} - c_s \right) - c_e. \quad (21)$$

Substituting back into (18), we obtain:

$$\rho^*(1) = \frac{n-m+1}{n+2} + \frac{n+1}{m} c_e - \frac{n-m+1}{m} c_s. \quad (22)$$

*Histories Beginning with  $e_1 = 0$ .* There are again two cases. First, suppose that both types continue experimentation in period 2. If  $e_2 = 0$ , then clearly  $\omega^*(\theta, (0, 0)) = 1$ . If  $e_2 = 1$ , then the high type that is acceptable to R (*i.e.*,  $\frac{m+1}{n+2} > k$ ), and the low type that is not (*i.e.*,  $\frac{m}{n+2} < k$ ).

Note that in this equilibrium, low types cannot be indifferent between submission and withdrawal. Because  $c_e > 0$ , experimentation at  $t = 2$  would then imply that  $v(m-1, 0) < 0$ . Thus the low type can only be present at  $t = 3$  if it is indifferent between experimentation and withdrawal at  $t = 2$ ; hence:

$$\frac{m-1}{n+1} \left( \frac{m}{n+2} (1 - \rho^*(0, 1)) - c_s \right) - c_e = 0, \quad (23)$$

which implies  $v(m-1, 0) = 0$  and  $\rho^*(0, 1) = 1 - \frac{n+2}{m} \left( \frac{n+1}{m-1} c_e + c_s \right)$ . This probability is interior if  $\frac{m-1}{n+1} \left( \frac{m}{n+2} - c_s \right) - c_e > 0$ , and is also sufficient to ensure that the high type experiments at  $t = 2$  when  $h_2 = 0$  (*i.e.*,  $\eta^*(m, 0) = 1$  and  $v(m, 0) \geq 0$ ). At this value of  $\rho^*(0, 1)$ , period 3 submissions

yield strictly positive payoffs for both types, and so  $\sigma^*(\theta, (0, 1)) = 1$  for all  $\theta$ . This information is then sufficient to characterize  $\eta^*(m-1, 0)$ :

$$p \binom{n-m}{n} \binom{m}{n+1} \frac{m+1}{n+2} + (1-p) \binom{n-m+1}{n} \binom{m-1}{n+1} \frac{m}{n+2} \eta^*(m-1, 0) = k. \quad (24)$$

Simplifying, we obtain:

$$\eta^*(m-1, 0) = \frac{kn(n+1)(n+2) - p(n-m)m(m+1)}{(1-p)(n-m+1)(m-1)m}. \quad (25)$$

Second, if  $\frac{m-1}{n+1} \left( \frac{m}{n+2} - c_s \right) - c_e \leq 0$  (*i.e.*, EW, or (14)), then (23) cannot hold for any  $\rho(0, 1) \in (0, 1)$ . In this case the low type must withdraw after a failure (*i.e.*,  $\omega^*(m-1, 0) = 1$ ). This implies that  $v(m-1, 0) = 0$  and  $v(m, 0) \geq 0$ , which ensures that if  $h_3 = (0, 1)$ , then  $\mu((0, 1), S) = \mu((0, 1), \emptyset) = 1$ . Because  $k < \frac{m+1}{n+2}$ ,  $\rho^*(0, 1) = 0$  and by (1) and (2),  $\sigma^*(m, (0, 1)) = 1$ .

To complete the derivation, we check whether players follow the prescribed strategies. For all conditions it is sufficient to check that the strategies are followed when  $k > \tilde{x}$ .

First, at  $t = 2$  the high type prefers submitting when  $h_2 = 1$  to experimenting if:

$$\begin{aligned} (1 - \rho^*(1)) \frac{m+1}{n+1} - c_s &> v(m, 1) \\ \frac{(m+1)^2}{(n+1)(n+2)} - \frac{m+1}{m} c_e + \left( \frac{1}{m} - \frac{m+1}{n+1} \right) c_s &> \frac{m+1}{n+1} \left( \frac{m+2}{n+2} - c_s \right) - c_e \\ c_s - c_e &> \frac{m(m+1)}{(n+1)(n+2)}, \end{aligned}$$

which is condition ES (*i.e.*, (13)). Thus existence requires that  $c_s$  be sufficiently higher than  $c_e$ .

Second, at  $t = 2$  the low type prefers submitting or experimenting when  $h_2 = 1$  to withdrawing if:

$$\begin{aligned} (1 - \rho^*(1)) \frac{m}{n+1} - c_s &> 0 \\ \frac{m(m+1)}{(n+1)(n+2)} - c_e - \frac{m}{n+1} c_s &> 0 \\ \frac{m}{n+1} \left( \frac{m+1}{n+2} - c_s \right) - c_e &> 0. \end{aligned} \quad (26)$$

Thus existence requires that  $c_s$  and  $c_e$  both be sufficiently low.

Finally, we verify that  $\eta^*(\theta, \emptyset) = 1 \forall \theta$ . For this purpose it is sufficient to ensure that  $\eta^*(m-1, \emptyset) = 1$ :

$$\begin{aligned} \frac{m-1}{n} v(m-1, 1) + \frac{n-m+1}{n} v(m-1, 0) - c_e &> 0 \\ \frac{m-1}{n} \left[ \frac{m}{n+1} \left( \frac{m+1}{n+2} - c_s \right) - c_e \right] - c_e &> 0 \\ \frac{m(m-1)}{n+1} \left( \frac{m+1}{n+2} - c_s \right) - (n+m-1)c_e &> 0. \end{aligned} \quad (27)$$

It is easily checked that (27) is satisfied by (1) and (2). It implies (26), and so along with ES is sufficient for existence of the equilibrium. ■

**Proof of Proposition 2.** We derive the result in three steps. First, we consider histories where  $e_1 = 1$ , then histories where  $e_1 = 0$ . Finally, we establish parametric conditions on existence of the equilibrium.

*Histories Beginning with  $e_1 = 1$ .* Suppose  $h_2 = 1$ . Since  $\rho^*(1, 1) = 0$ , the experimental continuation value for type  $\theta$  is:

$$v(\theta, 1) = \frac{\theta + 1}{n + 1} \left( \frac{\theta + 2}{n + 2} - c_s \right) + \frac{n - \theta - 1}{n + 1} \max \left\{ 0, (1 - \rho^*(1, 0)) \frac{\theta + 1}{n + 2} - c_s \right\} - c_e. \quad (28)$$

With a history of  $h_2 = (1, 0)$ , R will wish to accept only the high type. There are three subcases, of which only the first is possible under the assumptions of the model. In it R is indifferent between acceptance and rejection when faced with  $h_2$ , and the low type is indifferent between submission and withdrawal at  $t = 3$  (as with the ESE):

$$(1 - \rho^*(1, 0)) \frac{m}{n + 2} - c_s = 0, \quad (29)$$

Thus,  $\rho^*(1, 0) = 1 - \frac{(n+2)c_s}{m}$ . To calculate the submission probability for the low type, we determine the strategy that ensures an average quality of  $k$  and leaves R indifferent between rejection and acceptance:

$$p \binom{m}{n} \binom{n-m}{n+1} \frac{m+1}{n+2} + (1-p) \binom{m-1}{n} \binom{n-m+1}{n+1} \frac{m}{n+2} \sigma^*(m-1, (1, 0)) = k. \quad (30)$$

Solving, we obtain  $\sigma^*(m-1, (1, 0)) = \frac{kn(n+1)(n+2) - pm(n-m)(m+1)}{(1-p)(m-1)(n-m+1)m}$ , and hence  $\omega^*(m-1, (1, 0)) = 1 - \sigma^*(m-1, (1, 0))$ . Clearly, if the low type is indifferent between submission and withdrawal, the high type must strictly prefer submission, and thus  $\sigma^*(m, (1, 0)) = 1$ .

This case requires that  $\eta(\theta, 1) = 1$ . To verify this, the low type experiments at  $t = 2$  if:

$$\begin{aligned} v(m-1, 1) = \frac{m}{n+1} \left( \frac{m+1}{n+2} - c_s \right) + \frac{n+1-m}{n+1} (0) - c_e &\geq 0 \\ \frac{m}{n+1} c_s + c_e &\leq \frac{m(m+1)}{(n+1)(n+2)}. \end{aligned} \quad (31)$$

This condition is also sufficient for type- $m$  to experiment at  $t = 2$  ( $v(m, 1) = \frac{(m+1)(m+2)}{(n+1)(n+2)} + \frac{n-m(m+2)}{m(n+1)} c_s - c_e \geq 0$ ).

In the second subcase, R is also indifferent between acceptance and rejection when  $h_2 = (1, 0)$ . But this indifference occurs because (31) cannot hold and the low type is indifferent between

experimentation and withdrawal at  $t = 2$ . Thus,

$$\begin{aligned} v(m-1, 1) &= \frac{m}{n+1} \left( \frac{m+1}{n+2} - c_s \right) + \frac{n+1-m}{n+1} \left( \frac{m}{n+2} - c_s \right) (1 - \rho^*(1, 0)) - c_e \\ &= 0. \end{aligned} \tag{32}$$

Solving, this implies:  $\rho^*(1, 0) = 1 - \frac{(n+1)(n+2)c_e - m(m+1-(n+2)c_s)}{(n+1-m)(m-(n+2)c_s)}$ . But by (1) and (2),  $\rho^*(1, 0) > 1$ , and thus the subcase is ruled out by assumption.

In the last subcase,  $v(m-1, 1) < 0$ , so low types withdraw even after an initial success ( $\omega^*(m-1, 1) = 1$ ) and  $\rho^*(1, 0) = 0$ . This implies that neither (31) nor (32) can hold; *i.e.*,  $\frac{m}{n+1} < c_e + c_s$ . This subcase is also ruled out by (1) and (2).

*Histories Beginning with  $e_1 = 0$ .* In the case where  $h_2 = 0$ , the equilibrium is identical to that of the ESE (Proposition 1).

Finally, we check for conditions that ensure existence of this equilibrium. First, to verify that  $\sigma^*(\theta, h_2) = 0 \forall \theta, h_2$ , note that R's out of equilibrium beliefs require that  $\mu(h_2, S) = p$ , and because  $k > \tilde{x}$ ,  $\rho^*(h_2) = 1 \forall h_2$ .

Second, to verify that  $\eta^*(\theta, \emptyset) = 1 \forall \theta$ , it is sufficient to show that  $\eta^*(m-1, \emptyset) = 1$ . This will be true if:

$$\begin{aligned} v(m-1, \emptyset) &= \frac{m-1}{n} v(m-1, 1) + \frac{n-m+1}{n} v(m-1, 0) - c_e \geq 0 \\ &\frac{m-1}{n} \left[ \frac{m}{n+1} \left( \frac{m+1}{n+2} - c_s \right) - c_e \right] - c_e \geq 0 \\ &\frac{(n+1)(n+m-1)}{m(m-1)} c_e + c_s \leq \frac{m+1}{n+2}. \end{aligned} \tag{33}$$

This condition is identical to (27) and is assumed by (1) and (2). It furthermore implies (31). Thus, it is sufficient for existence of the LSE. ■

**Proof of Comment 2.** It is sufficient to show either that (i) different histories with identical  $\sum e_t$  yield different equilibrium strategies for the same type, or (ii) that histories ending with a failure  $H_t = (1, 0)$  induce submission with positive probability. Case (i) is observed in both the ESE (Proposition 1) and the LSE (Proposition 2) for type  $m-1$ . Case (ii) is observed in the LSE (Proposition 2) for both types. ■

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