Approval Regulation, Withdrawal, and Liability*

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Abstract

Dynamic adoption policies of activities with uncertain returns are characterized by three key decisions: in the ex ante experimentation phase, the decisions when to abandon experimentation and when to introduce to market; in the ex post learning phase, the decision when to withdraw following the accumulation of bad news. In a tractable continuous-time model, we study the optimal mix of the three instruments regulators employ to align the private incentives of firms: ex ante approval regulation, ex post withdrawal regulation, and liability. Our results can rationalize the array of regulatory environments observed across applications ranging from product safety to patent protection. We also consider costly lying and show that the social planner can be better off when the firm privately observes research results.

Keywords: Experimentation, approval regulation, liability, withdrawal.

JEL Classification: D18 (Consumer Protection), D83 (Learning; Information and Knowledge), K13 (Product Liability), K2 (Regulated Industries), M38 (Government Policy and Regulation).

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1 Introduction

In Wyeth v. Levine, 555 U.S. 555 (2009), the US Supreme Court held that FDA approval for marketing and labeling of a medication does not shield the manufacturer from product liability lawsuits under state law. Proponents of the so-called preemption doctrine argued that exposing pharmaceutical companies to liability would reduce innovation incentives prior to market introduction, while opponents maintained that the threat of liability would induce more timely information disclosure and voluntary withdrawals of harmful drugs; see Garber (2013). The controversy surrounding this ruling illustrates the difficulty of striking a balance between ex ante approval regulation, ex post withdrawal regulation, and liability.[1]

To analyze the law and economics of regulation of new drugs and other activities with uncertain returns, this paper formulates a novel two-phase model with ex ante experimentation and ex post learning. First, a phase of preliminary experimentation with market research and testing takes place prior to market introduction. This initial experimentation is carried out in a rather controlled environment; think of carefully monitored clinical trials.[2] In the ex ante experimentation phase, the decision is eventually taken to either abandon experimentation or to introduce to market. Second, in the ex post learning phase after market introduction, learning continues, often in a less controlled way and at a different speed, possibly leading to a final withdrawal decision following the accumulation of sufficiently bad news.[3]

Our main specification features a planner who regulates a firm undertaking an activity that generates an externality of uncertain sign. We capture the uncertainty in the sign of the externality by positing that the firm does not suffer the full social damage in the bad state and does not recoup the full social benefits in the good state. The role of regulation is then to re-align misaligned private incentives with social incentives. Our key focus is to determine the optimal mix of the three main regulatory instruments that are typically used in practice to regulate drugs and other activities with uncertain externalities: liability, approval (ex ante) regulation, and withdrawal (ex post) regulation.

The mix of these regulatory instruments vary across applications, as we argue in the institutional analysis in Section [4.1]. Three main regularities emerge from the summary in Table [1]. First, when regulation is used either ex ante or ex post, it tends to be lenient, as with postmarketing pharmacovigilance or patent grants and patent invalidations. Second, liability and ex

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[1]The preemption doctrine, also known as “regulatory compliance defence,” prevails for generic drugs and medical devices. Furthermore, even for regular drugs, application of preemption varies by states. Garber (2013) reports that “several state high courts such as those of California, Washington and Utah have adopted, as a practical matter, a regulatory compliance defense for prescription drugs.”

[2]More generally, theoretical research and “dry bench” experiments have similar features.

[3]In a similar vein, learning in this second phase could result also from “wet bench” experiments or observational learning.
post regulation are rarely used in conjunction. Third, liability tends to be common in areas where externalities are small (e.g., introduction of regular products), while regulation dominates with large externalities (e.g., drugs, patents, and environmental projects).

To capture and explain the main features of the regulatory environment across these applications, we formulate a tractable continuous-time model with a binary state of the world, either good or bad. Firm \( i \) collects information, which is publicly observed, in the form of a Wiener process whose drift depends on the state. Information acquisition is costly in the first phase and costless after implementation. Decision payoffs are collected only after the activity is implemented. The payoff of the planner is positive in the good state \( \nu^G_p \) and negative in the bad state \( \nu^B_p \), while the firm gets a payoff \( \nu_i \) that is independent of the state but does not capture the full social benefits in the good state, \( \nu_i = (1-e)\nu^G_p \). We perform comparative statics with respect to the externality \( e \) and the prior belief \( q_0 \) that the state is good.

Section 3 sets the stage by considering the planner solution, the first-best welfare benchmark for the model. Even though information is costless after adoption, the planner uses a balance between ex ante testing and ex post monitoring, given that information is indirectly costly in the ex post phase in the bad state. The ex post phase corresponds to a bandit problem, where the planner chooses between a safe arm (withdraw) and a risky arm (continue undertaking the activity). If the belief \( q \) about the state being good—the state variable representing the posterior belief summarizing all information at each point in time—becomes sufficiently low, \( q \leq z \), the planner withdraws. In the ex ante phase, the model corresponds to a Wald problem, characterized by two cutoffs, a research cutoff \( s \), such that the planner abandons and rejects the project as soon as the belief \( q \) falls below \( s \), and an adoption cutoff \( S \) such that the activity is implemented as

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<th>Ex Ante Regulation</th>
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<td>Patents</td>
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<td>Zoning/Environment</td>
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Table 1: Regulatory environments across applications.
soon as the belief reaches $S$. The social planner collects information for beliefs between these two cutoffs $q \in (s, S)$, which are centered around the withdrawal cutoff $z \in (s, S)$.

We then turn to studying the performance of different regulatory instruments in aligning the incentives of the firm with those of the planner. We first examine in Section 4.2 the properties of the instruments considered individually. Consider first liability, understood as a liability rate charged for each unit of time (in which a product is sold) on the market when the state is bad, so that the flow payoff in that state becomes $v - L$. Without externality ($e = 0$), the first best is clearly achieved by a strong liability rule requiring the firm to fully compensate for the whole social damage in the bad state, because the incentives are then perfectly aligned in both states. However, in the presence of a positive externality ($e > 0$), it is optimal for the planner to commit to being more lenient than under strong liability, in order not to discourage research.

By appropriately choosing $L$, the planner can induce the firm to withdraw at any standard $z$. In particular the planner could choose the liability rate $\hat{L}$ that induces the socially optimal withdrawal $z^*$. We show that if $e > 0$, it is optimal for the planner to deviate from $\hat{L}$. Indeed, when liability is set at $\hat{L}$, the firm rejects too early but also adopts too early. Increasing or decreasing liability thus has conflicting effects on research and approval. If the initial belief $q_0$ is low, it is optimal for the planner to be more lenient since encouraging experimentation is the most pressing issue. If $q_0$ is high, it is optimal for the planner to be tougher so as to discourage early approval.

Liability can be chosen to induce any withdrawal decision and is thus a substitute instrument to ex post regulation. However, the two tools have very different implications for ex ante incentives. Indeed, by decreasing ex post payoffs, liability chills research ex ante. Thus, liability tends to be preferred for low externalities, while ex post regulation dominates for higher level of externalities. This observation explains the difference between drugs (ex ante approval, high externality) and less risky products (liability, low externality) and also justifies why in practice liability and ex post regulation are rarely observed together.

The tradeoff between ex ante and ex post incentives is similar for all three instruments. When using a single instrument, the planner controls either the withdrawal standard (with liability or ex post regulation) or the adoption standard (with ex ante regulation). Moving away from the socially optimal level of the controlled standard implies a second-order loss that is traded off against first-order gains in the other standards. If there are conflicts between the first-order effects, the optimal policy depends on the prior belief $q_0$, determining whether providing incentives for ex ante experimentation is the key dimension.

Consider the case of ex ante regulation in isolation. When the adoption standard is set at

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4 Garber (2013) presents evidence that product liability resulted in the withdrawal of the drug Benedictin in 1983 as well as of a number of vaccines during the 1980s and 1990s.
the socially optimal level $S^*$, the firm never withdraws, an extreme version of insufficient withdrawal incentives. The level of the externality determines whether incentives to experiment are excessive or insufficient. If $e$ is low, since the firm never withdraws and does not suffer in the bad state, experimentation is excessive. In this case, setting a tougher approval standard than in the first-best solution is unambiguously socially beneficial. For sufficiently high $e$, however, experimentation incentives become insufficient. Being tougher when approving is beneficial ex post because once approved, a product is never withdrawn, but it is also costly ex ante because it decreases further experimentation incentives. The tradeoff between these two effects is resolved as a function of the prior belief.

Section ?? turns to our central question of the optimal combination of instruments. Our main result is that whenever ex ante or ex post regulation are used, they are always more lenient than the planner benchmarks. The idea is the following. If the externality is low, the planner achieves the first best by using a combination of all three instruments. In this case the liability is used in equilibrium to limit excessive research incentives. On the contrary, when the externality is large, the first best is no longer achieved; liability rates are set at zero and the planner, in order to encourage research, commits to being more lenient than the socially optimal levels both in approval and withdrawal, regardless of the initial belief $q_0$.

Our model does not allow the planner to subsidize research. This assumption is motivated by two observations. First, the agencies in charge of approval and withdrawal regulation (FDA for drugs, USPTO for patents) are typically not responsible for choosing subsidies. Second, in several applications there is in fact no subsidy program in place. In the absence of subsidies, for very large externalities, the main concern is to encourage experimentation; liability then is not used, as it chills research, and both ex ante and ex post regulation are weak. Moreover our results show that there is a critical level of externality at which the planner switches from using liability and socially optimal ex ante and ex post standards, to setting liability to zero in combination with weak regulation both ex post and ex ante. This critical level of externality is such that when the planner chooses the approval and withdrawal standards at the socially optimal levels, the firm responds by abandoning research as the planner would do.

Section 5 considers the case in which the firm collects private (rather than public) information in the ex ante experimentation phase. We assume that the firm can make any report but is fined with a probability increasing in the size of the lie if the state turns out to be bad. As we show, if liability cannot be used, as for generic drugs or medical devices where ex ante approval shields

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5Viscusi, Vernon, and Harrington (1995, pages 785-786) highlight that an issue is the lack of coordination between regulatory and liability efforts. As they explain “these are two different institutional mechanisms that affect similar classes of economic concerns. In some cases, the companies are hit twice by these institutions.” The issue is also relevant regarding subsidy programs.
from litigation, the planner is better off when evidence is privately observed by the firm than when it is public. Indeed, the fine for misreporting will be optimally set by the planner in such a way as to tolerate lying in equilibrium. The firm expects to pay with some probability a penalty in the bad state, thus chilling research incentives, an effect that is socially beneficial if the externality is small. The fine for misreporting serves as a substitute for liability.

1.1 Contribution to Literature

Our contribution straddles the theoretical literature on optimal experimentation and the more applied law and economics literature on safety regulation and liability.

Following up on Wald’s (1945) seminal work, the literature on sequential hypothesis testing focused on information acquisition before taking an irreversible action. Our ex-ante experimentation phase gains analytical traction by building on the continuous-time version of Wald’s model developed by Dvoretsky, Keifer, and Wolfowitz (1953), Mikhailovich (1958), and Shiryaev (1967); see also Gul and Pesendorfer (2012), Chan, Lizzeri, Suen, and Yariv (2018), Henry and Ottaviani (2017), and McClellan (2017) for economic applications building on the same workhorse.6

To an ex ante phase of experimentation à la Wald before adoption, we add a phase of ex post learning, which can eventually lead to withdrawal, effectively reversing the adoption decision.7 Learning in the ex post phase takes place only if the safe arm (represented by the withdrawal decision) is not pulled, as in the bandit literature.8

We isolate this contribution—blending Wald with bandit—in our (decision-theoretic) social benchmark introduced in Section 3 for the special case in which adoption can be reversed once at no cost. Appendix B analyzes in a self-contained way the case in which reversion of adoption is costly, thus recovering the classic Wald specification when reversion becomes prohibitively costly.9 Given the focus on regulatory issues created by the interaction between the firm and the

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6For applications to product search see also Branco, Sun, and Villas-Boas (2010) and Ke, Shen, and Villas-Boas (2016). Moscarini and Smith (2001) extend Wald’s model to allow the decision maker to undertake multiple experiments in each instant. We instead allow for different experimentation phases, but still with a single experiment in each instant. Within a setting with a single irreversible decision, Che and Mierendorff (2017) push Wald’s framework by allowing the decision maker to choose signal structures that favor learning about a state over the other.

7Within a setting with a single irreversible decision, Che and Mierendorff (2017) push Wald’s framework by allowing the decision maker to choose signal structures that favor learning about a state over the other.

8See Bergemann and Välimäki (2008) for classic references and an introductory treatment of bandit models. Bolton and Harris (1999) introduced strategic issues into bandit models; closer in spirit to us Strulovici (2010) analyzed a model of collective experimentation in which decision makers jointly control actions that result in information. For insightful analyses of agency models of experimentation see also Green and Taylor (2016), Guo (2016), Halac, Kartik, and Liu (2016), and Grenadier, Malenko, and Malenko (2016).

9The literature on real options and investment under uncertainty—spearheaded by Arrow and Fisher (1974) and Henry (1974) and overviewed by Dixit and Pindyck (1994)—focuses on the impact of exogenous information flow...
regulator, the model in the text focuses on the special case with costless reversibility.

Beyond characterizing the optimal balance between ex ante experimentation and ex post monitoring in the decision-theoretic benchmark, the bulk of the paper applies the framework to the strategic problem of dynamic regulation of an activity with uncertain externality. This applied contribution to law and economics appears to be novel to the literature, in spite of its many applications.\[10\]

The law and economics literature to date mostly focused on understanding the optimal ways of incentivizing firms to take precautions so as to limit the negative externalities generated by risky activities. Shavell (1984) and Kolstad, Ulen, and Johnson (1990) show that a mix of liability and ex ante regulation is welfare improving whenever injurers can escape suit or court’s behavior is uncertain. Schmitz (2000) shows that a mix of liability and ex ante regulation is optimal if wealth varies among injurers.\[11\] Closer to our setting, Carpenter and Ting (2007) analyze a discrete-time model of approval regulation in which the firm signals (private information about) quality to the regulator through the submission time. Ottaviani and Wickelgren (2009) and (2011) offer a complementary modeling approach in the context of a two-period model exploring also signaling of the firm’s private information, mostly in the context of competition policy and merger control.\[12\] Finally, Schwartzstein, and Shleifer (2013) show that when social returns to activity are higher than private returns, liability chills economic activity opening room for regulation.\[13\]

In an informal discussion, Viscusi, Vernon, and Harrington (1995, pages 785-786) raise precisely the issues our paper studies theoretically. They describe the ex ante and ex post modes of government regulation and point out how liability may chill research incentives. They highlight that “a final issue on the policy agenda is the overall coordination of regulatory and liability efforts.” Our formal analysis provides structure to think about this interaction.

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10 Orlov, Skrzypacz, and Zryumov (2018) analyze dynamic information control by an agent who aims at persuading a principal to delay withdrawal—the simpler information structure we posit allow us to analyze information arrival both before and after adoption up to withdrawal.

11 See also Daughety and Reinganum (2013) for a broader overview of the economic analysis of products liability.

12 In the area of competition policy Rey (2003, Section 4.2) also informally discusses the pros and cons of ex ante regulation v. ex post antitrust.

13 The literature on product recalls focuses on pricing by firms and incentives of consumers—aspects that are interesting but complementary to those we analyze—see, for example, Welling (1991), Marino (1997), and Rupp and Taylor (2002). Spier (2011) in particular analyzes a firm that, after selling the product, obtains information about the hazard faced by consumers, who are themselves privately informed about their value of consumption. The firm has to decide whether to initiate a costly recall program and what buyback price to offer to consumers. Spier (2011) shows that, even under strict liability whereby the firm needs to fully compensate any harm caused, the buyback price is inefficiently low because of the firm’s monopsonistic position.
2 Model

Model. Two players, a firm $i$ and a social planner $p$, interact in continuous time under uncertainty about the state of the world $\theta$, which can be either good $G$ or bad $B$. The game is divided in two phases. In the first phase, at each instant of time a decision needs to be made, either reject $R$, experiment $E$, or adopt $A$. Rejection is irreversible: the game ends following $R$ and players obtain zero payoff. Experimentation costs $c$ per unit of time and results in the public revelation of information as explained below. Adoption ends the first, ex ante phase of the game and starts the second, ex post phase in which at each instant of time the active player can either continue $C$ (staying on the market) or withdraw $W$ (ending the game).

Payoffs are collected only during the ex post phase, except for the cost of experimentation. While on the market (i.e., following adoption and up until withdrawal), the firm collects a flow payoff $v_i$, independent of the state $\theta$. The social planner, instead, collects flow state-dependent payoffs $v^G_p \geq v_i > 0$ in the good state and $v^B_p < 0$ in the bad state. Thus, the firm’s activity generates a positive externality $v^G_p - v_i \geq 0$ in the good state and a negative externality $v^B_p - v_i < 0$ in the bad state on the rest of society. For the purpose of comparative statics, it is useful parametrize the firm’s (private) payoff as $v_i = (1-e^\gamma)v^G_p$, where the externality rate $e^\gamma \in [0, 1]$ can be interpreted as the fraction of the planner (social) payoff that the firm does not capture when the state is good.

All players initially share the same prior about the state $q_0 = \Pr\{\theta = G\}$ and discount future payoffs at the same rate $r \geq 0$.

Information Arrival. We now describe information arrival in the two phases, $n \in \{1, 2\}$, where $n = 1$ denote the ex ante experimentation phase and $n = 2$ the ex post learning phase. Differently from the ex ante phase, information collection in the ex post phase does not entail a direct cost.

Let $(\Gamma, \mathscr{F}, P)$ be a filtered probability space, where $\Gamma = \Omega \times \Theta \times [0, \infty)$ with $\Theta = \{G, B\}$, and let $X : \Gamma \to \mathbb{R}$ be an $\mathscr{F}$-measurable function. When information arrives both players observe

$$X_t = \mu^\theta_n t + \rho W_t,$$

where $W_t$ is a Wiener process on the probability space $(\Omega, \mathscr{F}_\Omega, P_\Omega)$ and $\mu^B_n = -\mu_n < 0 < \mu^G_n = \mu^\theta_n$.

The realization of the stochastic process $x_t$ at time $t > 0$ is a sufficient statistic for all the information collected until this instant of time and will be used to update beliefs. By observing

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14 Fudenberg, Strack, and Strzalecki (2018) make strides in the analysis of a Wald experimentation problem a richer state space, with still with only one phase.

15 A justification for this assumption is that consumers don’t have access to the information about the state post approval and thus the price of the product does not change as a function of the state.
both players update belief about the state through Bayes rule

\[ q_t = \frac{q_0 h_t^G(x_t)}{q_0 h_t^G(x_t) + (1 - q_0) h_t^B(x_t)}, \]

where \( h_t^G \) is the density of a normal random variable with mean \( \mu_n^0 t \) and variance \( \rho^2 t \).

Finally, define the pair \((\tau, d_\tau) \in T \times D\) as a stopping decision rule where \( T \) is the set of measurable stopping times \( \tau : \Omega \times \Theta \to [0, \infty) \cup \infty \) such that

\[ \{ \tau \leq t \} = \{ (\omega, \theta) \in \Omega \times \Theta : \tau(\omega, \theta) \leq t \} \in \mathcal{F}_t \]

and \( d_\tau : \Omega \times \Theta \to \{0, 1\} \) is a \( \mathcal{F}_t \)-measurable decision rule.

**Log-odds Parametrization.** We express beliefs in terms of the log-odds ratio

\[ \sigma_t = \log \frac{q_t}{1 - q_t} = \log \frac{q_0}{1 - q_0} + \log \frac{h_t^G(x_t)}{h_t^B(x_t)}, \]  

and denote \( S = \log \frac{S}{1 - S} \), \( s = \log \frac{s}{1 - s} \), and \( z = \log \frac{z}{1 - z} \) respectively the log-odds of the adoption, rejection, and withdrawal standards, soon to be introduced. From (1) we have

\[ \sigma_t = \sigma_0 + \frac{\phi_n}{\rho} X_t, \]

where \( \phi_n = \frac{2 \mu_n}{\rho} \) is the signal to noise ratio in phase \( n \). Note that we allow the process to have different speed in the two phases.

### 3 Planner Benchmark

As a benchmark for the rest of our analysis, we consider the decision of the social planner when in charge of all decisions in both phases:

**Proposition 1** The solution of the social planner consists of three standards, \( s^* \) (the rejection standard), \( S^* \) (the adoption standard), and \( z^* \) (the withdrawal standard), such that:

(a) In the ex ante phase, the planner:

(i) stops experimentation and rejects if \( q \leq s^* \),

(ii) experiments if \( s^* < q < S^* \), and

(iii) stops experimentation and adopts moving to the ex post phase if \( q \geq S^* \).

(b) In the ex post phase, the planner withdraws if \( q \leq z^* \).
Furthermore all standards are independent of the current belief $q$ and are such that $s^* \leq z^*$ \( ^{16} \)

Proposition \( ^{1} \) characterizes the optimal balance between ex ante experimentation and ex post learning. Even though information is revealed at no direct cost in the ex post phase, an indirect cost is nevertheless incurred when the expected flow payoff is negative (because the belief favors the bad over the good state) so that it would be myopically optimal to withdraw. Next, we describe the mechanics of the model, starting from the last of the two phases.

### 3.1 Ex Post Learning: Bandit Problem

Consider first the ex-post phase. Assume that the ex ante phase resulted in adoption, so that the belief has reached the adoption threshold $S$. The ex post problem can be seen as a bandit in which at each instant of time the planner chooses between a safe arm (withdrawal $W$ with expected payoff of zero) or a risky arm (continue $C$ with a state dependent flow of profit whose value is uncertain). The planner solves

$$\hat{u}_p^2(\sigma_0) = \sup_d \mathbb{E}_{\Omega \times \Theta} \left[ \int_0^\infty e^{-r} d_t \left[ q_t v_p^G + (1 - q_t) v_p^B \right] dt \bigg| \sigma_0 \right]$$

where $d = (d_t)_{t \geq 0}$ is the decision rule, $d_t \in \{0, 1\}$ respectively for actions $W$ and $C$ and $\sigma_0 \geq S$. This problem is equivalent to a one-time one-option optimal stopping problem \( ^{17} \).

The expected payoff in the second phase can be expressed as

$$\hat{u}_p^2(S) = \frac{e^S}{1 + e^S} \left( \frac{v_p^G}{r} \right) (1 - \psi(S, G, z^*)) + \frac{1}{1 + e^S} \left( \frac{v_p^B}{r} \right) (1 - \psi(S, B, z^*))$$

where $\psi(\sigma, \theta, z^*)$ is the expected discounted probability of reaching withdrawal threshold $z^*$ in state $\theta$ starting at $\sigma$; closed-form expressions for $\psi(\sigma, \theta, z^*)$ are presented in the proof of Proposition \( ^{1} \).

The dashed-dotted blue line in Figure \( ^{1} \) shows the ex post value function and the optimal solution $z^*$ of the bandit problem. The value is positive for $q \geq z^*$, zero for $q \leq z^*$, and tangent to the zero horizontal line exactly at $z^*$ \( ^{18} \).

### 3.2 Ex Ante Experimentation: Reversible Wald

From the perspective of the ex ante phase, the optimal withdrawal $z^*$ pins down the expected payoff of the planner upon adoption denoted $\hat{u}_p^2(\sigma)$ if the belief at adoption is $\sigma$. The planner’s

\( ^{16} \) Notice that the withdrawal standard $z^*$ will not depend on the belief $S^*$ at which adoption took place.

\( ^{17} \) It can be shown that whenever it is optimal to pull the safe arm then it is optimal to keep pulling it afterwards. The optimal withdrawal must be an irreversible decision.

\( ^{18} \) $z^*$ solves $\hat{u}_p^2(\sigma_0) = \max_z u_p^2(\sigma_0, z)$, i.e. satisfies the smooth-pasting condition.
program in the ex ante phase is thus:

$$\hat{u}_p^1(\sigma_0) \equiv \sup_{\tau,d\tau} \mathbb{E}_{\Omega \times \Theta} \left[ d\tau \left( e^{-r\tau} \hat{u}_p^2(\sigma_\tau) \right) - \int_0^\tau e^{-rt} c dt \right] | \sigma_0 ,$$

where $\tau = \tau(s^*) \wedge \tau(S^*)$.

In the ex ante phase, this becomes a standard Wald problem where the planner abandons for sufficiently bad news ($q \leq s^*$), experiments for intermediate beliefs ($s^* < q < S^*$), and adopts following good news ($q \geq S^*$). Differently from the classic Wald problem, the payoff upon adoption (i.e. the ex post value) is now endogenous. Adoption at a higher $S$ yields a higher expected payoff from the ex post phase for two reasons: first, the expected flow benefit is higher at the start and, second, eventual withdrawal becomes less likely.

The expected payoff can be written as

$$\hat{u}_p^1(\sigma_0) = -\frac{c}{r} + \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \left[ (\hat{u}_p^2(S^*,G) + \frac{c}{r}) \Psi(\sigma_0,G,s^*,S^*) + \frac{c}{r} \psi(\sigma_0,G,s^*,S^*) \right]$$

$$+ \frac{1}{1 + e^{\sigma_0}} \left[ (\hat{u}_p^2(S^*,B) + \frac{c}{r}) \Psi(\sigma_0,B,s^*,S^*) + \frac{c}{r} \psi(\sigma_0,B,s^*,S^*) \right] ,$$

where $\Psi(\sigma,\theta,s,S)$ and $\psi(\sigma,\theta,s,S)$ are the expected discounted probabilities of reaching respectively the adoption $S$ and rejection $s$ standards in state $\theta$ starting at belief $\sigma$.

The withdrawal standard used in the ex post phase plays an important role in the ex ante phase. Indeed, $z^*$ is the belief $q = z^*$ at which in the ex ante phase the planner is indifferent between rejection (yielding 0 payoff) and adoption (as going to the ex post phase leads to immediate withdrawal yielding 0). Therefore, in the ex ante phase, around $z^*$ experimentation has

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19 Define $\tau(c) = \inf \{ t \in [0,\infty) : \sigma_t = c \}$ as the first time the beliefs hits threshold $c$. 

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Figure 1: Wald with reversible decision.
an option value—thus, the region of ex ante experimentation includes the withdrawal standard: \( s^* \leq z^* \leq S^* \)\(^{20}\).

Given \( z^* \), Figure 2 plots the dashed-dotted lower best reply \( b_p(S) \) (optimal choice of \( s \) for a given adoption standard \( S \)) and the continuous upper best reply \( B_p(s) \) (optimal choice of \( S \) for a given rejection standard \( s \))\(^{21}\). These two best replies are respectively defined implicitly by the two first-order conditions \( \frac{\partial u_p}{\partial s} = 0 \) and \( \frac{\partial u_p}{\partial S} = 0 \) presented in equations (2) and (3) in Appendix A. The optimal ex ante standards \((s^*, S^*)\) are then defined at the intersection of the two best replies.

As can be seen in Figure 1, the possibility of conducting research in the ex ante phase increases the expected welfare of the planner. In particular, around \( z^* \) there is value of information while immediate approval at \( z^* \) gives a zero payoff. The ex ante value is tangent to the ex post value (dashed-dotted blue) exactly at \( s^* \) and \( S^* \), i.e. the pair \((s^*, S^*)\) solving the smooth-pasting conditions.

\(^{20}\)Given \( z^* \), the pair \((s^*, S^*)\) solves \( \hat{u}_p^1(\sigma_0) = \max_{s,S} u_p^1(\sigma_0, s, S) \).

\(^{21}\)See Appendix B for the construction of \( b_p(S) \) and \( B_p(s) \).
Regulating research, approval and withdrawal

In practice, the firm’s interest are not aligned with those of the social planner. Three main tools are employed to align the firm’s incentives: liability, approval (ex ante) regulation and withdrawal (ex post) regulation. We first discuss more in detail in section 4.1 how these instruments are combined in two key applications, and then use our models to make sense of regularities observed in practice.

4.1 Regulatory Environments

Drug and Medical Devices. The key state variable that determines market introduction in the case of a drug is, conditional on the drug being effective, the risk of having serious side effects. The firm and the regulator can collect evidence on that state through clinical trials in the ex ante phase and through surveillance in the ex post phase.

- **Ex ante regulation**: To sell a new prescription drug, the sponsor must provide a series of codified clinical trial results based on which the FDA can allow market introduction. The FDA and the sponsor must also agree on the labelling of the product.

- **Ex post regulation**: Post approval, pharmaceutical firms are required by the FDA to report adverse events experienced by patients or results of additional clinical trials they conduct. Patients and doctors can also directly report to the FDA through the MedWatch system. The FDA can at any point request a change in the labeling of the drug or can order the firm to recall the drug.\(^{22}\)

- **Liability**: Product liability law in the case of drugs, like in the case of most products, imposes legal obligations to compensate people injured by the product. The defect most commonly invoked for pharmaceuticals is the warning failure, whereby the manufacturers is liable for failing to warn about risks they knew or should have known about.\(^{23}\) In most cases that led to large levels of liability (such as the Vioxx case), the defining feature is that the companies failed to report to the FDA or to the medical community evidence they

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\(^{22}\)It is hard to establish empirically what proportion was voluntarily recalled by the firm and what proportion of the recalls were triggered by FDA action. In both cases, the FDA plays a key role in influencing the event through its surveillance program. See Zuckerman, Brown, and Nissen (2011) on the prevalence of withdrawals of drugs and medical devices.

\(^{23}\)In addition to the failure to warn, product liability typically addresses two other categories of defects. First, manufacturing defects, when the product does not meet the manufacturer’s own design specification. Second, design defects, whereby manufacturers are liable of the foreseeable injury risks involved in the product that could have been avoided using a reasonable alternative design: see Henderson and Twerski’s (1998) account of the American Law Institute Restatement (Third) of Torts. These two categories are very rarely invoked for drugs.
A long lasting debate, as mentioned in the introduction is whether pharmaceutical companies should be protected from liability if they complied with FDA regulations—a defense that is valid for generic drugs and medical devices. The Supreme Court ruled against this defense in *Wyeth v. Levine*, even though certain states adopt this approach.

Lawsuits against pharmaceutical companies are much more common in the US than in other countries around the world. For instance, Lybecker and Watkins (2015) report that “there is no evidence of any court cases with positive settlement payments documented within the UK.” The essential difference is that a UK drug manufacturer can avoid litigation by arguing of having been unaware of the side effect. At the same time, prices of drugs are much higher in the US. We discuss in the conclusion how our model can explain this combination of features that characterizes the US.

In conclusion, the main regulatory tool for drugs remains ex ante regulation with strict clinical trial testing. Product liability, in particular due to failure to warn, still plays a role at least in the US, but in spite of the Supreme Court ruling remains partly preempted by ex post regulation. Ex post regulation does exist but tends to be still rather weak.

**Patents.** In the case of patents the state of the world is whether the patent is valid or not: a valid patent provides a positive payoff to society, while an invalid patent causes social harm as the patent holder can sue productive firms that are supposedly infringing. As Hall et al. (2004) frame it: “Low-quality patents can create considerable uncertainty among inventors or would-be commercializers of inventions and slow either the pace of innovation or investment in the commercialization of new technologies.”

- **Ex ante regulation:** The US patent office (USPTO) determines whether the patent meets the three criteria—novelty, usefulness and non obviousness—necessary for being approved. Many scholars (Jaffe and Lerner 2007) believe that in the US, this ex ante regulation is rather weak, in the sense that many invalid patents are being granted, partly because the

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24 It was judged in the Vioxx case that the warnings to physicians were inadequate in light of what Merck knew at the relevant times about cardiovascular risks from their own studies as well as published or unpublished literature.

25 In PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), the US Supreme Court rules that generic drug manufacturers are not liable for injuries arising out of their failure to warn of dangers from the use of their drug, provided that they use FDA required warnings. Thus, generic drug manufacturers are sheltered from the principal threat of liability. See Friedman and Wickelgren (2017) for an economic analysis.

26 Lybecker and Watkins (2015) report that UK manufacturers can use the defense that “the state of scientific and technical knowledge was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while under his control.”

27 Galasso and Schankerman (2015) provide causal evidence that patents can decrease cumulative innovation.
patent office is overcrowded, partly also because the incentives of the patent office used to be biased in favor of approval.\textsuperscript{28}

- **Ex post regulation**: If the patent holder sues for infringement, the defendant can adopt an invalidity defense and attempt to show that the patent is invalid. If the defendant wins that case, the patent is definitively withdrawn.\textsuperscript{29} This ex post regulation is considered weak for two reasons. First, as reported by Ford (2013), the defendant has more incentives to use a noninfringement defense rather than an invalidity defense as it cannot benefit from the positive externality it provides to others by having a bad patent invalidated. Second, there is a strong burden of proof on the defendant to prove a patent invalid; according to Hall et al. (2004), “patents are born valid, thus enjoying a presumption of validity during the court proceedings. Furthermore, the evidentiary standard for proving that a claim is invalid is clear and convincing evidence, a standard considerably higher than the mere preponderance of proof required in the typical civil suit.”\textsuperscript{30}

- **Liability**: No liability can be imposed on the holder of a bad patent that is proven invalid. Even though courts intervene ex post to potentially rule patents as invalid, firms that paid royalty fees to the patent holders prior to invalidation cannot claim financial compensation.

In comparison with the US, the European Patent Office appears to be stricter in granting patents (ex ante regulation). A similar system of ex post invalidation by courts is in place in Europe. It is hard to determine whether overall the ex post regulation is stricter in Europe or in the US, but there is one dimension that limits its scope in Europe: lawsuits for infringement and thus counter lawsuits for invalidity are brought in front of national courts, so that a patent can be ruled invalid in one country while still being valid in another.\textsuperscript{31}

In conclusion, in the case of patents, there is a mix of ex ante and ex post regulation, which tend to be weak, especially in the US. Liability is not part of the mix used by the planner.

**Other Applications.** The mix of regulatory instruments employed varies greatly across settings beyond drugs and patents. For safety regulation of products other than pharmaceuticals for which the risk of negative externalities is more limited, the main instrument is liability and regulation plays a minor role. In the case of projects with environmental risk (oil drilling in

\textsuperscript{28}Ford (2013) reports that recently the USPTO has received more than five hundred thousand applications per year and granted almost half as many.

\textsuperscript{29}The USPTO can also directly initiate a re-examination of the patent, but this is very rarely done in practice.

\textsuperscript{30}The law requires that patents be presumed valid and that a party asserting that a parent claim is invalid bears the burden of proof.

\textsuperscript{31}Coyle (2012) describes a case where a patent was invalidated in United Kingdom, France, Belgium, and Austria, yet upheld in Germany and the Netherlands.
sensitive areas or introduction of genetically modified organisms) or merger policy, withdrawal is very costly; ex ante regulation is the natural instrument. Finally, road safety is regulated both ex ante (requiring a driver’s license) and ex post (withdrawing the license following a series of traffic offenses) as well as through liability following accidents.

4.2 Strategic Interactions

We now use our model to understand how the different instruments can be used to align the firm’s incentives. We initially focus on three scenarios in which the planner controls at date zero each one of the three tools in isolation; CORRECT Section ?? analyzes the optimal combination of the three tools. Given a threshold \( x \in \{s, S, z\} \), we denote by \( x_{ab} \) the threshold resulting in the regulatory environment where player \( a \) controls ex ante adoption and player \( b \) controls ex post withdrawal.

4.2.1 Liability Regime and ex post regulation

The first regularity that emerges from the discussion in Section 4.1 is that liability (used for regular product introductions) and ex post regulation (used for drugs and patents) are rarely used in conjunction. We start by comparing these two instruments.

Liability regimes penalize the firm in the bad state. In the context of our model, we consider a liability rate \( L \in [0, v_{i} - v_{p}^{B}] \) that is imposed on the firm per unit of time on the market if \( \theta = B \). In state \( B \), the firm thus obtains payoff \( v_{i} - L \); in state \( G \), instead, the payoff remains unaffected at \( v_{i} = (1 - e)v_{p}^{G} > 0 \). Under the liability regime, the firm controls rejection \( s_{ii}(L) \), adoption \( S_{ii}(L) \), and withdrawal \( z_{ii}(L) \).

Under a strong liability regime, defined as a regime where the liability rate is set at \( L = \bar{L} = v_{i} - v_{p}^{B} \) in a way to fully compensate the damage caused, the incentives of the firm and the social planner are by construction perfectly aligned in the bad state. In the absence of externalities, \( e = 0 \), strong liability naturally achieves the first best since the firm and the social planner obtain the same payoff in all states. If \( e > 0 \), strong liability no longer induces the first best: since the firm’s payoff in the good state is socially insufficient, the firm rejects too early, \( s^{*} < s_{ii}(\bar{L}) \), adopts too late, \( S^{*} < S_{ii}(\bar{L}) \), and withdraws too early, \( z^{*} < z_{ii}(\bar{L}) \). The social planner should constrain the courts to be more lenient.

The planner can in fact choose the liability rate \( L \) to induce any withdrawal standard. In particular, we denote by \( \hat{L} \) the liability rate that induces the ex post optimal withdrawal, \( z_{ii}(\hat{L}) = \).

\[^{32}\text{Appendix B extends our baseline model to introduce reversibility costs.}\]

\[^{33}\text{For applications in the area of consumer financial protection see Posner and Weyl (2013).}\]

\[^{34}\text{We purposefully abstract away from the details of the judicial procedure by assuming that courts impose an expected penalty equal to } L \text{ per unit of time in the market conditional on state } B.\]
$z^*$. Under this liability rate, as illustrated in Figure 3, the firm’s lower best reply $b_i(S)$ (dashed-dotted blue) is to the right of the social planner’s $b_p(S)$ (dashed-dotted red); intuitively, the firm expects a lower payoff from adoption and thus rejects too early, $s^* < s_{ii}(\hat{L})$. The firm’s upper best reply $B_i(s)$ (continuous blue) is below the social planner’s $B_p(s)$ (continuous red), given that the firm attaches a lower value to information and thus adopts too early $S_{ii}(\hat{L}) < S^*$.

The planner can achieve a higher level of social welfare by committing to a liability rate different from $\hat{L}$. From the ex post perspective, this increase in liability induces a second-order loss, as withdrawal is moved away from the optimal ex post standard $z^*$. Deviating from that level, however, may generate a first-order gain in the change of ex ante actions that the firm is induced to take. Recall that the planner wants to encourage research at the bottom (decrease $s_{ii}$) and delay approval (increase $S_{ii}$). Given that any change that decreases $s_{ii}$ also decreases $S_{ii}$, the planner must trade off conflicting forces in terms of ex ante actions.

Varying $z$ around $z^*$, has conflicting effects on the rejection and adoption standards. By choosing a liability rate strictly above $\hat{L}$, the value of information for the firm is increased, leading the firm to adopt later and reject earlier. If the rate is chosen strictly below $\hat{L}$, the expected payoff upon approval is increased, leading the firm to adopt earlier and reject later. Overall, the planner optimally commits to a liability rate below $\hat{L}$ if the starting belief $q_0$ is low and the main concern is to encourage experimentation. On the contrary if $q_0$ is high, the main concern of the planner is to discourage early adoption and the planner should commit to a liability rate strictly above $\hat{L}$.
Proposition 2 If $e > 0$, optimal liability $L^*$ is interior $0 < L^* < \bar{L}$ and such that:

(a) The firm rejects too early $s_{ii}(L^*) > s^*$ and adopts too early $S_{ii}(L^*) < S^*$;

(b) $L^*$ is decreasing in $e$ and function of initial belief $q_0$: $\exists \hat{q} \in (q, \bar{q})$ such that:

(i) for any $q_0 \in (\hat{q}, \bar{q})$, the planner commits to low liability $L^*(q_0) < \hat{L}$,

(ii) for any $q_0 \in (\hat{q}, \bar{q})$, the planner commits to high liability $L^*(q_0) > \hat{L}$.

Proposition 2 implies that, in a system that relies exclusively on liability such as regulation of product introduction, the optimal liability rate is a function of both the level of externality and the starting belief.

As was highlighted before, in a number of situations, the planner does not rely on liability, but rather on ex post regulation, i.e. the planner commits at $t = 0$ to a withdrawal standard $z_{ip}$ and, taking into account the withdrawal rule, the firm chooses the rejection and adoption standards $s_{ip}$ and $S_{ip}$. Ex post regulation is in fact very similar to liability, given that both instruments regulate withdrawal. In particular liability can be set to induce the same withdrawal as ex post regulation: for any $z_{ip}$, there exists $L \in (0, \bar{L})$ such that $z_{ii}(L) = z_{ip}$.

However, liability results in more powerful ex ante incentives since it has a stronger chilling effect on experimentation (i.e. increases rejections more), for the same ex post standard. Liability thus dominates for low $e$ while ex post regulation dominates for high $e$.

Proposition 3 There exists $\hat{e}$, such that an optimal liability system is preferred to an optimal ex post regulation if and only if $e \leq \hat{e}$.

The comparison of welfare under optimal liability and optimal ex post regulation as a function of the externality $e$ is illustrated in Figure 4. The figure illustrates the fact that liability yields higher welfare if and only if the externality is low enough. When $e$ is high liability chills experimentation incentives too much. On the contrary, ex post regulation has a softer effect on those incentives and hence welfare dominates, explaining why, for patents or drug introduction this instrument is not used. On the contrary, when the externality is low, as in the case of the introduction of regular products, liability will be preferred.

4.3 Regulation: weak or tough?

The second regularity that emerges from the discussion in Section 4.1 is that regulation, be it ex ante or ex post, tends to be lenient. In the case of patents, ex post regulation takes the form of patent invalidation. This procedure tends to be lenient, given that the burden of proof is put
on the challenger. Similarly in drug regulation, there is limited monitoring of side effects for approved drugs through so-called post marketing studies.

When constrained to use a single instrument, the planner controls directly either the withdrawal (through liability or ex post regulation) or adoption (ex ante regulation) standards. Optimal regulation, as in the case of optimal liability characterized in Proposition 2, rests on the logic that it is socially optimal to incur a second-order loss by moving away from the optimal standard under control against a first-order gain in the other standards.

**Proposition 4** The optimal withdrawal standard $z_{ip}^*$ is a function of $q_0$. Furthermore, there exists $\bar{e}$ such that:

(a) If $e \leq \bar{e}_{ip}$ the planner commits to be **tougher** than the socially optimal withdrawal level: $z_{ip}^* > z^*$; 

(b) If $e > \bar{e}_{ip}$, there exists $\bar{q}(e)$ such that:

(i) if $q_0 < \bar{q}(e)$, the planner commits to be **more lenient** than the socially optimal withdrawal level: $z_{ip}^* < z^*$,

(ii) if $q_0 \geq \bar{q}(e)$, the planner commits to be **tougher** than the socially optimal withdrawal level: $z_{ip}^* > z^*$.
The optimal adoption standard $S^*_{pi}$ is a function of $q_0$. Furthermore, there exists $\bar{e}_{pi}$ such that:

(a) If $e \leq \bar{e}_{pi}$, the planner commits to be **tougher** than socially optimal adoption level: $S^*_{pi} > S^*$;

(b) If $e > \bar{e}_{pi}$, there exists $\bar{q}(e)$ such that:

   (i) if $q_0 < \bar{q}(e)$, the planner commits to be **more lenient** than the socially optimal adoption level: $S^*_{pi} < S^*$,

   (ii) if $q_0 \geq \bar{q}(e)$, the planner commits to be **tougher** than the socially optimal adoption level: $S^*_{pi} > S^*$.

When constrained to use only ex post regulation, the planner might want to commit to a withdrawal standard different from the ex post optimal standard $z^*$ in order to influence ex ante incentives. When $e$ is small, the firm, since it does not incur a negative payoff in the bad state and has a payoff in the good state similar to that of the planner, has excessive incentives both to approve ($S_{ip}(z^*) < S^*$) and to experiment ($s_{ip}(z^*) < s^*$). Thus, when $e$ is small, it is unambiguously optimal to increase $z_{ip}$ above $z^*$ to chill experimentation incentives, thus pushing the firm to reject earlier and approve later.

When $e$ is larger, it is no longer necessary to chill research at the bottom. As illustrated in Figure 5, there exists a benchmark value $\bar{e}_{ip}$ such that if the withdrawal is set at the socially optimal level $z_{ip} = z^*$ the firm chooses $s_{ip} = s^*$: the externality is sufficiently big that, even though the firm does not obtain a lower payoff in the bad state, the low payoff in the good state implies that the incentives to keep experimenting are sufficiently chilled. If the externality is above this benchmark value, $e > \bar{e}_{ip}$, it becomes necessary for the planner to encourage experimentation. Changing $z_{ip}$ then has two conflicting effects on the ex ante standards $s_{ip}$ and $S_{ip}$. Lowering $z_{ip}$ below $z^*$ has the positive effect of encouraging experimentation (by delaying rejections) but the negative one of speeding up adoption. The optimal balance between these two effects thus depends on the starting belief $q_0$. If the prior is sufficiently low, the most pressing concern is to encourage experimentation, thus pushing the planner to be more lenient. If instead $q_0$ is high, adoption incentives are more important, thus the planner is induced to be tougher.

Similarly, in the case of ex ante regulation, starting from the socially optimal adoption standard $S^*$, the firm has insufficient withdrawal incentives and excessive (resp. insufficient) experimentation incentives if the externality level $e$ is low (resp. high). Similar to the case described above, there is a tradeoff between a second-order loss from moving away from $S^*$ versus a first-order gain in rejection standard $s_{pi}$. 

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Figure 5: Commitment to $z_{ip} = z^*$ and induced ex ante incentives as a function of $e$.

The cutoff value $\bar{e}_{pi}$ is defined as the level of externality such that, if the planner commits to an adoption standard $S_{pi}^* = S^*$, the firm responds by choosing the socially optimal research standard $s_{pi}^* = s^*$. This is represented in Figure 6 where $\bar{e}_{pi}$ is the externality such that $s_{pi}$ as a function of $e$ crosses the horizontal line equal to $s^*$. By definition of $\bar{e}_{pi}$, if the externality is smaller than $\bar{e}$, increasing $S_{pi}^*$ above $S^*$ is beneficial both because it discourages excessive experimentation, increasing rejections and delays adoption, which is socially beneficial since the firm has no incentive to withdraw once the product is adopted. On the contrary, when $e > \bar{e}_{pi}$, experimentation incentives need to be encouraged. Changing $S_{pi}^*$ has conflicting effects. If $q_0$ is small, the effect on experimentation incentives is most pressing and the planner encourages experimentation by reducing adoption standards $S_{pi}^* < S^*$. On the contrary, when $q_0$ is higher, the planner is more worried about the fact that the firm won’t withdraw once approval has been granted and thus prefers to be tougher on adoption $S_{pi}^* > S^*$.

Overall the results suggest that whether regulatory commitments are tougher or weaker than the social optimal levels depends on the level of $e$ and on the starting belief $q_0$. For instance Proposition 4 shows that if the externality is small, the planner will commit to a tougher withdrawal standard to discourage excessive experimentation. Weaker commitments are only optimal for large $e$ and low starting beliefs $q_0$, such that the priority is to encourage experimentation.

We now characterize the optimal combination of instruments, $(S_{pp}^*, z_{pp}^*, L_{pp}^*)$ and show in our main result, that the first best can be achieved only for small values of the externality and that regulation (ex post and ex ante) is always weaker or equal than the socially optimal levels.

**Proposition 5 (a)** The socially optimal mix of instruments is such that:
Figure 6: Research incentives of the firm when planner commits to $S_{pi} = S^*$. 

Figure 7: Optimal combination of instruments.

(i) the first best is achieved if and only if $e < \hat{e}$, and all three instruments are used,

(ii) liability is set to zero if $e \geq \hat{e}$.

(b) In an optimal mix of instruments, both ex post and ex ante commitments are chosen equal or more lenient than the socially optimal levels $z^*$ and $S^*$.

Proposition 5 shows that there is a critical level of externality $\hat{e}$, such that if $e$ is less than $\hat{e}$, the planner chooses approval and withdrawal standards at the socially optimal levels and uses
liability to chill research incentives. On the contrary, when $e$ is greater than $\hat{e}$, the planner stops using liability and encourages research by being more lenient on both ex ante and ex post regulatory standards. Thus liability is only used when experimentation needs to be discouraged.

To understand how the critical level $\hat{e}$ is determined, consider the case where the planner commits to a combination of the socially optimal ex ante standard $S^*$ and ex post standard $z^*$, but does not use liability. Given these commitments, the firm optimally decides on when to abandon experimentation, a decision we denote $s_{pp}$. For $e = 0$, incentives to experiment are excessive ($s_{pp} < S^*$) since the firm has the same payoffs in the bad and good state. For $e = 1$, on the contrary experimentation incentives of the firm are insufficient $s_{pp} > S^*$. Since the lower best reply $b_i(S)$ increases when $e$ increases, there exists a critical value $\hat{e}$, such that if $e = \hat{e}$ then $s_{pp} = S^*$. By definition, $\hat{e}$ induces the socially optimal rejection decision by the firm, so for that level of externality the first best can be achieved using only a combination of ex ante and ex post commitments.

If $e < \hat{e}$, the first best is no longer achieved by using solely a combination of the two regulatory instruments. The planner can use in addition liability that, for the same level of approval and withdrawal standards, discourages excessive experimentation. In the limit where $e = 0$, we already saw in Section 4.2.1 that strong liability alone achieves the first best. When $e = \hat{e}$ liability is set to zero and, as already highlighted, and first best is achieved only with ex ante and ex post regulation. If, instead, $e \in (0, \hat{e})$ there exists an interior liability level that achieves the first best.

On the contrary, if $e > \hat{e}$, the first best is no longer achievable. In this case, when the adoption and withdrawal standards are chosen at the socially optimal levels, experimentation incentives are insufficient. Liability is no longer a useful instrument since it further discourages experimentation. To provide experimentation incentives, the planner needs to be more lenient in adoption $S_{pp} < S^*$ or/and more forgiving in withdrawal $z_{pp} < z^*$. As shown in Proposition 5 whenever $e > \hat{e}$, the planner is more lenient with both standards since in both cases the second-order losses associated with deviations from the optimum are swamped by the first-order gains in experimentation incentives.

Figure 7 plots the commitment path as a function of the externality. For $e \leq \hat{e}$, all three standards are at the socially optimal level. For $e > \hat{e}$, as $e$ increases, the rejection standard $s_{pp}^*$ increases, and in response both the adoption and withdrawal standards decrease.

\[^{35}\text{If } e = 1 \text{ the firm obtains 0 regardless of the state therefore } s_{pp} = b_i(S^*) = S^* > S^*\]
5 Private Information Collection and Costly Lying

Up to now information was publicly disseminated. However firms, being in control of the research process before approval, have private access to research results and could potentially lie about them. For example, pharmaceutical firms may misrepresent the evidence presented to the FDA, the medical profession, or the public at large. For example, the alleged withholding of negative results by pharmaceutical companies in the recent cases of Vioxx (an anti-inflammatory drug proven to increase the risk of cardiovascular events) or Paxil (an anti-depressant that could increase the suicide rates among children) generated major uproar and large demands for compensation.

We now depart from the public information assumption and assume that information obtained during the first experimentation phase is privately observed and non verifiable, so that the firm can make any report regardless of actual knowledge held by the firm. However, we assume that misreporting is costly. Misreporting involves in practice risks both in terms of reputation as well as financial sanctions. Moreover, the probability that a lie is detected or condemned increases in the size of the lie. For instance, in the case of Vioxx, it is because Merck was shown to have withheld evidence that the penalties were very large: it allegedly paid over 4.85 billion dollars for settling individual complaints from patients.

Specifically we assume that, if the state is bad and the firm, when approval is granted, has collected evidence showing that the belief is \( S_i \) and chooses to report \( S \), the probability of obtaining a given fine \( F \) is given by \( P(S - S_i) \) where \( P \) is increasing and convex and \( P(0) = P'(0) = 0 \).

We consider \( F \) as an additional instrument and show that, when the planner cannot charge liability, costly lying will actually be beneficial and the fine will be set at intermediate levels that allow for some lying in equilibrium. In Appendix A.1 we consider fixed values of \( F \) and show that the results of Proposition 5 are preserved under costly lying for \( F \) sufficiently high.

5.1 Tolerating Lies

In many instances, the use of ex ante regulation shields the firm from product liability. As explained in Section 4.1 this is the case in the US for generic drugs and medical devices, where the approval by the FDA shields from product liability, but not from suits alleging misreporting. This is also the case more generally in other developed countries.

So we now consider a case where information is privately collected by the firm, the planner does not have access to liability and can commit at date \( t = 0 \) to a required report for approval, a withdrawal standard and a fine for misreporting \( (S, z, F) \). The following result shows that the

\[36\text{We build on Kartik, Ottaviani, and Squintani’s (2007) specification of costly lying.}\]
fine, for low levels of externality, will be set at intermediate levels that tolerate some lying in equilibrium. Furthermore the planner is better off than if information was publicly collected.

**Proposition 6 (a)** In an optimal mix of ex ante, ex post commitments and fines for misreporting \((S, z, F)\) there exists \(\hat{e}\) such that:

(i) The first best is achieved if and only if \(e < \hat{e}\) and all three instruments are used,

(ii) If \(e < \hat{e}\), the optimal fine is interior, first decreasing then increasing and the firm lies in equilibrium: \(S_i < S\). If \(e > \hat{e}\), the optimal fine is \(F = \infty\) and the firm does not lie.

(b) In an optimal mix of instruments, the ex post commitment is chosen equal or more lenient than the socially optimal levels \(z^*\) and the belief of the firm at approval \(S_i\) is lower or equal than the socially optimal approval standard \(S^*\).

(c) Welfare under costly lying is higher than welfare under public information.

Whenever an interior fine is chosen, the firm lies in equilibrium. This is directly implied by the fact that the marginal cost of lying at zero is zero \((P'(0) = 0)\). However, the planner knows precisely the size of the lie in equilibrium. Indeed for any approval standard \(S\) required for approval, even though the firm can make any report, the planner knows at what level \(S_i\) the firm stopped searching given that the firm takes into account the expected level of penalty it will incur for any lie \(S - S_i\). Our planner optimally selects a combination of fine and report \((F, S)\) that satisfies the firm’s first order conditions (4) and (5) in Appendix A.\(^{37}\)

Figure 8 represents the firm’s best replies for two levels of required reports \((S' \text{ and } S^*)\), when the externality is fixed at \(e' < \hat{e}\). First, if the required report is \(S = S'\), then the firm’s best replies intersect at the socially optimal level \(S^*\). If, instead, the planner requests a report \(S = S^*\), keeping the other tools unchanged, the lower best reply shifts to the left, since for any given belief \(S_i\) at which approval is requested, the size of the lie is smaller \((S^* - S_i < S' - S_i)\) and thus the expected payoff in the bad state is higher, encouraging the firm to reject later. Overall this leads the firm to adopt at a lower level denoted \(S_i\) in Figure 8.

In the absence of liability, the fine for misreporting \(F\) serves two purposes. First, as explained above, for a given required report \(S\), the choice of the fine determines the actual belief \(S_i\) at which the firm approves. Second, the fine, as a substitute for liability, serves to decrease excessive incentives for research when \(e\) is low.

Part (a-ii) of Proposition 6 and Figure 10 describe the behavior of the optimal fine as a function of the externality. The fine \(F\) in combination with the required report to obtain approval

\(^{37}\)The planner maximizes its expected payoff for \((S, S_i, s_i, F, z)\) subject to (4) and (5) à la Stackelberg.
$S$ define the actual knowledge at approval $S_i$. When $e = 0$ the planner selects a report standard $S = 1$ forcing the probability of being caught lying to 1. In this way, the fine $F$ serves exactly as a liability and the planner can perfectly align firm incentives in the bad state. As the externality increases, the planner cannot simply rely on the fine level $F$ to align incentives. Keeping the required report $S$ too high makes too costly for the firm to influence and reduce the size of the lie. Thus, the planner optimally decreases both the fine level and the required report standard $S$. This way, the firm can effectively influence the size of the lie reducing the expected penalty in the bad state and the first best obtains for low externality.

The optimal standards $(S, S_i, s, z)$ as a function of $e$ are plotted in Figure 9. As we saw in Proposition 5, when the externality is sufficiently high, the planner gives up on aligning the incentives of the firm by imposing liability in the bad state because the liability would reduce too much the firm’s ex ante incentives for experimentation. This logic remains valid also when information is private. It is then optimal for the planner to set the fine as high as possible in order to kill the firm’s incentives to lie. This way, no lying results in equilibrium and the firm adopts exactly at the required report level $S_i = S$, shutting down any risk of being caught lying and of incurring any penalty. In equilibrium, the planner provides research incentives to the firm by being more lenient both in the required report $S$ and in the withdrawal standard $z$, analogously to the public information environment presented in Section ??.

To sum up, for low externality $e < \hat{e}$ the firm lies in equilibrium, the fine level is interior and the first best is achieved. For $e > \hat{e}$ there is no lying in equilibrium and the planner relies

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38The resulting regime is equivalent to a situation in which the planner imposes both liability and withdrawal commitments on the firm.
only on ex ante regulation through the required report standard $S$ and on ex post regulation to incentivize experimentation. Overall in Proposition 6-c, when the planner is prevented to use liability, private information collection by the firm can be welfare improving. Because of costly lying, the planner knows the size of the lie in equilibrium and the fine for lying thus gives rise to an additional instrument. This fine thus serves as a substitute instrument for liability and serves to chill research when it is socially desirable to do so, i.e., when the externality is small.

6 Conclusion

The paper formulates a tractable model to study the optimal mix of ex ante approval regulation, ex post withdrawal regulation, and liability to manage the adoption of activities with an externality of uncertain sign. The model combines optimal experimentation before implementation of the activity with learning after implementation. According to our main result, for low externality levels, using all three tools achieves the first best; when instead the externality is sufficiently high, liability would chill experimentation incentives too much, and in equilibrium a more lenient combination of only ex ante and ex post regulation is optimal.

For the baseline model we focused on the case with public information, and then extended the analysis to the case with privately collected information that can be misreported. In addition to the applications mentioned in the introduction and in Section 4.1 our model also speaks to other public policies that can be tested before approval (for instance through randomized or gradual implementation) and that then can be withdrawn following unsatisfactory results.
To wrap up, we now confront our main results with the regularities for the regulation of product/drug safety, patents, and environmental projects reported at the outset of the paper. First, regulatory commitments in practice, and in particular ex post commitments, are typically designed to be weak either through legal commitments, as in the case of patents, or through commitments to imperfect monitoring technologies, as in the case of drug ex post surveillance. By Proposition 5(b), ex ante or ex post regulation, whenever they are used in equilibrium, tend to be weak. Intuitively, whenever the concern is to discourage excessive experimentation, liability is a more efficient tool than regulation and regulation will serve to guarantee that the approval and withdrawal standards are optimally set. It is only when experimentation needs to be encouraged that liability is no longer useful and the planner must become more lenient in the other standards to prevent excessive/early rejections.

Second, regulation tends to be preferred to liability when the externality is large. For instance, this is the case for patents and new drugs where the innovator’s private returns are often thought to fall short of the social returns. These regularities are consistent with Proposition 5’s prediction that ex post regulation dominates liability if and only if the externality is large. This result also justifies the combination of features that distinguishes the US from Europe in terms of pharmaceutical regulation: in the US prices are higher (in other words \( e \) is smaller, i.e., \( v_i \) larger) and liability is more common. Our model suggests that liability is a less useful tool in Europe since it will have a chilling effect on research incentives.

Third, litigation and ex post regulation are rarely used together. This is consistent with Section ??’s results showing that both can generate the same ex post standard. They just differ in the sense that for the same withdrawal standard, liability discourages more ex ante experimentation. Thus, if the externality is low and experimentation needs to be stifled, liability is preferred, while regulation is preferred for large levels of the externality.

Finally, most applications are characterized by the use of essentially a single instrument, the main exception being patent regulation that combines ex ante and ex post regulations. The use of limited instruments is typical for product safety, which mostly focuses on liability. This exclusive use of liability is somewhat at odds with the prediction of Proposition 5 that for low levels of the externality, all three instruments should be used in an optimal mix. When \( e \) is small, if the planner is constrained not to use regulation, the welfare loss is minimal since at \( e = 0 \) all standards are at the socially optimal level and moving away from them only induces second order losses. Moreover, it is reasonable to think that implementing an ex ante regulatory system and/or an ex post system of surveillance entails some costs. In this case, even small implementation costs would imply that only liability is used for low externality levels. Explaining this regularity could be the object of interesting future work.
7 References


A Appendix A: Derivations and Proofs

The two general lemmas that follow play a key role in our analysis.

**Lemma 1** In the Bandit problem in the ex post phase, if it is initially optimal to withdraw $W$, in the sense that there exists $\delta > 0$ such that $\hat{u}_p^2(\sigma_0) \equiv \sup_{(d_t)_{t \geq 0}} u_p^2(\sigma_0, d) = \{ u_p^2(\sigma_0) | d_t = 0, 0 \leq t \leq \delta \}$, then it is always optimal to choose $W$.  

**Proof of Lemma 1**  
Fix $\epsilon > 0$ and $d = (d_t)_{t \geq 0}$ such that $d_t = 0 \ \forall \ 0 \leq t \leq \delta$ and $u_p^2(\sigma_0, d) \geq \hat{u}_p^2(\sigma_0) - \epsilon$. Then we have  

$$u_p^2(\sigma_0, d) = \mathbb{E}_{\Omega \times \Theta} \left[ \int_0^\infty e^{-r t} d_t [ q_t \left( v_p^G \right) + (1 - q_t) \left( v_p^B \right) ] dt \bigg| \sigma_0 \right]$$

$$= e^{-r \delta} \mathbb{E}_{\Omega \times \Theta} \left[ \int_0^\infty e^{-r t'} d_t' [ q_t' \left( v_p^G \right) + (1 - q_t') \left( v_p^B \right) ] dt' \bigg| \sigma_0 \right] \leq e^{-r \delta} \hat{u}_p^2(\sigma_0),$$

where $t' = t - \delta$ and $d_t' \equiv q_t + \delta$. Therefore, we conclude that $\hat{u}_p^2(\sigma_0) - \epsilon \leq e^{-r \delta} \hat{u}_p^2(\sigma_0)$ from which $\hat{u}_p^2(\sigma_0) \leq \frac{\epsilon}{1 - e^{-r \delta}}$. Since $\epsilon$ was arbitrary then $\hat{u}_p^2(\sigma_0) \leq 0$ which is achievable by always pulling the safe arm $W$.  

**Lemma 2** Let $X_t$ be a one-dimensional stochastic process that solves $dX_t = \mu(X_t)dt + \sigma(X_t)dW_t$, where $W_t$ is a Wiener process. Then for the problem  

$$\sup_{(\tau, d_\tau)} \mathbb{E} \left[ e^{-r \tau} (d_\tau g_1(X_\tau) + (1 - d_\tau) g_2(X_\tau)) \bigg| X_0 = x \right]$$

there exists a solution of the form $\tau = \inf \{ t : X_t \notin (x, x) \}$ with $d_\tau = 1(X_\tau = x)$ for $x = \underline{x}$ and $x = \bar{x}$.  

**Proof of Lemma 2**  
Given any stopping time $\tau$ then $d_\tau = 1 \iff g_1(X_\tau) \geq g_2(X_\tau)$. Therefore defining $g(X_\tau) = \max \{ g_1(X_\tau), g_2(X_\tau) \}$ we can rewrite this as an optimal stopping problem,  

$$\sup_{\tau} \mathbb{E} \left[ e^{-r \tau} g(X_\tau) | x \right].$$

It follows from Peskir and Shiryaev (2006) that an optimal stopping time is the first time at which $X_t$ exits the continuation set $C = \{ x : U(x) > g(x) \}$ where $U(x) \equiv \sup_t \mathbb{E} [ e^{-r t} g(X_t) | x ]$ is the value function. Under our assumptions $C$ is an open set in $\mathbb{R}$ and therefore it can be represented as a countable union of disjoint (open) intervals. For this reason, the problem of determining the optimal stopping time can be reduced to determining an optimal first exit time from an interval $(\underline{x}, \bar{x})$ which contains the initial point $x$ of the process $X_t$. In general, even if the threshold strategy is optimal, the continuation set $C$ may not have a threshold structure. For instance, let $C = \{ x : U(x) > g(x) \} = (x_1, x_2) \cup (x_3, x_4)$ with $x_1 \leq x_2 \leq x_3 \leq x_4$ and $D = \{ x : U(x) = g(x) \}$ the stopping region. Set $C$ does not have a threshold structure but given $x \in C$ being the process continuous we can find $C' = (\underline{x}', \bar{x}')$ which achieves the same expected payoff when starting at
\[ x \text{ such that } \mathcal{X} = \sup_y \{ y \in \partial C : y \leq x \} \text{ and } \mathcal{O} = \inf_y \{ y \in \partial C : y \geq x \}. \] Hence, there is always an optimal stopping policy in the form of a threshold strategy around \( X_0 = x \).

**Proof of Proposition 1**

The model is solved by backward induction starting from the ex post monitoring phase.

**Step 1:** The optimal solution to the ex post problem requires the planner to select the recall threshold \( z^* \) independent from the belief at which the agent chooses to adopt (A).

Let \( S \) be the belief at which the social planner adopts. By Lemma 1 we know that the bandit problem in the ex post phase can be rewritten as the stopping problem

\[
\hat{u}^2_p(S) \equiv \sup_{\tau} \mathbb{E}_{\Omega \times \Theta} \left[ (1 - e^{-rt}) \left( q \frac{v_p^G}{r} + (1 - q) \frac{v_p^B}{r} \right) S \right].
\]

By Lemma 2 we know that there exists an optimal thresholds policy around the initial belief \( S \). Therefore let us define the two thresholds \((z, Z)\). Following Stokey (2009, Chapter 6), this ex post monitoring phase setup is a one-time one-option problem in which the agent selects the withdrawal (lower) threshold \( z \) below which it is optimal to stop the flow of benefits and withdraw, whereas the higher threshold is \( Z = 1 \). Hence, the planner ex post utility is

\[
u^2_p(S, \tau(z)) = \frac{e^S}{1 + e^S} \left( 1 - \mathbb{E}_{\Omega} \left[ e^{-\tau |G, S]} \right] + \frac{1}{1 + e^S} \left( 1 - \mathbb{E}_{\Omega} \left[ e^{-\tau |B, S]} \right] \right).\]

As in Stokey (2009), we have a closed form expression for \( \mathbb{E}_{\Omega}[e^{-\tau |G, \sigma}] = \psi(\sigma, \theta, z) \) with \( \psi(\sigma, G, z) = e^{-r_2(\sigma - z)} \) and \( \psi(\sigma, B, z) = e^{r_1(\sigma - z)} \), where \( r_1 = \frac{1}{2} \left( 1 - \sqrt{1 + \frac{4r}{\mu_1^2}} \right) < 0 \) and \( r_2 = \frac{1}{2} \left( 1 + \sqrt{1 + \frac{4r}{\mu_2^2}} \right) > 0 \). Therefore, the planner maximizes the following expression

\[
\max_z \left\{ \frac{e^S}{1 + e^S} \left( 1 - e^{-r_2(S - z)} \right) + \frac{1}{1 + e^S} \left( 1 - e^{r_1(S - z)} \right) \right\}
\]

with solution \( z^* = -\ln \frac{v_p^G}{v_p^B} \frac{r_2}{r_1} \), which is independent from the initial adoption belief \( S \).

**Step 2:** In the ex ante testing phase the social planner selects two thresholds \((s^*, S^*)\) independent from the initial belief.

By step 1 we know that regardless of the belief at which the adoption decision is taken our planner will always select the optimal threshold \( z^* \). Therefore, from the ex ante perspective \( z^* \) pins down the expected payoff upon adoption

\[
\hat{u}^2_p(S) = \frac{e^S}{1 + e^S} \left( 1 - e^{-r_2(S - z^*)} \right) + \frac{1}{1 + e^S} \left( 1 - e^{r_1(S - z^*)} \right),
\]

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where $S$ is the belief at which the planner adopts. Hence, our planner solves a classic Wald problem,
\[
\hat{u}_p^1(\sigma_0) \equiv \sup_{\tau, d\tau} \mathbb{E}_{\Omega \times \Theta} \left[ d\tau \left( e^{-r\tau} \hat{u}_p^2(\sigma_\tau) \right) - \int_0^\tau e^{-r t} d\tau \left| \sigma_0 \right. \right].
\]
Notice that for a given stopping time $\tau$ we have $d\tau = 1 \iff \hat{u}_p(\sigma_\tau) \geq 0$. Therefore this is an optimal stopping with
\[
\hat{u}_p^1(\sigma_0) \equiv \sup_{\tau} \mathbb{E}_{\Omega \times \Theta} \left[ e^{-r\tau} \left( \hat{u}_p^2(\sigma_\tau) + \frac{c}{r} \right) \right] - \frac{c}{r}.
\]
By Lemma 2 we know that the optimal solution consists of selecting a policy with two thresholds $(s, S)$ around the initial belief $\sigma_0$, one for rejection and one for adoption. Following Stokey (2009, Chapter 5), define the expected discounted probabilities that given state $\theta$ the adoption and rejection standards are reached first respectively,
\[
\Psi(\sigma_0, \theta, s, S) = \mathbb{E}_{\Omega}[e^{-r\tau}|\sigma_\tau = S, \theta, \sigma_0] \Pr(\sigma_\tau = S|\theta, \sigma_0)
\]
\[
\psi(\sigma_0, \theta, s, S) = \mathbb{E}_{\Omega}[e^{-r\tau}|\sigma_\tau = s, \theta, \sigma_0] \Pr(\sigma_\tau = s|\theta, \sigma_0)
\]
where $\Pr(A) = P_T\{\sigma_t^{-1}(\omega, \theta)\} = P_T\{(\omega, \theta) \in \Omega \times \Theta|\sigma_t(\omega, \theta) \in A\}$ and $A$ is a Borel set. Hence we can rewrite the planner’s utility as
\[
u_p^1(\sigma_0, \tau(s) \land \tau(S), \theta) = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} u_p^1(\sigma_0, \tau(s) \land \tau(S), G) + \frac{1}{1 + e^{\sigma_0}} u_p^1(\sigma_0, \tau(s) \land \tau(S), B),
\]
where for $\theta \in \{A, B\}$
\[
\hat{u}_p^1(\sigma_0, \tau(s) \land \tau(S), \theta) = \sum_{\gamma \in \{s, S\}} \Pr(\sigma_\tau = \gamma|\theta, \sigma_0) \mathbb{E}_{\Omega} \left[ e^{-r\tau} \hat{u}_p^2(\sigma_\tau, \theta) - \int_0^\tau e^{-r t} dt \right] \sigma_\tau = \gamma, \sigma_0, \theta
\]
\[
= -\frac{c}{r} + \left( \hat{u}_p^2(S, \theta) + \frac{c}{r} \right) \Psi(\sigma_0, \theta, s, S) + \frac{c}{r} \psi(\sigma_0, \theta, s, S)
\]
and $\hat{u}_p^2(\sigma_\tau, \theta) = \left( \frac{\nu_p}{\nu} \right)^\theta \left( 1 - \psi(\sigma_\tau, \theta, z^*) \right)$. The planner solves $\max_{s, S} u_p^1(\sigma_0, \tau(s) \land \tau(S))$. Using the closed-form expressions for $\Psi$ and $\psi$ defined in Henry and Ottaviani (2017),
\[39\] the first order conditions are
\[
\frac{\partial u_p^1}{\partial S} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \left\{ a \left[ u_p^2(S, G) + e^{-S} u_p^2(S, B) + \left( 1 + e^{-S} \right) \frac{c}{r} \right] + b \left( 1 + e^{-S} \right) \frac{c}{r} + e^{-S} e^{-\frac{c}{r}} \right\}
\]
\[
\frac{\partial u_p^1}{\partial S} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \left\{ f \left[ u_p^2(S, G) + e^{-S} u_p^2(S, B) + \left( 1 + e^{-S} \right) \frac{c}{r} \right] + g \left( 1 + e^{-S} \right) \frac{c}{r} \right\}
\]
\[39\]In Appendix A of Henry and Ottaviani (2017), it is shown that $\Psi(\sigma, G, s, S) = e^{-R_1(\sigma - g)} e^{-R_2(\sigma - g)}$ and $\psi(\sigma, G, s, S) = e^{-R_1(\sigma - g)} e^{-R_2(\sigma - g)}$. Moreover in Lemma B1 they show that $\Psi(\sigma, B, s, S) = e^{-S} \Psi(\sigma, G, s, S)$ and $\psi(\sigma, B, s, S) = e^{-S} \psi(\sigma, G, s, S)$.
from which one can verify that the optimal solution \( s^* \) and \( S^* \) are independent from the initial belief \( \sigma \).

**Step 3:** The optimal triplet solution \((s^*, S^*, z^*)\) is such that \( s^* \leq z^* \leq S^* \).

The continuation value, upon transferring at any belief \( \sigma \) is given by \( \hat{u}_p^2(\sigma) \). Notice that the continuation value \( \hat{u}_p^2(\sigma) \) is always nonnegative (i.e. \( \hat{u}_p^2(\sigma) \geq 0 \)). In particular, we have that \( \hat{u}_p^2(\sigma) = 0 \) for all \( \sigma \leq z^* \) and \( \hat{u}_p^2(\sigma) > 0 \) and strictly increasing for \( \sigma > z^* \). In other words, \( z^* \) is the highest belief at which the planner is indifferent between rejecting and adopting. Therefore, around \( z^* \) the option value of experimenting is non-negative.

**Proof of Proposition 2**

**Step 1:** Adoption and rejection standards are decreasing in \( v^G_p \).

By the implicit function theorem it is enough to study the sign of \( \frac{\partial u^1_p}{\partial s \partial v^G_p} \) to infer the sign of \( \frac{\partial b_p(S)}{\partial v^G_p} \). Taking the derivative we have

\[
\frac{\partial u^1_p}{\partial s \partial v^G_p} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \psi e^0 \left\{ \left[ u^2_{p,z}(S, G, z) + e^{-S} u^2_{p,z}(S, B, z) \right] \frac{\partial z}{\partial v^G_p} + \left( 1 - e^{-r_2(S-z)} \right) \right\}
\]

by the Envelope Theorem the first term in the round brackets is zero. Therefore, we obtain

\[
\frac{\partial u^1_p}{\partial s \partial v^G_p} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \psi e^0 \left( 1 - e^{-r_2(S-z)} \right) \frac{1}{r} < 0,
\]

which is negative since \( a < 0 \) and the last fraction is positive.

Following the same reasoning for \( b_p(S) \), we can show that \( \frac{\partial B_p(s)}{\partial v^G_p} < 0 \) under strong liability \( L = \bar{L} \) the firm solves a stand-alone problem with insufficient incentives in the good state \( v_i < v^G_p \), hence \( z_{ii}(\bar{L}) > z^* \), \( s_{ii}(\bar{L}) > s^* \), and \( S_{ii}(\bar{L}) > S^* \).

**Step 2:** The optimal liability \( L^* \) is interior: \( v_i < L^* < \bar{L} \).

Notice that for any \( L \leq v_i \) the firm as no incentive in conducting costly experimentation neither ex ante nor ex post. Indeed, \( s_{ii} = z_{ii} = S_{ii} = 0 \) since in both states the firm will get a strictly positive payoff. Therefore it must be the case that \( L^* > v_i \). From step one we know that at \( L = \bar{L} \) the firm incentives in the good state are insufficient and consequently she performs insufficient experimentation ex ante, adopts too late and withdraws too early. By selecting \( L < \bar{L} \) the planner increases the firm value in the bad state of the world. Since the firm solves a stand alone problem, it is enough to study how the social planner reacts when \( v^B_p \) increases. The withdrawal standard decreases in \( v^B_p \) indeed let \( z^* = -\ln \frac{v^B_r}{v^B_p} \) then \( \frac{\partial z^*}{\partial v^B_p} = \frac{1}{v^B_p} < 0 \). For the rejection standard by the

\[\text{The terms } a, b, f, g \text{ are functions of } s \text{ and } S \text{ and are defined in Appendix A Lemma B0 of Henry and Ottaviani (2017).}\]
Following the same reasoning, as before we have \( \frac{\partial u_{p,s}^1}{\partial v_p^B} \). By taking the derivative and proceeding as in step 1 we obtain

\[
\frac{\partial u_{p,s}^1}{\partial v_p^B} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \frac{ae^{-S}}{r} < 0.
\]

For the adoption standard \( S^* \), following the same reasoning we have \( \frac{\partial u_{p,s}^1}{\partial v_p^B} < 0 \).

Therefore, by reducing the liability the planner pushes the firm to increase experimentation, to adopt earlier and to withdraw later. Hence, it must be the case that \( L^* < \hat{L} \).

**Step 3:** There exists \( \hat{L} \) such that \( s^* \leq s_{ii}(\hat{L}) \leq S^*_i(\hat{L}) \leq S^* \).

We can easily solve for \( L \) such that \( z^* = z_{ii}(L) \) to find that \( \hat{L} = \frac{\nu_i(v_p^G - v_p^B)}{(v_p^B)^2} \). To show that the amount of ex ante experimentation under liability at \( L = \hat{L} \) is lower than the socially optimal level, consider the single decision maker problem and perform comparative statics with respect to the payoffs \( v^G \) and \( v^B \) when they change in order to keep the withdrawal standard at the same level. Recall that for a decision maker with payoffs \( v^G > 0 \) and \( v^B < 0 \), the optimal withdrawal standard is given by \( z^* = -\ln \left( \frac{r_G}{r_B} \right) \). To keep \( z^* \) constant when we change the payoffs it must hold that

\[
\frac{\partial v_B}{\partial v_G} = \frac{v^B}{v^G}.
\]

The marginal value for any given \( S \) of rejecting earlier is given by

\[
\frac{\partial u_1^1(\sigma_0)}{\partial S} \bigg|_{s=b(S)} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \left\{ a \left[ u^2(S, G) + e^{-S}u^2(S, B) + \left( 1 + e^{-S} \right) \frac{c}{r} \right] + b \left( 1 + e^{-S} \right) \frac{c}{r} - e^{-S} \frac{c}{r} \right\}
\]

by the implicit function theorem and the concavity of the problem it suffices to study the sign of

\[
\frac{\partial u_1^1(\sigma_0)}{\partial S} \bigg|_{s=b(S)} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \frac{a}{v_G} \left[ u^2(S, G) + e^{-S}u^2(S, B) \right] < 0
\]

for \( S > z^* \), to imply that \( \frac{\partial b(S)}{\partial v^G} < 0 \). Therefore, if \( v^G \) decreases and \( v^B \) increases to keep \( z^* \) unchanged, the ex ante rejection standard \( s = b(S) \) is higher for any adoption standard \( S > z^* \).

Turning to the marginal value of adopting later for any given \( s \), we have

\[
\frac{\partial u_1^1(\sigma_0)}{\partial S} \bigg|_{S=B(s)} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \left\{ f \left[ u^2(S, G) + e^{-S}u^2(S, B) + \left( 1 + e^{-S} \right) \frac{\xi}{r} \right] + g \left( 1 + e^{-S} \right) \frac{\xi}{r} - e^{-S} \frac{\xi}{r} \right\}.
\]

Following the same reasoning, as before we have

\[
\frac{\partial u_1^1(\sigma_0)}{\partial S} \bigg|_{S=B(s)} = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} \Psi \left\{ f \left[ u^2(S, G) + e^{-S}u^2(S, B) \right] - e^{-S}u^2(S, B) \right\} > 0
\]
which implies that \( \frac{\partial B(s)}{\partial L} > 0 \). When \( \nu G \) decreases and \( \nu B \) increases to keep \( z^* \) unchanged, the adoption standard will be lower for any given \( s \). Notice that the term \( f \left( u^2(S, G) + e^{-S}u^2(S, B) \right) - e^{-S}u^2(S, B) \) is positive. Indeed at \( S = B(s) \),

\[
f \left( u^2(S, G) + e^{-S}u^2(S, B) \right) - e^{-S}u^2(S, B) = - \left[ f \left( 1 + e^{-S} \right) \frac{c}{r} + g \left( 1 + e^{-S} \right) \frac{c}{r} - e^{-S} \frac{c}{r} \right].
\]

and the term in brackets on the right hand side can be seen as the marginal value of approving later for an agent that obtains zero payoff regardless of the state and pays research cost \( c > 0 \), hence it has to be negative\(^{[41]}\).

**Step 4:** The optimal liability \( L^* \) is such that \( s^* \leq s_{ii}(L^*) \leq S_{ii}(L^*) \leq S^* \).

Suppose \( L = \hat{L} \) then the ex post value is maximized but from step 3 we know that the ex ante amount of experimentation is insufficient. If \( L^* \geq \hat{L} \) and \( S_{ii}(L^*) \geq S^* \) then reducing the liability would move all standards closer to the socially optimal levels, hence it must be the case that \( S_{ii}(L^*) \leq S^* \). Analogously, one can show that \( s^* \leq s_{ii}(L^*) \).

**Step 5:** The optimal liability \( L^* \) is a function of the initial belief \( q_0 \) and such that \( L^* \leq \hat{L} \) (resp. \( L^* \geq \hat{L} \)) if \( q_0 \in (q, \bar{q}) \) (resp. \( q_0 \in (\hat{q}, \bar{q}) \)).

First recall that \( u^1_p(q_0) \) is increasing in \( \sigma_0 \) and it can be rewritten as

\[
u^1_p(\sigma_0, s, S) = \frac{e^{\sigma_0}}{1 + e^{\sigma_0}} u^1(\sigma_0, s, S, G) + \frac{1}{1 + e^{\sigma_0}} u^1_p(\sigma_0, s, S, B)
\]

where for \( \theta \in \{ G, B \} \)

\[
u^1_p(\sigma_0, s, S, \theta) = -\frac{c}{r} + \left[ \partial \hat{u}^2_p(S, \theta) + \frac{c}{r} \right] \Psi(\sigma_0, \theta) + \frac{c}{r} \psi(\sigma_0, \theta).
\]

Clearly, if \( q_0 \leq s^* \) or \( q_0 \geq S^* \) then the planner will select a liability level such that the firm immediately rejects in the first case and immediately adopts in the second case. Let us focus on the case in which \( q_0 \in (s^*, S^*) \), we have two cases. If \( e = 0 \) then \( L^* = \hat{L} = \bar{L} \) for any \( q_0 \). If \( e > 0 \), we now show that it is optimal for the planner to impose a liability level \( L^* \neq \hat{L} \). Suppose that \( L = \hat{L} \), then \( z_{ii}(\hat{L}) = z^* \); we now study the sign of

\[
\frac{\partial u^1_p(\sigma_0)}{\partial L} = \frac{\partial u^1_p(\sigma_0)}{\partial z} \frac{\partial z}{\partial L} + \frac{\partial u^1_p(\sigma_0)}{\partial s} \frac{\partial s}{\partial L} + \frac{\partial u^1_p(\sigma_0)}{\partial S} \frac{\partial S}{\partial L}
\]

evaluated at \( (s_{ii}(\hat{L}), z_{ii}(\hat{L}), S_{ii}(\hat{L})) \). The first term is zero since \( z_{ii}(\hat{L}) = z^* \), the second term is negative and the third is positive, hence the sign depends on the initial belief \( q_0 \). As \( q_0 \to s_{ii}(\hat{L}) \) the marginal value of delaying adoption goes to zero \( \frac{\partial u^1_p(\sigma_0)}{\partial S} \to 0 \) and \( \frac{\partial u^1_p(\sigma_0)}{\partial s} = \frac{\partial u^1_p(\sigma_0)}{\partial L} < 0 \). Therefore, \( L^* < \hat{L} \). By the same argument when \( q_0 \to S_{ii}(\hat{L}) \) we have \( \frac{\partial u^1_p(\sigma_0)}{\partial L} = \frac{\partial u^1_p(\sigma_0)}{\partial S} > 0 \) and clearly, \( L^* > \hat{L} \). By continuity there exists \( \hat{q} \) such that \( \frac{\partial u^1_p(\sigma_0)}{\partial s} = \frac{\partial u^1_p(\sigma_0)}{\partial L} = 0 \) and \( L^* = \hat{L} \).

\(^{[41]}\)Given that zero is obtained regardless, it is optimal to set \( B(s) = s \) for any given \( s \). Thus, \( \frac{\partial B(s)}{\partial s} < 0 \) for any \( s \).
Taking the cross derivative with respect to \( z \) we obtain

\[
\frac{\partial^2 u^1(\sigma)}{\partial S \partial z} = \frac{\sigma}{1 + \sigma} \Psi \left\{ f \left( \frac{\partial u^2(S,G,z)}{\partial z} + e^{-S} \frac{\partial u^2(S,B,z)}{\partial z} \right) - e^{-S} \frac{\partial u^2(S,B,z)}{\partial z} + \frac{\partial u^2(S,G,z)}{\partial z} + e^{-S} \frac{\partial u^2(S,B,z)}{\partial z} \right\},
\]

where \( \frac{\partial u^2(S,G,z)}{\partial z} = -r_2(\frac{\sigma}{\tau})e^{-r_2(S-z)} = -\frac{\partial u^2(S,G,z)}{\partial S} \) and \( \frac{\partial u^2(S,B,z)}{\partial z} = r_1(\frac{\sigma}{\tau})e^{-r_1(S-z)} = -\frac{\partial u^2(S,B,z)}{\partial S} \).

Noticing that \( \frac{\partial u^2(S,G,z)}{\partial S} = r_2(\frac{\sigma}{\tau})e^{-r_2(S-z)} = -r_2 \frac{\partial u^2(S,G,z)}{\partial z} \) and \( \frac{\partial u^2(S,B,z)}{\partial S} = r_1(\frac{\sigma}{\tau})e^{-r_1(S-z)} = r_1 \frac{\partial u^2(S,B,z)}{\partial z} \),

we can rewrite

\[
\frac{\partial^2 u^1(\sigma)}{\partial S \partial z} = \frac{\sigma}{1 + \sigma} \Psi \left\{ f \left( \frac{\partial u^2(S,G,z)}{\partial z} + e^{-S} \frac{\partial u^2(S,B,z)}{\partial z} \right) - e^{-S} \frac{\partial u^2(S,B,z)}{\partial z} - r_2 \frac{\partial u^2(S,G,z)}{\partial z} + e^{-S} \frac{\partial u^2(S,B,z)}{\partial z} \right\}
\]
and thus
\[ \frac{\partial^2 u_1^1(\sigma)}{\partial S \partial z} = \frac{e^\sigma}{1 + e^\sigma} \Phi(f - r_2) \left( \frac{\partial u_2^2(S,G,z)}{\partial z} + e^{-S} \frac{\partial u_2^2(S,B,z)}{\partial z} \right) , \]
using \( r_1 + r_2 = 1 \). Hence, the sign of the numerator will be determined by the last term. Clearly, if \( z > z^* \) then the term above is negative, which implies that the sign of \( \frac{\partial B(s)}{\partial z} \) is positive. Following the same argument one can show that \( \frac{\partial b(S)}{\partial z} > 0 \) if and only if \( z > z^* \). Notice that the optimal withdrawal for the firm would be \( z_i^* = 0 \), therefore whenever the social planner commits to a positive withdrawal, the firm will increase both adoption and rejection standards.

**Step 2:** There exists \( \bar{e} \) such that \( s_{ip}^* = s^* \) when the planner commits to \( z_{ip} = z^* \).
The rejection standard is decreasing in \( v_p^B \) when the planner commits to the optimal withdrawal \( z^* \). Indeed, we have
\[ \frac{\partial u_1^1}{\partial S \partial v_p^B} = \psi \alpha e^{-S} \frac{\partial u_2^2(S,z^*,B)}{\partial v_p^B} < 0. \]
Hence, when \( e = 0 \) it must be the case \( s_{ip} < s^* \) when the planner commits to the optimal ex post withdrawal. On the contrary, if \( e \rightarrow 1 \) the firm has no value in experimenting ex ante. Therefore, \( s_{ip} \rightarrow z^* > s^* \). By continuity, there exists \( \bar{e} \) such that \( s_{ip} = s^* \) when the planner commits to the optimal withdrawal. With some algebra one can verify that \( \frac{\partial u_1^1}{\partial s \partial e} = \frac{e^\sigma}{1 + e^\sigma} \psi(\sigma,G,S,s) \left[ -\frac{G}{r} (1 - \psi(S,G,z)) - e^{-S} \frac{G}{r} (1 - \psi(S,B,z)) \right] > 0 \), so that \( \frac{\partial b_{0}(S_{ip})}{\partial e} > 0 \). Thus, \( \bar{e} \) is also unique.

**Step 3:** If \( e \leq \bar{e} \) then \( z_{ip}^* > z^* \), whereas if \( e > \bar{e} \) there exists \( \bar{q}(e) \) such that if \( q_0 \leq \bar{q}(e) \) (resp. \( q_0 > \bar{q}(e) \)) then \( z_{ip}^* < z^* \) (resp. \( z_{ip}^* > z^* \)).
If \( e \leq \bar{e} \) it is unambiguously optimal for our planner to commit to be tougher ex post \( z_{ip}^* > z^* \). Indeed,
\[ \frac{\partial u_1^1(\sigma_0)}{\partial z} = \frac{\partial u_1^1(\sigma_0)}{\partial S} \frac{\partial S}{\partial z} + \frac{\partial u_1^1(\sigma_0)}{\partial s} \frac{\partial s}{\partial z} + \frac{\partial u_1^1(\sigma_0)}{\partial z} \]
evaluated at \((s_{ip}, z^*, S_{ip})\) is positive. In fact, by step 1 we know that the first and second term are positive, while the last term is zero since the withdrawal is set at the optimal level.

If \( e > \bar{e} \) the role of the initial belief matters, since the second term of the expression above is not negative \( \frac{\partial u_1^1(\sigma_0)}{\partial s} \frac{\partial s}{\partial z} < 0 \). Overall the sign will depend on the initial belief \( q_0 \). As \( q_0 \rightarrow s_{ip} \) then the marginal value of delaying adoption goes to zero. Hence, we are left with \( \frac{\partial u_1^1(\sigma_0)}{\partial s} = \frac{\partial u_1^1(\sigma_0)}{\partial s} \frac{\partial s}{\partial z} < 0 \) which implies that \( z_{ip}^* < z^* \). The opposite holds if \( q_0 \rightarrow S_{ip} \). In this case the planner commits to be tougher \( z_{ip}^* > z^* \). Therefore, there exists \( \bar{q}(e) \in (s_{ip}, S_{ip}) \) such that \( z_{ip} = z^* \).

**Proof of Proposition 4**

**Step 1:** The rejection standard is increasing in \( S \).
First notice that under the ex ante regulation framework firm \( i \) controls the withdrawal standard
and therefore $z_{pi} = 0$. The lower best reply is then implicitly defined for any given adoption standard $S$ as

$$\frac{\partial u_1^i}{\partial s} = \frac{e^{\sigma}}{1 + e^{\sigma}} \Psi \left\{ a \left( \frac{(1 - e) v_p^G}{r} + \frac{c}{r} \right) \left( 1 + e^{-S} \right) + b(1 + e^{-s}) \frac{c}{r} - e^{-s} c \right\}. $$

By the implicit function theorem we can see that $b(S)$ is increasing in $S$. Indeed,

$$\frac{\partial u_1^i}{\partial s \partial S} = -a \left( \frac{(1 - e) v_p^G}{r} + \frac{c}{r} \right) e^{-S} > 0.$$

**Step 2:** There exists $\tilde{e}$ such that $s_{pi} = s^*$ if the planner commits to the socially optimal adoption standard $S^*$.

If $e = 0$ then the firm payoff is aligned to our planner’s one in the good state $v_p^G$. From Step 2 in Proposition 2 we know that $\frac{\partial u_1^i}{\partial s \partial v_p^G} < 0$ therefore it must be the case that $s_{pi} < s^*$.

If $e \to 1$ then the value of ex ante experimentation goes to zero, which implies that $s_{ip} \to S^* > s^*$ (as in Figure 6). This implies that there exists an externality level $\tilde{e}$ such that $s_{ip} = s^*$ which by step 1 is also unique.

**Step 3:** There exists $\hat{e}$ and $\tilde{e}$ such that $\tilde{e} \in (\hat{e}, \tilde{e})$. Moreover if $e \geq \hat{e}$ (resp. $e \leq \tilde{e}$) then there exists $\bar{q}(e)$ such that if $q_0 \leq \bar{q}(e)$ (resp. $q_0 \geq \bar{q}(e)$) the planner commits to be more lenient $S_{pi}^* < S^*$.

First notice that under Ex Ante regulation only, our planner has no way of change the ex post withdrawal incentives of firm $i$, therefore we will always have no ex post withdrawal $z_{pi} = 0$. The problem reduces to the Planner Commitment problem described by Henry and Ottaviani (2017). The social planner will select the adoption standard as in the classic Wald framework (i.e. with only the ex ante phase) taking into account that ex post $z_{pi} = 0$.

Step 1 of Proposition 4 implies that when $z = 0$ the planner upper (resp. lower) best reply has to be above (resp. to the left) of the planner upper (resp. lower) best reply when $z = z^*$. Moreover, recall that as $e$ increases the firm lower best reply $b_i(S)$ shifts to the right.

Now define $\hat{e}$ (resp. $\tilde{e}$) be the externality level such that, when $z = 0$, the firm lower best reply $b_i(S)$ intersects the planner upper best reply $B_p(s)$ (resp. the planner lower $b_p(S)$) exactly at $(b_i(S^*), S^*)$. Moreover, for a given $e$, let $\tilde{S}$ be the adoption standard that is identified at the intersection between the lower best replies, i.e., $\tilde{S}$ for which $b_i(\tilde{S}) = b_p(\tilde{S})$.

Henry and Ottaviani (2017) show that the planner commitment $S_{pi}^*(q_0) \in (\tilde{S}, S^N)$ and can be

---

42 It is easy to verify that $\frac{\partial u_1^i}{\partial s \partial e} > 0$.

43 This point corresponds to the Informer Authority solution proposed in Henry and Ottaviani (2017) in the game between the planner and the firm (our firm).
either increasing or decreasing in $q_0$. In particular, if $e \in (\hat{e}, \tilde{e})$ then by construction $S_{ip}^*(q_0) > S^*$ for any $q_0$. If $e \geq \hat{e}$ then the commitment path is increasing and $S^* \in (\tilde{S}, S^N)$ hence it is enough to define $\tilde{q}(e)$ the belief such that $S_{pi}^*(\tilde{q}(e)) = S^*$. If instead $e \leq \hat{e}$ the commitment path is decreasing and $S^* \in (S^N, \tilde{S})$ again it is enough to define $\tilde{q}(e)$ the belief such that $S_{pi}^*(\tilde{q}(e)) = S^*$.

We can thus conclude that if $e \geq \hat{e}$ there exists $\tilde{q}(e) \geq 0$ such that whenever $q_0 \leq \tilde{q}(e)$ the planner wants to be more lenient $S_{pp}^* < S^*$.

Figure 12 shows this property. The dotted green represents the optimal ex ante commitment solution as function of the externality. The externality level $\hat{e}$ is such that $S_{pi}^*(\hat{e}) = S^*$ (i.e. were the dotted green intersects the green continuous horizontal line).

**Proof of Proposition 5**

**Step 1:** There exists $\hat{e}$ such that the socially optimal policy $(s^*, z^*, S^*)$ is achieved when the planner commits to $S_{pp} = S^*$ and $z_{pp} = z^*$.

At $e = 0$, we know that the firm lower best reply is always to the left of the planner’s one. In fact, $\frac{\partial u_{1p}}{\partial s_{ip}} < 0$ which implies that $s_{pp} < s^*$ when the planner commits to $S_{pp} = S^*$ and $z_{pp} = z^*$. If $e \to 1$ then the value of ex ante experimentation goes to zero, implying that $s_{pp} \to S^* > s^*$. By continuity there exists $\hat{e}$ such that $s_{pp} = s^*$, moreover since $\frac{\partial u_{1p}}{\partial s_{ip}} > 0$ this is also unique.

**Step 2:** Suppose the planner can use all three instruments and denote the resulting policy as $(s_{pp}(L), z_{pp}(L), S_{pp}(L))$. If $\hat{e} \leq \tilde{e}$ the planner achieves the first best, by committing to $S_{pp} = S^*$ and $z_{pp} = z^*$.

44For given level of $e$, $S^N$ identifies the adoption standard at the intersection between $b_i(S)$ and $B_p(S)$ when $z = 0$. This points correspond to the Nash solution in Henry and Ottaviani (2017).
If \( e = 0 \) then strong liability \( L = \bar{L} \) achieves the first best. If instead, \( e = \hat{e} \) step 1 tells us that committing to the socially optimal withdrawal and adoption standards is enough to obtain the first best policy. Hence, in this case \( L = 0 \) and \( s_{pp}(0) = s^*, S_{pp}(0) = S^*, z_{pp}(0) = z^* \).

Now fix \( e \in (0, \hat{e}) \). If \( L = \bar{L} \) then \( s^* < s_{pp}(\bar{L}) \). To see this, notice that when \( e = 0 \) and \( L = \bar{L} \) the planner and firm marginal value of rejecting earlier are perfectly aligned \( \frac{\partial u^1_p}{\partial s} = \frac{\partial u^1_i}{\partial s} \), and \( \frac{\partial u^1_i}{\partial s_{de}} > 0 \). On the contrary if \( L = 0 \) by step 1 we have \( s_{pp}(0) < s^* \). By continuity there exists \( L(e) \in (0, \hat{L}) \) such that \( s_{pp} = s^* \), moreover this liability level is unique since \( \frac{\partial u^1_i}{\partial s_{de}} > 0 \).

**Step 3:** If \( e > \hat{e} \) liability is set to zero \( L = 0 \) and the planner commits to be more lenient \( S_{pp} < S^* \) and \( z_{pp} < z^* \).

If \( e > \hat{e} \) from step 2, we know that \( L = 0 \). Moreover, if the planner commits to \( S^* \) ex ante and \( z^* \) ex post, then the firm has insufficient research incentives \( s_{pp} > s^* \). By committing to be more lenient, the planner incurs in a second order loss in the adoption and withdrawal standards but first order gains since the firm will reduce the rejection standard.

**Proof of Proposition 6**

**Step 1:** If \( F = \infty \) there exists \( \hat{e} \in (0, 1) \) such that the planner requires report \( S = S^* \), commits to \( z = z^* \) and the firm replies with \( s_i = s^* \) and \( S_i = S^* \).

If \( F = \infty \) then for the firm is clearly optimal to acquire information up to the required approval \( S_i = S^* \). In fact, the firm has controls only \( s \). If \( e = 0 \) for any \( S \) the best reply of the informer is to the left of the planner’s one, therefore \( s_i < s^* \). On the contrary, if \( e \to 1 \) then the value of ex ante experimentation goes to zero, implying that \( s_i \to S_i = S^* > s^* \). By continuity there exists \( \hat{e} \) such that \( s_i = s^* \), moreover since \( \frac{\partial u^1_i}{\partial s_{de}} > 0 \) this is also unique.

**Step 2:** If \( e \leq \hat{e} \) the planner achieves the first best by requiring \( S = S^* \) and committing to \( z = z^* \). The firm lies in equilibrium.

The upper and lower best replies of the firm under costly lying are implicitly defined respectively by

\[
\frac{\partial u^1_i}{\partial S_i} - f e^{-S_i} FP(S - S_i) + e^{-S_i} FP'(S - S_i) = 0 \quad (4)
\]

\[
\frac{\partial u^1_i}{\partial S_i} - ae^{-S_i} FP(S - S_i) = 0. \quad (5)
\]

If \( e = 0 \), the planner can perfectly align the incentives in the bad state by setting \( F = \bar{L} \) and requiring \( S = 1 \) which in turns pushes \( P(S - S_i) = 1 \) and \( P'(S - S_i) = 0 \). In this case the firm will reply by selecting \( S_i = S^* \) and \( s_i = s^* \). The expected penalty is \( FP(S - S_i) = \bar{L} \). As \( e \) increases, the planner needs to reduce through \( S \) and \( F \) the expected penalty since \( \frac{\partial u^1_i}{\partial s_{de}} > 0 \) and \( \frac{\partial u^1_i}{\partial s_{de}} > 0 \). For \( e \in (0, \hat{e}) \) if the planner keeps \( S = 1 \) the resulting regulatory regime would be equivalent to one in which the planner commits \( L \) and \( z \) under public information. In fact, in this case the firm will not be able to significantly influence the size of the lie since the probability of reaching the
report $S = 1$ is zero. Thus, simply reducing the fine $F$ will not allow the planner to achieve the first best.

By setting the required report $S < 1$ at an interior level, the planner can effectively control the firm incentives to lie (i.e., $F'(S - S_i) > 0$). For a given $S$ the upper(resp. lower) best reply shift up(resp. left) as $F$ increases. The same comparative statics holds for $S$, given $F$. The optimal combination $(F, S)$ solves simultaneously the two equations above evaluated at $s_i = s^*$ and $S_i = S^*$.

**Step 3:** If $e > \hat{e}$ then $F = \infty$, there is no lying in equilibrium $S = S_i < S^*$ and the ex post commitment is lenient.

This follows directly from Proposition 5, indeed for $e > \hat{e}$ the planner shuts liability and commits to a more lenient regulation in both $S$ and $z$. Under costly lying the planner puts $F = \infty$ thus pushing the informer not to lie $S = S_i$. In this way the expected penalty for lying is zero, the planner controls directly the approval in equilibrium while the firm best replies with $s$.

### A.1 Robustness of Optimal Mix of Instruments under Costly Lying

The planner commits at $t = 0$ to a combination of instruments $(S, z, L)$. Information collection in the first phase is private and non verifiable, so that the firm can at any stage report $S$ and obtain approval. We assume that $F$, the fine imposed if the firm is found lying, is given and is not an instrument strategically chosen by the planner. Proposition 7 shows the conditions under which the results of Proposition 5 are preserved under private information collection with costly lying.

**Proposition 7 (a)** With private information collection in the ex ante phase, there exists a level of fine $\tilde{F}$, such that for $F > \tilde{F}$:

(i) There exists $\tilde{e} < \hat{e}$ such that the first best is achieved if and only if $e < \tilde{e}$ and all three instruments are used,

(ii) liability is set to zero if $e \geq \tilde{e}$ and is lower than with public information for all $e$,

(iii) In an optimal mix of instruments, the ex post commitment is chosen equal or more lenient than the socially optimal levels $z^*$ and the belief of the firm at approval $S_i$ is lower or equal than the socially optimal approval standard $S^*$.

(b) If $e > 0$, the firm lies in equilibrium: $S_i < S$.

For a given fine $F$, changing the standard for approval $S$ has two effects. First it affects the level $S_i$ at which the firm requests approval. Indeed, $S_i$ is increasing in $S$ since the firm reacts to the higher standard by searching more to decrease the size of the equilibrium lie. Second, $S$ also affects the rejection standard $s$ through its effect on the size of the lie. The expected penalty, that is incurred only in the bad state, plays a similar role as a liability rate, by decreasing the
expected payoff in the bad state. This explains result (a-ii) that states, as visible in Figure 14 that the liability rate will be smaller than the one imposed in the case with public information, since part of the benefit of reducing excessive research by the firm is provided by the expected fine for lying.

The main result of Proposition 5, that highlights that ex post and ex ante commitments are always lenient in an optimal mix of the three instruments, is preserved under private information collection when the fine is sufficiently high $F$. As showed in Figure 13 there is a first phase (for $e < \tilde{e}$) where withdrawal is set at the socially optimal level $z^*$, the required report standard $S$ is fixed in such a way that the firm asks for approval at the socially optimal level $S^*$ and the liability is chosen in such a way as to prevent socially excessive research and induce a rejection standard at the socially optimal level $s^*$. At some cutoff value $\tilde{e}$, the first best is no longer attainable and the planner is forced to stop using liability and be more lenient on the approval cutoffs compared to the socially optimal level in order to encourage research at the bottom. Proposition 7 shows that the cutoff externality $\tilde{e}$ is smaller than the cutoff under public information $\hat{e}$, introduced in Proposition 5. Indeed, for $e = \hat{e}$, where under private information the first best is attained with liability set at zero, this is no longer the case under private information since the payoff in the bad state is lower due to the expected penalty for lying, leading to insufficient research at the bottom. The planner is thus forced to decrease the ex post standards to encourage research ex ante.

What does this imply in terms of the optimal level of fine $F$? In the limit, when $F \to \infty$, there is no lying in equilibrium and welfare converges to the welfare in the case of public information. In the other extreme, when $F = 0$, the firm can at no cost provide any report and therefore can introduce the product in the market at any time. This second case is equivalent to the case with public information when the planner has access to only two instruments, $z$ and $L$, but cannot
use ex ante regulation. In between these two extremes, welfare is increasing in $F$, since as Proposition 7 demonstrates, the fine is a substitute instrument to liability to limit research at the bottom, but the expected fine cannot be set to zero since it also serves to prevent lying. It is thus more efficient to only use liability and set the fine very high in order to prevent misreporting in equilibrium.

Result (b) indicates that the firm always lies in equilibrium. This is directly implied by the fact that the marginal cost of lying at zero is zero ($P'(0) = 0$). Furthermore, the planner, for any approval standard $S$ required for approval, knows at what level $S_i$ the firm stopped searching and thus knows the size of the lie in equilibrium.

**Proof of Proposition 7**

**Step 1:** For any $F$ there exists $\bar{e}$ such that the first best is achieved if and only if $e < \bar{e}$.

If $F = \infty$ then $S_i = S$ there is no lying in equilibrium the problem reduces to find the optimal mix of instruments when information is public. Thus $\bar{e} = \hat{e}$ and the result in Proposition 5 hold.

By slightly decreasing $F$, the firm incentives to lie increase and in equilibrium the firm always lies. At $e = \hat{e}$ we have $S_i < S^*$. Since even if $L = 0$ there is still the risk of incurring in the penalty for lying and thus the planner cannot completely shut down all the liabilities in the bad state, and achieve the first best as under public information. Since the optimal liability when information is public and planner controls all three instruments (i.e. $F = \infty$) decreases in $e$, there must exist a $\bar{e}$ such that the expected fine equals the liability level $L(\hat{e})$ that the planner would impose under public information and thus achieve the first best. For all $e \in (0, \bar{e})$ the planner can reduce liability accordingly in order to align the payoff in the bad state between public and private information.

If $F = 0$ then the firm fully controls approval and the problem reduces to the planner optimally mixing $(L, z)$. Clearly, in this case $\bar{e} = 0$.

**Step 2:** There exists $\hat{F}$ such that for $F > \hat{F}$ we have $S_i < S^*$ and $z < z^*$ whenever $e > \bar{e}$.

For any $F$ we have that $S_i < S^*$ for $e > \hat{e}$. To see this notice that when $F = \infty$ this holds from Proposition 5. Decreasing $F$ thus pushes the firm to lie thus decreasing $S_i$.

If $F = 0$ for low externality $e$ the planner might need to be tougher on withdrawal $z > z^*$ to delay approval by the firm. If $F = \infty$ instead the commitment is always lenient $z < z^*$. As $F$ increases ($\bar{e}$ increases as well). For given $e \in (\bar{e}, 1)$ by continuity there exists $\hat{F}$ such that commitment to $z$ is lenient for all $e > \bar{e}$.
B Appendix B: Planner Benchmark with Costly Withdrawal

In the ex post phase of our baseline model the social planner is able to withdraw \((W)\) and reverse adoption at no cost. In many instances, however, unscrambling the eggs is costly. This appendix extends the model by requiring the planner to pay cost equal to \(K\) to exercise the withdrawal option. This extension makes our model applicable to settings such as mergers between companies where reversing the initial decision is costly. By introducing a fixed reversibility cost we can also connect our Wald problem with reversible decision (where \(K = 0\)) to the classic Wald problem with irreversible decision \((K = \infty)\).

In the ex post phase, the planner solves the optimal stopping problem

\[
\hat{u}^2_p(\sigma_0) \equiv \sup_{\tau} \mathbb{E}_{\Omega \times \Theta} \left[ -e^{-r\tau}K + q_\tau \left( \int_0^\tau e^{-r\tau}v^G_p dt \right) + (1 - q_\tau) \left( \int_0^\tau e^{-r\tau}v^B_p dt \right) \right] | \sigma_0
\]

for \(\theta \in \{G,B\}\) with \(K \geq 0\), where \(\tau^+ = \infty\) if \(K \geq -v^B_p/r\).

**Proposition 8 (a)** The withdrawal standard \(z^+(K)\) is decreasing in the fixed cost, \(K\).

**Proposition 8 (b)** The rejection standard \(s^+(K)\) and the adoption standard \(S^+(K)\) are both increasing in \(K\).

**Proposition 8 (c)** If \(K \geq -v^B_p/r\) all the optimal standards coincide with the solution to the classic Wald problem.

The intuition for (a) is straightforward. According to part (b), the ex ante standards increase in \(K\). The higher the withdrawal cost, the less valuable the withdrawal option for the planner, so that the planner becomes more careful before adopting \((S^+\) increases) and rejects more frequently \((s^+\) increases). Figure 16 shows the value function at the optimal three-thresholds policy \((s^+, S^+, z^+)\). Notice that Proposition 8-(c)’s property (that the ex ante optimal standards are centered around the withdrawal threshold \(z^+)\) does not necessarily hold when \(K > 0\).

According to part (c), when the cost of withdrawal is sufficiently high, we have \(z^+ = 0\) and the planner never reverses adoption, as in the classic Wald problem with irreversible adoption. Figure 15 displays the classic Wald value function in red and the ex post value in blue which is then in linear in \(q\). As \(K\) is reduced below \(-v^B_p/r\), the planner withdraws at positive beliefs \(z^+(K) > 0\); the ex post value becomes convex in \(q\), as shown in Figure 16. In the limit when withdrawal is costless \((K = 0)\) we are back to our baseline model, as shown in Figure 1.

B.1 Best Replies Construction

As also explained in the main text, the optimal solution of our two-phase experimentation problem can be represented in terms of thresholds. The solution thresholds are the belief levels at which the smooth-pasting conditions in all experimentation phases are satisfied. The optimal adoption standard \(S\), for instance, solves the corresponding optimality condition for a given
Figure 15: Value function for classic Wald problem.

Figure 16: Value function with withdrawal cost $K$. 
rejection $s$ and optimal withdrawal $z^*$ standards. Solving simultaneously also for the optimal rejection standard $s^*$ given $S$ and $z^*$, the optimal solution is found at the intersection of the the upper best reply $S = B(s)$ and the lower best reply $s = b(S)$ given the optimal withdrawal $z^*$.

To connect the optimality conditions in the classic Wald problem (with $K = \infty$) to the solution of our model with reversible adoption (with $K = 0$), we now analyze the impact of the cost $K$ of exercising the withdrawal option on these best replies. When the withdrawal cost $K$ is sufficiently high, the upper and lower best replies are as in Figure 17 and the optimal policy $(s^*, S^*)$ at their intersection is the well-known solution of the classic Wald problem. Given that withdrawing is too costly, in this case the planner never withdraws (i.e. $z^* = 0$). Figure 15 shows the resulting value ex ante function along with the ex post value function which is linear in $q$ in this specific case.

When $K$ is sufficiently low, the planner optimally withdraws as soon as the belief hits the withdrawal standard $z^*(K) > 0$. The continuation value becomes convex in $q$, as displayed in Figure 16. The fact that, differently from the classic Wald, the continuation value upon adoption is not linear influences the shape of the upper best reply $B(s)$. To understand this new shape, we need to analyze the continuation value upon adoption.

**Proposition 9** Given any commitment to a suboptimal withdrawal standard $z \neq z^*$ there exists a fixed withdrawal cost $K > 0$ such that when optimizing (taking $K$ into account) the continuation value upon approval is the same as the value under commitment.

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45See Henry and Ottaviani’s (2017) Appendix B.
Figure 18: Value under commitment or with costly withdrawal.

Figure 18 highlights the result in Proposition 9. The dashed-dotted line tangent at \( z^* \) to the horizontal axis represents the optimal continuation value when \( K = 0 \). If the planner commits to a suboptimal withdrawal such as \( z < z^* \) or \( z > z^* \), the continuation value shifts down. Clearly, there exists a withdrawal cost \( K > 0 \) such that when solving for the optimal withdrawal \( z^*(K) \) the continuation value coincides with the value resulting under commitment and \( K = 0 \).

As described in Proposition 1, the optimal solutions to this problem consist in a triplet of standards \((s^*, S^*, z^*)\), each one solving the corresponding smooth-pasting condition given the other standards. To understanding the shape of the upper best reply in Figure 20, Figure 19 shows an example of this solution. Fix \( s_1 < s^* \) and \( z^*(K) \), the smooth-pasting condition for the adoption standard admits two solutions. In particular, there are two value functions tangent to the continuation value respectively at \( S_1 \) (from below) and at \( S_1 \) (from above), both solving the smooth-pasting condition for a given \( s_1 \). To find the adoption standard that best responds to \( s_1 \), we keep \( S_1 \) (a point of maximum) but exclude \( S_1 \) (a point of minimum).\(^{46}\) Thus, \( S_1 = B(s_1) \) defines the upper best reply to \( s_1 \).

Repeating the process for any \( s \) given \( z^*(K) \) we plot the upper best reply function \( S = B(s) \) in Figure 20 along with \( B(s) \) of the classic Wald problem. When the withdrawal cost is not excessive, the upper best reply shifts down and becomes loop-shaped around \( z \) and \( z^* \). Fixing \( s_1 \) on the horizontal axis, Figure 20 shows the two solutions \( S_1 \) and \( S_1 \) to the optimality condition for the adoption standard; these solutions are generated by the loop-shaped part of the upper best reply, as in Figure 19.

\(^{46}\)The second-order conditions given by Arkin and Slastnikov (2013) allow us to discard solution \( S_1 \) as a point of minimum.
As $K$ decreases the loop shrinks and closes up at $z^*$ when $K = 0$, as illustrated in Figure 21. The highest dotted curve is the upper best reply for high withdrawal cost $K$ corresponding to the classic Wald with irreversible decision, when $z^* = \bar{z} = 0$ and $\bar{z} = \hat{q}$. As $K$ decreases, the upper best reply becomes loop-shaped and the planner withdraws at the positive belief $z^*(K) \in (\bar{z}, \bar{z})$. At $K = 0$, as in our baseline model, the loop closes up at the optimal withdrawal level $z^*$. Finally, the green line represents the path of the optimal ex ante rejection and adoption standards as a
function of $K$. Consistent with Proposition 8 (b), the path $(s^*(K), S^*(K))$ is increasing in $K$.

In our baseline model we have $K = 0$, thus when plotting the upper best reply in Figure 2 we need to exclude the lower part of the loop, corresponding to the solutions to the smooth pasting that are points of minimum.

**B.2 Proofs for Appendix B**

**Proof of Proposition 8**

**Step 1:** The optimal withdrawal standard $z^*$ is decreasing in $K$.

If the adoption decision has been taken at belief $S$, we can write the planner problem as

$$\max_{z} \left\{ e^{S} \left[ \left( \frac{v^G_p}{r} \right) - \left( \frac{v^G_p}{r} + K \right) \psi(S, G, z) \right] + \frac{1}{1+e^S} \left[ \left( \frac{v^B_p}{r} \right) - \left( \frac{v^B_p}{r} + K \right) \psi(S, B, z) \right] \right\}.$$ 

Taking first-order condition and rearranging we have $z^*(K) = -\log \frac{r_2(v^G + rK)}{r_1 v^G_p + rK}$ from which $\frac{\partial z^*(K)}{\partial K} = \frac{r(v^G_p - v^B_p)}{(v^G_p + rK)(v^B_p + rK)} < 0$ for $F < -\frac{v^B_p}{r}$ which is the relevant region for interior solutions.

**Step 2:** The optimal ex ante standards $s^*$ and $S^*$ are increasing in $K$.

The first order condition with respect to $S^*$ is

$$u^1_{p,s}(s, S, \sigma) = \frac{e^{\sigma_0}}{1+e^{\sigma_0}} \Psi \left\{ f \left[ u^2_{p}(S, G, z) + e^{-S} u^2_{p}(S, B, z) + (1 + e^{-S}) \xi \right] + g(1 + e^{-S}) \xi - e^{-S} \left[ \xi + u^2_{p}(S, B, z) \right] \right\},$$

Figure 21: Ex ante standards path as function of $K$. 
where \( u_p^2(S,G,z) = \left( \frac{v_p^G}{r} \right) - \left( \frac{v_p^G}{r} + K \right) e^{-r_2(S-z)} \), \( u_p^2(S,B,z) = \left( \frac{v_p^B}{r} \right) - \left( \frac{v_p^B}{r} + K \right) e^{r_1(S-z)} \) and \( f < 0 \) and \( g > 0 \). By the implicit function theorem we have that

\[
\frac{\partial S^*(K)}{\partial K} = -\frac{\frac{\partial u_p^1, S}{\partial K}}{\frac{\partial u_p^1, S}{\partial S}}_{S=S^*}.
\]

The denominator is negative being \( S^* \) a point of maximum, hence we can focus on the sign of the numerator. After some computations we have

\[
\frac{\partial u_p^1, S}{\partial K} = e^{\sigma_0} \Psi \left\{ f \left[ u_{p,K}^2(S,G,z) + e^{-S} u_{p,K}^2(S,B,z) \right] - e^{-S} u_{p,K}^2(S,B,z) \right\},
\]

where the term

\[
u_{p,K}^2(S,G,z) + e^{-S} u_{p,K}^2(S,B,z) = \left( -e^{-r_2(S-z)} - e^{-S} e^{r_1(S-z)} + [u_{p,z}^2(S,G,z) + e^{-S} u_{p,z}^2(S,B,z)] \frac{\partial z(K)}{\partial K} \right)
\]

is negative because by the Envelope Theorem we have \( u_{p,z}^2(S,G,z) + e^{-S} u_{p,z}^2(S,B,z) = 0 \) at \( z = z^* \). Moreover, \( u_{p,K}^2(S,B,z,z) = -e^{r_1(S-z)} + r_1 \left( \frac{v_p^B}{r} + K \right) e^{r_1(S-z)} < 0 \) at any interior solution \( z^* \). Overall, \( \frac{\partial u_p^1, S}{\partial K} > 0 \) proving that \( S^* \) is increasing in \( K \). Using the same argument one can show that also \( s^*(K) \) is increasing in \( K \).

**Step 3: If \( K \geq -\frac{v_p^B}{r} \) then the \( z^* = 0 \) the ex ante standards are the one solving the classic Wald problem.**

In this case the cost of exercising the withdrawal option is higher than the whole flow of profit resulting in the bad state of the world. Clearly, for the planner it is never optimal to select an interior withdrawal threshold. Therefore, the planner never withdraws, \( z^* = 0 \). The ex post value at \( z^* = 0 \) (corresponding to \( z^* = -\infty \)) is

\[
u_p^2(S,0) = \frac{e^S}{1 + e^S} \left( \frac{v_p^G}{r} \right) + \frac{1}{1 + e^S} \left( \frac{v_p^B}{r} \right),
\]

a straight line in the regular belief space \( q \). The planner ex ante solves a classic Wald problem for which abandoning results in a payoff of 0 and irreversibly adopting results in an expected payoff of \( u_p^2(S,0) \).

**Proof of Proposition 5**

Assume \( K = 0 \), then the continuation value upon adoption at \( S = \sigma \) is

\[
u_p^2(\sigma) = \frac{e^\sigma}{1 + e^\sigma} \left( \frac{v_p^G}{r} \right) \left( 1 - e^{-r_2(\sigma-z^*)} \right) + \frac{1}{1 + e^\sigma} \left( \frac{v_p^B}{r} \right) \left( 1 - e^{r_1(\sigma-z^*)} \right).
\]

\(^{47}\)Henry and Ottaviani (2017) characterize the properties of the functions \( \Psi, \psi, f, \) and \( g \).
Notice that \( \hat{u}^2_p(\sigma) \geq 0 \) for any \( \sigma \), decreasing for \( \sigma < z^* \) and increasing for \( \sigma > z^* \). At \( \sigma = z^* \) the continuation value is tangent to the horizontal axis and \( \hat{u}^2_p(z^*) = 0 \). If our social planner commits to a suboptimal \( z \neq z^* \) then \( \hat{u}^2_p(\sigma) \) shifts down in the belief space (see the blue dotted lines in Figure 18). Therefore, there are two beliefs \( z \) and \( \bar{z} \) such that \( \hat{u}^2_p(z) = 0 \) for \( z \in \{z, \bar{z}\} \) where either one of those is the suboptimal commitment and \( z^* \in (z, \bar{z}) \).

If instead \( K > 0 \) then the continuation value upon adoption at \( S = \sigma \) is

\[
\hat{u}^2_p(\sigma) = \frac{e^\sigma}{1 + e^\sigma} \left( \frac{v^G_p}{r} \right) \left( 1 - e^{-r_2(\sigma - z^*(K))} \right) + \frac{1}{1 + e^\sigma} \left( \frac{v^B_p}{r} \right) \left( 1 - e^{r_1(\sigma - z^*(K))} \right) - K \left( \frac{e^\sigma}{1 + e^\sigma} e^{-r_2(\sigma - z^*(K))} + \frac{1}{1 + e^\sigma} e^{r_1(\sigma - z^*(K))} \right).
\]

Notice that \( \hat{u}^2_p(\sigma) \geq -K \) for any \( \sigma \), decreasing for \( \sigma < z^*(K) \), and increasing for \( \sigma > z^*(K) \). At \( \sigma = z^*(K) \) the continuation value is tangent to the horizontal level \(-K\) and \( \hat{u}^2_p(z^*(K)) = -K \).

Given \( K = 0 \) and any suboptimal commitment \( z^c \neq z^* \), the withdrawal option cost \( K > 0 \) that solves

\[
l(\sigma, K) \equiv \hat{u}^2_p(\sigma, z^*(K)) - u^2_p(\sigma, z^c) = 0
\]

is such that the optimal solution taking into account the continuation value is the same as the solution under commitment \( z^c \) and no cost, \( K = 0 \). Notice that \( \frac{\partial l(\sigma,K)}{\partial K} < 0 \), \( l(\sigma,0) > 0 \), and \( l(\sigma,K) \leq 0 \) for \( K \) sufficiently high for any \( \sigma \). Hence, given \( z^c \) there exists \( K > 0 \) such that \( l(\sigma,K) = 0 \).