Indemnification, Monitoring, and Competition: Evidence from R&D Contracts*

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April 13, 2022

*We thank J.J. Prescott (the editor), two referees, Albert Choi, Kohei Kawaguchi, Kathryn E. Spier, Peng Wang, Abraham Wickelgren, and participants at the 29th American Law and Economics Association Annual Meeting for their valuable comments and suggestions. We also thank Whitney Chan, Kai Lung Chung, Andy Ko, Joshua Wong, David Yiu, and Long Zhong for their excellent research assistance. This work was supported by the Hong Kong Research Grants Council (GRF Grant Number: 16513916). All mistakes remain our own. Declarations of Interests: None.

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Abstract: This article examines the adoption of indemnification clauses in research and development (R&D) contracts, in which a firm commits to reimbursing its agent against liabilities and legal costs. Indemnification achieves efficient risk-sharing but dilutes the agent's incentives to take precautions. Such incentives may be restored if the firm offers contingent indemnification and monitors the agent's activities. Additionally, tougher competition can motivate the firm and agent to take more aggressive R&D activities, which leads to higher liability risks. We show that the optimal contract is more likely to include an indemnification clause when monitoring is more effective and market competition is tougher. By investigating R&D agreements between pharmaceutical firms and biotech agents, we find relevant empirical observations. We also observe a positive correlation between the use of indemnification clauses and termination rights that allow firms to terminate projects without cause.

1. INTRODUCTION

Outsourcing research and development (R&D) has become increasingly common, especially in the pharmaceutical industry. In designing R&D collaboration contracts, the contracting parties strive to minimize risks while providing incentives for both parties to enhance innovation. The seminal study by Aghion et al. (2001) shows that tougher market competition raises firms' innovation incentives in industries with neck-to-neck competition.[1] However, more aggressive R&D activities can raise potential harm to third parties and elevate legal risks to agents. For example, in R&D alliance projects between pharmaceutical clients and biotech agents, the agents' activities (especially clinical trials) can cause damage to subjects and, therefore, expose agents to liabilities.[2] In R&D alliances and other collaborations in the supply chain, agents and retailers may also become the targets of patent-infringement litigation and bear "joint and several liability."

Anticipating these legal risks, clients can include an indemnification clause in R&D agreements, in which they commit to reimbursing agents for liabilities and other legal costs if the agents' activities harm third parties or violate the law. Many R&D collaboration agreements employ such indemnification clauses. According to the Thomson Reuters Recap Dataset (Recap), approximately 89.59% of the R&D agreements (with contract details) signed between 1974 and 2009 in the pharmaceutical industry had indemnification clauses, while the other agreements did not include such clauses. In this article, we intend to investigate, both theoretically and empirically, the adoption of indemnification clauses in R&D contracts.

The decision to include indemnification clauses or not depends on various factors. When clients are less risk-averse than agents, contractual indemnification achieves efficient risk-sharing and, therefore, provides incentives for agents to take aggressive R&D activities. Yet, indemnification may mitigate agents' incentives to take precautions, thereby increasing the likelihood of accidents or the expected indemnification payment.[3] In practice, clients can and do take costly monitoring actions, for example, by forming joint management

committees and requiring agents to disclose relevant information in R&D alliance deals. It is also common for R&D agreements to impose the condition that indemnification (if any) does not apply to liabilities arising from agents' negligence ("contingent indemnification").

We investigate how clients' monitoring and market competition are related to the adoption of indemnification clauses. To illustrate their possible relationships, we consider a framework in which a risk-neutral client hires a risk-averse agent to conduct R&D activities that may harm third parties and expose the agent to liabilities. The gross return of the R&D project depends on the level of market competition and the intensity of R&D activities, which can be verified. More intensive R&D activities lead to greater harm to third parties and higher liabilities to the agent. The agent can take private precautions to reduce the likelihood of harm, while the client can engage in costly monitoring to generate evidence about whether the agent has been negligent (i.e., has not taken precautions). The client specifies the intensity of R&D activities and offers a royalty payment in the R&D contract. The client also chooses whether or not to include a contingent indemnification clause to reimburse the agent for the potential liability.

Monitoring by the client can restore the agent's precaution incentives. In our analysis, the client cannot commit to monitoring so that, if the contract contains a contingent indemnification clause, both the client and agent may adopt mixed strategies (i.e., randomizing on monitoring or not, or taking precautions or not taking precautions). We show that the client's optimal contract contains an indemnification clause only when the client's monitoring is not too costly (or more effective) and the agent's potential liability is not small. When the potential liability is small and an indemnification clause is included in the contract, monitoring cannot motivate the agent to take precautions, and the client would still conduct inefficient monitoring to avoid making indemnification payments. Anticipating this lack of commitment (to no monitoring), the client would instead offer a contract with no indemnification.[4] When market competition is tougher, the client would specify more intensive R&D activities, which would lead to larger liabilities. Accordingly, under tougher

competition, the optimal contract is more likely to contain an indemnification clause.

We extend the basic model by considering the possibility for the client to include a termination right in the contract and to observe a non-verifiable signal of the agent's negligence. The termination right allows the client to terminate the project without cause and prevent harm to third parties or potential liabilities. The threat of termination can motivate the agent to take precautions, in which case the client is more likely to include indemnification in the contract.

The theoretical analysis illustrates that the adoption of indemnification clauses can be positively correlated with clients' monitoring capabilities and the level of market competition. We obtain relevant empirical observations by investigating the Recap dataset of R&D agreements between pharmaceutical firms and their biotech agents. Specifically, we measure a client's monitoring capability by the client's experience in clinical trials. We also use the number of other firms that have conducted clinical trials of the same disease type as a proxy for the level of competition in each market segment.

We observe that R&D agreements are more likely to contain (contingent) indemnification clauses when the clients are more experienced in clinical trials and more firms have conducted clinical trials of the same disease type. These observations highlight the importance of considering monitoring and market competition in contract design. We also observe a significant and positive correlation between the adoption of indemnification and the adoption of termination rights, suggesting a complementary relationship between the two types of clauses.

This article contributes to the literature on law and economics, particularly about indemnification and liability insurance. The first formal analysis on indemnification by Mullin and Snyder (2010) shows that a firm offers full indemnification to its employees only when the employees' potential liability is below a certain threshold and that imposing sanctions on the firm instead of employees can be more efficient. Mullin and Snyder (2010) focus on the policy question of whether indemnification should be allowed and whether courts

should impose sanctions on employees, without discussing employees' precautionary actions or the firm's monitoring effort. In contrast, our paper examines clients' incentives to use contingent indemnification by considering the trade-off between risk-sharing and agents' precaution incentives.[5] Similar trade-offs have been discussed in studies on liability insurance, particularly by Shavell (1982), Danzon (1985), Sarath (1991), Gutierrez (2003), and Fagart and Fluet (2009), but these studies do not consider insurance companies' monitoring or market competition.[6] Arlen (1994), Chu and Qian (1995), and Arlen and Kraakman (1997), without considering indemnification or liability insurance, discuss firms' incentives to monitor their agents, which increases the likelihood of collecting evidence on agents' criminal actions. In contrast to these studies, our paper describes how monitoring and market competition can be related to the adoption of indemnification clauses.[7]

The empirical literature on indemnification is limited and treats contractual indemnification as exogenously given. Bhagat et al. (1987) show that indemnification and liability insurance for corporate directors and officers do not significantly impact shareholder value. More generally, our study is related to empirical studies on contracts. Lafontaine and Slade (2013) provide a detailed review of this literature, including studies on various control rights, payment schemes, and exclusive dealing. In particular, Lafontaine (1992, 1993) discusses the different motivations for firms to use share contracts, including, but not limited to, risk-sharing. Dubois et al. (2008) investigate risk-sharing in agricultural production through both formal and informal contracts. Lerner and Malmendier (2010) examine the use of control rights in biotech R&D-alliance deals when contracts are incomplete. Guo et al. (2017) show that firms have greater incentives to use strategic rights in contracts with their R&D agents when there is a greater entry threat.[8] This empirical literature on contracts has not considered liability risks or the use of indemnification clauses.

The rest of this article is organized as follows. Section 2 provides the industry and institutional background. Section 3 formulates the model and illustrates how monitoring and market competition are related to the adoption of indemnification clauses. Section 4

describes the data and presents relevant empirical observations. Section 5 concludes the article. The proofs for the theoretical results are in Appendix A and one extension is presented in Appendix B.

2. INDUSTRY AND INSTITUTIONAL BACKGROUND

2.1 R&D Alliances and Legal Risks for Agents

The formation of R&D alliances between pharmaceutical firms and biotech agents (small firms or non-profit organizations) has become a trend, given biotech agents' innovation expertise and the huge uncertainty in drug development.[9] It is estimated that the global market size of R&D outsourcing services will rise to about $45 billion by 2022.[10] According to the Recap Dataset, there were more than 29,900 R&D alliance projects in the pharmaceutical industry between 1974 and 2009. Pharmaceutical clients provide funding while biotech agents conduct R&D activities. Contracts between these clients and agents often contain an exclusive or (less frequently) non-exclusive license for the clients to use the agents' discoveries for further drug development, manufacturing, and distribution, in which case the clients would make royalty payments to the agents.

High and growing liability costs have been a major threat to innovation in the pharmaceutical industry.[11] In particular, R&D activities and drugs resulting from R&D discoveries can cause harm to third parties and, therefore, expose biotech agents to liabilities. The legal risks to biotech companies can arise in several areas. First, there have been many lawsuits related to damages during clinical trials.[12] Participants in clinical trials may be harmed and then file lawsuits, even though they signed informed-consent clauses. For example, in a few lawsuits against Fred Hutchinson Cancer Research Center in 2002, the plaintiffs claimed that the Center's clinical investigators failed to disclose relevant information about potential risks and alternative treatments.[13] Second, biotech agents can also become the targets of patent litigation and bear "joint and several liability" - liability shared by two or

more parties- when products arising from their discoveries infringe third parties' patents.[14] For example, in *Akamai Techs v. Limelight Networks* (2012), the defendant faced litigation when the buyer of its technology performed the last step of activities infringing third parties' patents.[15] Finally, researchers and executives of biotech companies may face potential liabilities when their work violates the law or regulations.[16]

2.2 Contractual Indemnification and State Laws in the U.S.

To address legal risks for biotech agents, many (but not all) R&D-alliance contracts contain an indemnification clause, under which pharmaceutical firms promise to reimburse the agents against liability and legal costs. By reading through 922 contracts (with details) in the Recap Dataset, we find that 826 agreements (about 89.59% of the sample) contained indemnification clauses. Typically, the indemnification clause follows the section on warranties and adopts a standard format. For example, in 1992, Lilly and OPI (a biotech company) entered into an R&D collaboration agreement, which included the following indemnification clause:

"Lilly agrees to indemnify, defend, and hold OPI harmless from and against any losses... which arise from any claim, lawsuit or other action by a third party... except to the extent such losses result from (i) the breach by OPI or (ii) the negligence or willful misconduct of OPI, its employees or its agents."

Similarly, in 2009, the agreement between Merck and Cardiome (a biotech company) stated: "Merck shall indemnify, defend and hold harmless Cardiome, its affiliates, their respective directors, officers, employees...against all losses...as a direct result of claims arising out of the use, development, manufacture, promotion, marketing, distribution or sale by MERCK...except with respect to any claim or losses that result from...the gross negligence or willful misconduct of Cardiome."

These examples, as well as all the other R&D agreements in the Recap Dataset, lead to

two important observations. First, biotech R&D agreements seldom impose monetary caps on indemnification. In other words, these agreements offer "full indemnification" instead of "partial indemnification" to agents. One possible explanation for such full coverage is that it can be very costly for contracting parties to predict potential liability costs given the significant uncertainty of legal risks in this industry. In practice, many contracts impose caps or deductibles on "direct damages" (how much one contracting party can get from the other because of direct harm, for example, due to product failure or breach of contract), but seldom do so for third-party claims.[17]

The other observation is that the indemnification clauses in all these agreements contain a "non-negligence" condition, such that agents forfeit indemnification protection if they have been negligent. As we will show in the next section, such "contingent" indemnification clauses can motivate agents to take precautions and reduce liability risks. A natural question is whether courts would support "non-contingent" indemnification (i.e., indemnification even if agents have been negligent).

All states in the U.S. have laws supporting contractual indemnification, and most of the states (except for Michigan and New York) allow for non-contingent indemnification. However, the laws in thirty-three states, including California and Delaware, impose various restrictions to limit the use of non-contingent indemnification. In particular, the New York General Obligation Law §5-322.1 (2019) prohibits the enforcement of an indemnification agreement for damage arising "out of bodily injury to persons or damage to property contributed to, caused by, or resulting from the negligence of...(an) indemnitee."[18] The state law of California specifies that an indemnity agreement providing for indemnification against an indemnitee's own negligence "must be clear and explicit and is to be strictly construed against the indemnitee."[19] Delaware law allows for non-contingent indemnification but indicates that indemnification contracts against a person's own negligence are not favored by law, and where possible, will be construed so as not to confer immunity from liability.[20] Similarly, Georgia law makes it clear that terms such as "against any and all

claims" do not include indemnification against indemnitees' own negligence.[21]

Figure 1 highlights the states that either ban or impose restrictions on non-contingent indemnification. In the Recap dataset, 715 R&D agreements contain indemnification clauses with the governing law in the U.S. Among these agreements, 634 observations (or 88.67%) are governed by the laws in New York, Michigan, or one of the states with strict restrictions on non-contingent indemnification.

(*Insert Figure 1 here*)

2.3 Monitoring and Market Competition

One potential issue with contractual indemnification is that agents may lose incentives to take precautions to mitigate the risk of harming third parties. The above observations of state laws and non-negligence conditions in R&D agreements indicate that both courts and clients would like to maintain agents' incentives for such precautions. However, in practice, pharmaceutical clients may not be able to observe or obtain evidence of whether agents have taken precautions or not.

In many R&D alliance projects, pharmaceutical clients form joint steering committees and require agents to submit periodic reports. For example, in the above-mentioned agreement between Lilly and OPI in 1992, the contracting parties formed a steering committee made of three members from each party. This agreement required the steering committee to meet at least every six months and each party to "provide the other (party) with...including all safety information." Similarly, the agreement between Merck and Cardiome in 2009 required the agent to "provide Merck with all data, results, and information...including all investigator safety letters and other safety information."

Intuitively, these monitoring mechanisms would be more effective if clients have more experience in conducting R&D activities themselves.[22] Conducting a clinical trial is a major milestone in drug development and thereby a good measurement of the experience of

pharmaceutical firms.[23] The R&D agreements between the same pharmaceutical clients and different biotech agents reveal that the experience of the clients in clinical trials is positively correlated with the adoption of contractual indemnification.[24] In the Recap dataset, twelve clients had more than ten R&D alliance agreements with only some of them containing indemnification terms. Figure 2 illustrates that a positive correlation between experience in clinical trials and the usage of indemnification holds for most of these clients. For example, among 26 agreements signed between Merck and different agents between 1987 and 2009, five agreements did not have indemnification clauses.[25] Among the agreements without indemnification, on average, Merck had been involved in 7.6 clinical trials before entering into each agreement. By contrast, among the agreements with indemnification, on average, Merck had been involved in 15.6 clinical trials. Similarly, among 35 agreements between Lilly and various agents between 1978 and 2009, seven agreements did not contain indemnification clauses.[26] Before signing the agreements without indemnification, on average, Lilly had been involved in 4.4 clinical trials. By contrast, before entering into the agreements with indemnification, Lilly had been involved in 18.4 clinical trials on average.

(*Insert Figure 2 here*)

The benefit of contractual indemnification can be greater when the potential liability risk is greater. Aghion et al. (2001) show that greater competition tends to raise firms' innovation incentives in those industries with neck-to-neck competition. The pharmaceutical industry is competitive and the process of drug development is highly uncertain. Survival in this industry depends on the success of new drug development. However, only a handful number of new drugs are approved each year and the turnover of firms in the industry has been extremely high in recent decades (Kinch et al., 2014). If tougher competition induces clients and agents to engage in more aggressive R&D activities, the expected harm to third parties would be larger. Accordingly, the level of competition would be correlated with the adoption of indemnification clauses. Since each R&D alliance in the pharmaceutical industry typically aims to develop drugs for a particular type of disease, those pharmaceu-

tical firms that have conducted clinical trials of the same disease type are more likely to be competitors.[27]

Figure 3 illustrates that there exists a positive correlation between the number of other firms in the same disease category and the adoption of contractual indemnification, for most of the clients that had more than ten R&D alliance agreements. Again, taking the contracts signed by Merck as examples. On average, 15.8 other firms had conducted clinical trials of the same disease type before Merck entered into the agreements without indemnification, while 37.9 other firms had done clinical trials of the same disease type before Merck signed the agreements with indemnification. Similarly, on average, 12 other firms had conducted clinical trials of the same disease type before Lilly entered into the agreements without indemnification, while 22.9 other firms had done clinical trials of the same disease type before Lilly signed the agreements with indemnification.

(*Insert Figure 3 here*)

These observations suggest that the effectiveness of monitoring and market competition are related to the design of R&D alliance contracts. We will illustrate their relationship within a theoretical framework in the next section and then describe more empirical observations in Section 4.

3. THEORETICAL FRAMEWORK

A risk-neutral client hires a risk-averse agent to conduct one R&D project. The project requires the client to make a fixed investment I. The gross return of the project is $R \equiv R(N, e)$, where N is the level of market competition and e measures the intensity (or aggressiveness) of the agent's R&D activities. Let $R_N = \frac{\partial R}{\partial N} < 0$, $R_e = \frac{\partial R}{\partial e} > 0$, $R_{ee} = \frac{\partial^2 R}{\partial e \partial e} < 0$, and $R_{Ne} = \frac{\partial^2 R}{\partial N \partial e} > 0$. That is, the gross return decreases in the level of market competition, but increases in the intensity of R&D activities. Importantly, with tougher competition, the marginal impact of raising the intensity of R&D activities becomes larger.

This assumption is consistent with the study by Aghion et al. (2001), who show that, given more competition, the incremental gain from innovation becomes greater.

In this paper, we focus on the agent's moral hazard problem in taking safety precautions and abstract away from other agency problems. Thus, we assume that e can be verified by both the client and third parties. The agent's R&D activities in the project may cause an accident, and when the accident happens, the damage to third parties (the "victims") is $D \equiv D(e)$, with $D'(e) > 0$. That is, more aggressive R&D activities (larger e) lead to greater damage to victims. However, the agent can take precautions to mitigate the likelihood of such accidents. Denote the agent's precautionary action as $a = \{0, 1\}$. If the agent does not take precautions ($a = 0$), the probability of having an accident is $\pi_0 \in (0, 1)$. If the agent takes precautions ($a = 1$), the agent incurs the precaution costs $C > 0$, while the probability of having an accident drops to $\pi_1 \in [0, \pi_0)$. We assume it is socially efficient to have the agent take precautions, that is, $C < (\pi_0 - \pi_1)D$ for any $D = D(e)$. The agent has initial wealth $w > D$ and his/her utility over wealth is $u()$, with $u(0) = 0$, $u'() > 0$, and $u''() < 0$.[28] The precaution costs C are additively separable from $u()$.

The client cannot observe the agent's choice of precautions but can resort to monitoring effort with costs $K \in (0, \pi_0 D)$.[29] If the agent does not take precautions and the client undertakes monitoring, the client will receive verifiable evidence that the client has been negligent.[30] However, if the agent takes precautions or if the client does not undertake monitoring, the client will not receive any verifiable evidence. That is, monitoring generates evidence of negligence.

We further assume that $R(N, e)$ is sufficiently larger than $I + \pi_0 D + K$ so that it is jointly beneficial for the client and agent to carry on with the project.[31]

For simplicity, we consider the strict-liability rule, under which the agent pays full compensation D to the victims whenever an accident occurs. That is, we abstract away from the possibility that courts may use negligence rules and obtain evidence about the agent's precautions. Note that, even if courts use negligence rules, in our model the client's moni-

toring does not generate evidence that the agent has taken precautions and therefore does not change the agent's liability.[32] Additionally, we do not consider non-contractual indemnification or shared liabilities imposed by courts. Even if courts allow victims to sue both clients and agents and allocate liabilities, clients could still offer contractual indemnification to agents for the agents' shares of the liabilities.[33]

The client first chooses e, the intensity of R&D activities. Given e and the potential damage $D = D(e)$, the client offers the agent a take-it-or-leave-it contract, which can include a royalty payment $r \geq 0$ (that is, the royalty rate is r/R) and a contingent indemnification payment s to compensate the agent for his/her liability to the victims. In the baseline model, we focus on the client's choice in offering "full" indemnification or not, that is, $s = \{0, D\}$. Note that a partial indemnification $s \in (0, D)$ (i.e., an indemnification with a monetary cap) is theoretically possible. In practice, to specify a cap, the contracting parties would have to predict potential damages to any third party, which can be costly. This difficulty in making predictions limits the contracting parties' ability to draft a "complete" contract. We shall relax the assumption and consider partial indemnification in Appendix B.

We also assume that the client cannot indemnify against the agent's liability if the agent has been negligent (i.e., has not taken precautions). As discussed in the previous section, non-contingent indemnification is rare in practice and many state laws in the U.S. impose strict restrictions on non-contingent indemnification.

The timing of the model is as follows.

Date 1: The client specifies e and then makes a take-it-or-leave-it contract offer (r, s). If the agent rejects it, the client's reservation utility then is 0 and the agent gets a reservation utility $u(w)$. If the agent accepts, then the client makes the investment and the game moves to Date 2.

Date 2: The agent chooses whether to take precautions with costs C; at the same time, the client chooses whether to undertake monitoring with costs K.

Date 3: The project generates a gross return $R = R(N, e)$ and causes damage $D(e)$ to the

victims with probability π_0 if $a = 0$ and π_1 if $a = 1$. The client makes the royalty payment r. The indemnification payment is made if the agent faces liabilities and the client does not have evidence showing that the agent has been negligent.

3.1 Indemnification, Monitoring, and Competition

We will start characterizing the client's optimal contract given the intensity of R&D activities fixed. Given e and the gross return $R(N, e)$, the client's objective is to minimize the expected costs by choosing the royalty payment r and deciding whether to offer indemnification or not, $s = \{0, D\}$, where $D = D(e)$. We first derive the client's optimal royalty offer with and without indemnification.

Contracts without Indemnification

Suppose that the contract does not contain an indemnification clause ($s = 0$). Define $r_0 = r_0(D)$ and $r_1 = r_1(D)$ by

$$\begin{aligned} (1-\pi_0)u(w+r_0) + \pi_0 u(w+r_0-D) &\equiv u(w). \\ (1-\pi_1)u(w+r_1) + \pi_1 u(w+r_1-D) - C &\equiv u(w). \end{aligned}$$

The client's optimal royalty offer is $r^* = \min\{r_0(D), r_1(D)\}$. Given that $u()$ is concave, $r_0(D)$ and $r_1(D)$ strictly increase in D. Intuitively, to motivate the agent to accept the contract offer, the royalty payment increases with the level of potential liability. We then have the following result.

Lemma 1 *Suppose the contract does not contain an indemnification clause. The client's optimal royalty payment is* $r^* = \min\{r_0(D), r_1(D)\}$, *which increases in* D, *and there exists a unique cut-off* $\overline{C}(D) > 0$ *such that the agent takes precautions if and only if* $C \leq \overline{C}(D)$.

Contracts with indemnification

Now suppose that the contract contains full (and contingent) indemnification $s = D$. If the client does not conduct monitoring, the agent will never take precautions and his/her expected utility will be $u(w + r)$. In this scenario, the client's optimal royalty offer is $r = 0$ and the expected indemnification payment is $\pi_0 D$. Since $K < \pi_0 D$, the client is better off by monitoring the agent's activities. Thus, given the indemnification clause, an equilibrium without monitoring does not exist.

Also, there is not an equilibrium in which the client undertakes monitoring for sure and the agent takes precautions, as the client could save costs by deviating to no monitoring. Furthermore, given any contract $(r, s = D)$, if the client undertakes monitoring for sure while the agent does not take precautions, the client would never make the indemnification payment, and therefore he/she would be better off by offering another contract $(r, s = 0)$ and not conducting monitoring.

To summarize, the client never uses a contract $(r, s = D)$ that would induce an equilibrium where the client and agent play pure strategies. Consider mixed strategies where the client conducts monitoring with probability p and the agent takes precautions with probability q. Define r^{**} by

$$u(w + r^{**}) - C \equiv u(w).$$

Since the agent plays mixed strategies, he/she must be indifferent between taking precautions and not taking precautions. Also, the agent should receive at least the reservation utility. Note that, if the agent does not take precautions, an accident occurs with probability π_0 and the client obtains evidence of the agent's negligence with probability p, in which case the agent does not receive any indemnification payment. We then have

$$u(w + r) - C = p\pi_0 u(w + r - D) + (1 - p\pi_0)u(w + r) \geq u(w), \tag{1}$$

which implies the royalty payment satisfying $r \geq r^{**}$ and the client's monitoring probability

as

$$p(r) = \frac{C}{\pi_0[u(w+r) - u(w+r-D)]}.$$

If the client conducts monitoring, he/she will make indemnification payments only when the agent takes precautions (with probability q) and an accident occurs (with probability π_1). If the client does not conduct monitoring, he/she will make indemnification payments whenever an accident occurs. Since the client plays a mixed strategy, he/she is indifferent between monitoring and not monitoring, that is,

$$-K - q\pi_1 D = -q\pi_1 D - (1-q)\pi_0 D,$$

which implies $q = q^{**} \equiv 1 - \frac{K}{\pi_0 D} \in (0,1)$ given $K \in (0, \pi_0 D)$.

The following lemma shows a necessary condition for the client's optimal contract to include the indemnification clause. It also shows that, given indemnification, the optimal royalty payment must be r^{**}.

Lemma 2 *If $C \geq \frac{\pi_0}{1-\pi_0}u(w)$, the client's optimal contract does not contain indemnification. If $C < \frac{\pi_0}{1-\pi_0}u(w)$ and the contract contains indemnification, the optimal royalty payment is r^{**}, which leads to a unique equilibrium where the client conducts monitoring with probability $p^{**} = p(r^{**}) \in (0,1)$ and the agent takes precautions with probability $q^{**} \in (0,1)$.*

Lemma 2 suggests that if the contract contains an indemnification clause, the client's expected cost would be

$$T(D) \equiv r^{**} + K + q^{**}\pi_1 D = r^{**} + \pi_1 D + \frac{\pi_0 - \pi_1}{\pi_0}K,$$

which increases in D. As shown in Lemma 1, without the indemnification clause, $r^* =$

$\min\{r_0(D), r_1(D)\}$ increases in D. Since $u()$ is concave, we have

$$\begin{aligned}
\frac{dr_0(D)}{dD} &= \frac{\pi_0 u'(w + r_0(D) - D)}{(1-\pi_0)u'(w + r_0(D)) + \pi_0 u'(w + r_0(D) - D)} > \pi_0 > \pi_1 = \frac{dT(D)}{dD}; \\
\frac{dr_1(D)}{dD} &= \frac{\pi_1 u'(w + r_1(D) - D)}{(1-\pi_1)u'(w + r_1(D)) + \pi_1 u'(w + r_1(D) - D)} > \pi_1 = \frac{dT(D)}{dD}.
\end{aligned}$$

We then have the following result.

Proposition 1 *Given $C < \frac{\pi_0}{1-\pi_0}u(w)$, there exists a unique cut-off $\overline{D}$ and, for any $D > \overline{D}$, a unique cut-off $\overline{K} > 0$, such that the client's optimal contract contains an indemnification clause and a royalty of r^{**} if and only if $K < \overline{K}$. For all other parameter values, the optimal contract does not include indemnification but just a royalty payment of* $\min\{r_0(D), r_1(D)\}$.

Intuitively, indemnification allows for efficient risk-sharing but may mitigate the agent's incentives to take precautions. With contingent indemnification, the client's monitoring effort can restore the agent's precaution incentives only when the monitoring cost is not too large and the potential liability is not small. When the potential liability is small, the agent would never take precautions even if the client conducts monitoring for sure. In this scenario, the client would be better off by not having the indemnification clause in the contract. Note that this result arises partly due to the lack of commitment. If the client could commit not to conduct monitoring, he/she may offer non-contingent indemnification (under which the agent would not take precautions).[34]

Now we turn to the impact of competition (N) on the inclusion of indemnification clauses. The earlier analysis suggests that the client's expected cost under the optimal contract is

$$\min\{r_0(D(e)), r_1(D(e)), T(D(e))\},$$

which increases in D and correspondingly increases in e. The client chooses e^* to maximize

the net return,

$$Max_e R(N,e) - \min\{r_0(D(e)), r_1(D(e)), T(D(e))\}.$$

Given $R_{Ne} = \frac{\partial^2 R}{\partial N \partial e} > 0$, we can show that $\frac{de^*}{dN} > 0$. Intuitively, with more fierce competition, the client would prefer more intensive R&D activities. Since more intensive R&D activities lead to higher (expected) damages, $D(e)$, the client's optimal contract is more likely to include an indemnification clause according to Proposition 1.

Corollary 1 *The client's optimal choice of* e*, and accordingly, the incentive to include an indemnification clause in the contract, increases in the competition level* N*.*

3.2 Indemnification and Termination Rights

The baseline model considers verifiable evidence of the agent's negligence. In practice, clients may also observe non-verifiable signals of agents' actions and then terminate R&D projects to save investments or avoid potential harm to third parties. In this subsection, we do not intend to investigate various reasons for which firms include termination rights in R&D contracts.[35] Instead, we will illustrate how the existence of termination rights might be related to the likelihood for the contract to include an indemnification clause. In particular, we extend the baseline model by assuming that the contract can contain a termination right that allows the client to terminate the project without cause but raises the client's contracting costs by $\delta > 0$. Upon termination, the client receives a residual value v and the agent would not get any royalty payment. Moreover, if the agent does not take precautions, the client observes a non-verifiable signal of the agent's negligence with probability $\theta > 0$ before any harm occurs.

Without loss of generality, assume that $R - \pi_1 D - r^{**} > v > R - \pi_0 D - r^{**}$. Thus, given the royalty payment r^{**}, if the client only receives the non-verifiable signal and expects to make the indemnification payment with probability π_0, he/she would terminate the project. Note that, if the client conducts monitoring and obtains the verifiable evidence

of the agent's negligence, he/she would not make indemnification payments and, therefore, would not terminate the project.[36]

The termination right can increase the agent's incentive to take precautions, even without monitoring by the client. Therefore, the client is more likely to include an indemnification clause in the contract. That is, termination rights and indemnification clauses can be complementary in contract design.[37]

Proposition 2 *Suppose that* $C < \frac{\pi_0}{1-\pi_0}u(w)$ *and* $D \geq \overline{D}$. *If* δ *is sufficiently small, the client's optimal contract contains the termination right and the indemnification clause under a larger set of parameter values than in the scenario without termination rights.*

4. EMPIRICAL ANALYSIS

The theoretical analysis in Section 3 illustrates that the adoption of indemnification clauses could be correlated with clients' monitoring costs (or capabilities) and the level of market competition. Moreover, contractual indemnification and termination rights could be complementary. We will provide relevant empirical observations in this section.

4.1 Data and Variables

One challenge facing researchers is that most R&D contracts are confidential in practice. The Recap Dataset provides 1,703 original R&D agreements between pharmaceutical firms and their biotech agents between 1974 and 2009. This dataset has been used in the empirical literature on R&D agreements (e.g., Elfenbein and Lerner, 2003 and 2012; Lerner and Malmendier, 2010; Guo et al., 2017). We will use this dataset to gain a deeper understanding of the design of indemnification contracts. Following the literature, we clean this dataset by eliminating duplicate agreements, non-R&D agreements,[38] agreements involving more than three biotech agents,[39] agreements with universities or non-profit organizations as

agents, and agreements with a lot of text missing. This selection process results in 922 data observations, among which 826 agreements (about 89.59% of the full sample) contained indemnification clauses. We create a dummy variable "indemnification," which equals 1 if an agreement contained an indemnification clause, and 0 otherwise.

In the Recap dataset, all the agreements granted clients termination rights, some with verifiable conditions and others without cause. However, the verifiable conditions listed are typically not related to liability risks, while termination rights without cause allow clients to terminate the projects upon receiving non-verifiable signals of agents' negligence. Thus, we focus on termination rights without cause and create a dummy variable "termination," which equals 1 if an agreement contained the termination right without cause for the client and 0 otherwise. About 44.79% of the agreements included termination rights without cause.

We intend to investigate the relationship between clients' monitoring capabilities and the adoption of contractual indemnification. A client's monitoring can be more effective if the client has more experience in R&D activities. As discussed in Section 2, entering into a clinical trial is a major milestone in drug development and, thereby, a good measurement of the experience of pharmaceutical firms.[40] Based on the Recap data about all the clinical trials that pharmaceutical firms have filed with the U.S. Food and Drug Administration (FDA) since 1963, we construct a variable "client experience," which is the total number of trials in which the client had been involved before the agreement was signed. In the empirical analysis, we shall use "client experience (log)," which equals the log value of 1 plus "client experience." We expect that the more clinical trials in which a client has been involved, the more effectively the client can monitor agents' R&D activities and identify legal risks.

We are also interested in the relationship between the use of indemnification clauses and the level of market competition. As mentioned in Section 2, since each R&D alliance in the pharmaceutical industry typically aims to develop drugs for a particular type of disease,

those pharmaceutical firms that have conducted clinical trials of the same disease type are more likely to be competitors. The Recap dataset classifies all the R&D agreements into 21 disease types, and we treat each disease type as one market segment.[41] Based on the dataset of clinical trials, we define "market competition" as the total number of other firms that had conducted clinical trials of the same disease type before a client entered into the R&D alliance agreement. In the empirical analysis, we shall use "market competition (log)," which equals the log value of 1 plus "market competition." A larger value of this variable indicates greater competition within the market segment.[42]

We also control for the development stage of R&D activities in each agreement.[43] Drug development involves multiple stages, which in terms of timing include discovery, lead molecule, preclinical/formulation, Phase I, Phase II, and Phase III clinical trials, and BLA/NDA filing and approval. Each R&D alliance project typically covers only one or a few stages of drug development. As stated by Lerner and Malmendier (2010), R&D projects involving the earlier stages tend to face larger uncertainty in R&D outcomes. The potential liability risks and the effectiveness of clients' monitoring can also differ across the various stages. Thus, we include a dummy variable, "late stage," which equals 1 if an R&D agreement involves preclinical/formulation or later stages, and 0 otherwise.[44]

The market size and the nature of R&D activities could differ across disease types.[45] We include two dummy variables, "Cardio," which equals 1 if an R&D agreement involves cardiovascular disease, and "Cancer," which equals 1 if an R&D agreement is related to cancer.[46] Among the top 200 branded drugs sold between 2000 and 2010, drugs dealing with cardiovascular and cancer diseases have consistently recorded the highest sales.[47]

Additionally, our dataset covers a long period. Changes in liability rules, government regulations, or the market environment, can potentially affect the contract design. We utilize two different sets of timing dummies to account for period fixed effects. The first set includes two dummies, "period 00-09" and "period 90-99," to identify agreements signed between 2000 and 2009, and between 1990 and 1999, respectively. The second set includes

a series of five-year dummies ("period 05-09," "period 00-04," etc.), to identify agreements signed during the corresponding periods.[48]

In our dataset, some clients were publicly listed during the contracting year, while the others were not. Thus, we also create a dummy "listed client," which equals 1 if a client was publicly listed during the contracting year and 0 otherwise. A client with a larger size or better financial performance can be less risk-averse, and thus more willing to offer indemnification. For each publicly-listed client, using information from Wharton Research Data Services, we measure "client size" by the log value of the client's asset (in million USD) and the client's financial status by "client ROA," which equals the client's net earnings (EBITDA) divided by its asset value in the contracting year and then multiplied by 100.[49] Since most of the agents in our dataset are privately held, we cannot obtain their financial data.

Table 1 provides summary statistics for all the variables and Table 2 compares the mean values of each variable between those agreements with indemnification and those without indemnification. In particular, before entering the agreements without indemnification, the clients conducted 5.29 clinical trials on average; before entering the agreements with indemnification, the clients conducted 11.10 clinical trials on average. Moreover, before the agreements without indemnification were signed, an average of 19.31 other firms had conducted clinical trials of the same disease type; before the agreements with indemnification were signed, an average of 31.82 other firms had conducted trials of the same disease type. These observations indicate that the adoption of indemnification clauses is positively correlated with client experience and the level of market competition. A similar pattern can be observed in the binned scatterplots about client experience in Figure 4 and market competition in Figure 5.

(Insert Tables 1 and 2 here)

(Insert Figures 4 and 5 here)

4.2 Empirical Results

We use the following Logit model:[50]

$$\Pr(Indemnification_{g,i,j,t}) = \beta_0 + \beta_1 \ln(1+Exp_{i,t}) + \beta_2 \ln(1+Comp_{g,t}) + \beta_3 X_g + \beta_4 X_{i,t} + \varepsilon_{g,i,j,t},$$

where

$\Pr(Indemnification_{g,i,j,t})$ is the probability for an agreement g between client i and agent j at time t to contain an indemnification clause;

$Exp_{i,t}$ is the number of clinical trials in which client i involved before time t;

$Comp_{g,t}$ is the number of other firms that have conducted clinical trials of the same disease type as in the agreement g before time t;

X_g is a set of agreement-specific covariates including "late stage," "Cardio," "Cancer, " and the timing dummies, indicating whether the agreement involved the late stages of drug development, whether the agreement targeted discoveries dealing with cardiovascular or cancer diseases, and whether the agreement was signed during a certain period.

$X_{i,t}$ is a set of client-specific variables including "listed client" (i.e. whether client i was publicly listed or not at time t) in Tables 3, 4, and 6, and including "client size" and "client ROA" at time t in Table 5.

Moreover, we cluster standard errors at the client level which helps to adjust possible correlations within the same client.[51] Table 3 presents the empirical findings concerning the adoption of indemnification clauses in the full sample.[52] The results are robust under the two different sets of timing dummies.

(Insert Table 3 here)

First, "client experience (log)" has a significant and positive relationship with the inclusion of indemnification clauses. As illustrated in Section 3, one possible explanation is that contractual indemnification mitigates agents' incentives to take precautions but clients'

monitoring actions can identify agents' negligence and, therefore, restore agents' incentives. When clients have more experience, their monitoring actions are more effective and, accordingly, can increase the likelihood for R&D agreements to use indemnification terms.

Second, the level of market competition also has a significant and positive relationship with the inclusion of indemnification clauses. When facing more fierce competition in a particular market segment, a client and its agent tend to conduct more aggressive R&D activities, which may lead to greater liability risks. As shown in Section 3, under greater liability risks, the net benefit of contractual indemnification becomes larger.

Note that our estimations do not contain a reverse causality problem, as the two variables, "client experience (log)" and "market competition (log)," are based on data from the years before a certain agreement is signed.

The stage of drug development ("late stage") does not have a significant impact on the use of contractual indemnification. Although R&D projects involving late stages can face more liability risks, clients' monitoring may also become less effective given the larger scale of R&D activities. These two conflicting effects might offset each other.

In the full sample, some clients only had one R&D alliance agreement, while the others had multiple agreements with different agents. One natural question is whether these clients with multiple R&D alliances exhibit different behavior in contract design. To address this question, we examine the subsample of those clients that signed multiple agreements with various agents. This subsample contains 432 data observations. As shown in Table 4, "client experience (log)" and "market competition (log)" have significant and positive relationships with the inclusion of indemnification clauses, consistent with the results under the full sample.

(*Insert Table 4 here*)

Clients with more assets or better financial performance might be more willing to offer indemnification. Moreover, a client's experience with clinical trials in previous years might be correlated with its size. To address these issues, we investigate the subsample of those

publicly listed clients. Table 5 shows that the effects of "client experience (log)" and "market competition (log)" are robust (albeit at a weaker level of significance) in most of the specifications. It also shows that client size or ROA does not have a significant impact on the use of indemnification clauses.

(*Insert Table 5 here*)

The theoretical analysis in Section 3 illustrates a positive correlation between contractual indemnification and termination rights. However, both clauses are choice variables. Table 6 shows a positive relationship between these two types of clauses, without indicating any causality. Termination rights without cause can raise agents' incentives to take precautions to reduce liability risks; therefore, the net benefit of contractual indemnification is larger. Studies on the interaction among contract terms have been limited and focus on franchising contracts.[53] Our analysis complements the literature by providing evidence of a possible complementary relationship between various terms in R&D alliance agreements.

(*Insert Table 6 here*)

One caveat of our empirical analysis is that we could not observe whether or not agents in our dataset purchased liability insurance plans from insurance companies. In practice, liability insurance plans contain monetary limits for reimbursements, while indemnification clauses do not include such limits. Additionally, insurance companies may have less information about the potential risks associated with biotech R&D projects than pharmaceutical firms. Given these observations, contractual indemnification can be more efficient than liability insurance plans. Meurer (2017) also states that liability insurance for patent infringement defense is not often purchased in practice.

5. CONCLUSION

This article examines R&D contracts between clients and agents when R&D activities may harm third parties and, therefore, expose the agents to liabilities. Contractual in-

demnification achieves efficient risk-sharing between a client and its agent but reduces the agent's incentive to take precautions. The client's monitoring effort, together with the non-negligence condition, can restore the agent's precaution incentives, though the client's inability to commit to monitoring limits the effectiveness of the condition. Moreover, tougher competition motivates the client and agent to conduct more aggressive R&D activities, which lead to larger liabilities. Given these effects, the optimal contract includes (contingent) indemnification only when monitoring is sufficiently effective and market competition is tough.

Using a dataset of R&D agreements between pharmaceutical clients and biotech agents, we observe that R&D agreements are more likely to contain indemnification clauses when clients have more experience in clinical trials and more other firms have conducted clinical trials of the same disease type. Our theoretical and empirical analysis also shows that indemnification and termination rights can be complementary in contract design.

We restrict our attention to specific contract forms as observed in practice (i.e., royalty payments and an indemnification clause). It would be meaningful to examine whether the observed contract forms are indeed optimal mechanisms. Furthermore, it remains an important policy question whether and when non-contingent indemnification increases or decreases social welfare. Additionally, our empirical results are obtained under data limitations and we do not have direct measures of liability levels. Finally, to focus on the adoption of indemnification clauses, we ignore possible mergers or equity links between clients and agents.[54] Future studies combining the various contractual and organizational arrangements for the allocation of liability risks would be desirable.

APPENDIX A: PROOFS

Proof of Lemma 1. Denote

$$\overline{C} = \overline{C}(D) \equiv (\pi_0 - \pi_1)[u(w + r_0(D)) - u(w + r_0(D) - D)].$$

If and only if $C \leq \overline{C}(D)$, we have

$$\begin{aligned} & (1-\pi_1)u(w+r_0(D)) + \pi_1 u(w+r_0(D)-D) - C \\ \geq\ & (1-\pi_0)u(w+r_0(D)) + \pi_0 u(w+r_0(D)-D) \\ =\ & (1-\pi_1)u(w+r_1(D)) + \pi_1 u(w+r_1(D)-D) - C, \end{aligned}$$

which implies $r_0(D) \geq r_1(D)$ if and only if $C \leq \overline{C}(D)$. The result then follows. ■

Proof of Lemma 2. Suppose that the contract includes $s = D$ and $r' \geq r^{**}$. Then condition (1) implies

$$u(w + r') - C = p\pi_0 u(w + r' - D) + (1 - p\pi_0)u(w + r') \geq u(w). \tag{2}$$

that is,

$$C = p\pi_0[u(w + r') - u(w + r' - D)],$$

where the right-hand side decreases in r'. The client's expected cost is $r' + K + q^{**}\pi_1 D$. We must have $r' = r^{**}$. If otherwise $r' > r^{**}$, then for positive and arbitrarily small ε, there exists $p' < p$ such that

$$u(w + r' - \varepsilon) - C = p'\pi_0 u(w + r' - \varepsilon - D) + (1 - p'\pi_0)u(w + r' - \varepsilon) > u(w),$$

Thus, the client is better off by offering the lower royalty payment $r' - \varepsilon$, under which

condition (2) still holds. Therefore, the optimal royalty payment is r^{**}.

Finally, note that

$$p^{**} \equiv p(r^{**}) = \frac{C}{\pi_0[u(w+r^{**}) - u(w+r^{**}-D)]}.$$

If $C \geq \frac{\pi_0}{1-\pi_0}u(w)$ or equivalently $C \geq \pi_0[u(w)+C] = \pi_0 u(w+r^{**})$, then for any D, we have $p^{**} \geq 1$. In this case, the optimal contract does not include an indemnification clause. ■

Proof of Proposition 1. Lemma 2 shows that, if $C \geq \frac{\pi_0}{1-\pi_0}u(w)$, the optimal contract does not include an indemnification clause. Now suppose $C < \frac{\pi_0}{1-\pi_0}u(w)$. When $D = r^{**}+w$, $p^{**} < 1$; when $D = r^{**}$, $p^{**} > 1$. Thus, there exists a unique $\widehat{D} \in (r^{**}, r^{**}+w)$ such that $p^{**} = 1$ if and only if $D = \widehat{D}$, that is,

$$C = \pi_0[u(w+r^{**}) - u(w+r^{**}-\widehat{D})].$$

Then by the definitions of $r_0(\widehat{D})$ and r^{**}, we have

$$\begin{aligned} & (1-\pi_0)u(w+r_0(\widehat{D})) + \pi_0 u(w+r_0(\widehat{D})-\widehat{D}) \\ = \;& u(w) \\ = \;& u(w+r^{**}) - C \\ = \;& (1-\pi_0)u(w+r^{**}) + \pi_0 u(w+r^{**}-\widehat{D}). \end{aligned}$$

Therefore, we have $r_0(\widehat{D}) = r^{**}$, which further implies

$$\begin{aligned} C &= \pi_0[u(w+r_0(\widehat{D})) - u(w+r_0(\widehat{D})-\widehat{D})] \\ &> (\pi_0-\pi_1)[u(w+r_0(\widehat{D})) - u(w+r_0(\widehat{D})-\widehat{D})] \\ &= \overline{C}(\widehat{D}). \end{aligned}$$

As defined in Section 3.1, $T = T(D)$ is the client's expected cost under full indemnification and $r^*(D)$ is the payment without indemnification. As shown in Lemma 1, since $C > \overline{C}(\widehat{D})$,

$$\begin{aligned} r^*(\widehat{D}) &= r_0(\widehat{D}) = r^{**} \\ &< r^{**} + \pi_1 \widehat{D} \\ &= T(\widehat{D}; K = 0). \end{aligned}$$

Thus, when $D = \widehat{D}$, the contract would not include an indemnification clause.

Now suppose $D > \widehat{D}$. The optimal royalty payment without indemnification is $\min\{r_0(D), r_1(D)\}$, which increases in D at a rate higher than the client's payment with indemnification, given $\frac{dr_0(D)}{dD} > \frac{dT(D)}{dD}$ and $\frac{dr_1(D)}{dD} > \frac{dT(D)}{dD}$ (as shown in Section 3.1). Therefore, there exists a unique cut-off $\overline{D} > \widehat{D}$ such that $T(\overline{D}; K = 0) = r^*(\overline{D})$. Moreover, $T(D; K = 0) < r^*(D)$ if and only if $D > \overline{D}$. Accordingly, given $D > \overline{D}$, there exists a unique cut-off $\overline{K} > 0$ such that the optimal contract contains an indemnification clause if and only if $K < \overline{K}$. ■

Proof of Proposition 2. First, consider the equilibrium where the client does not conduct monitoring. Then the only mechanism preventing the agent from shirking is the termination right. Suppose that the contract contains the termination right and indemnification clause. Assume that the client would terminate the project if observing the non-verifiable signal about negligence but not terminate if otherwise. Later we will show that this assumption holds whenever θ is large enough. In this case, the agent takes precautions if and only if

$$u(w + r) - C \geq (1 - \theta)u(w + r) + \theta u(w).$$

The optimal royalty $r'(\theta)$ satisfies $u(w + r') - u(w) = \frac{C}{\theta}$ and the client's expected payment is $T'(D; \theta) = r'(\theta) + \pi_1 D$, which decreases in θ. Note that $r'(\theta = 1) = r^{**}$.

By contrast, if the contract does not contain indemnification, the expected payment is $r^*(D) = \min\{r_0(D), r_1(D)\}$. As shown in the proof of Proposition 1, $r^*(\overline{D}) = T(\overline{D}; K =$

$0) = r^{**} + \pi_1 \overline{D}$. Therefore, if $\theta = 1$, $T'(\overline{D}; \theta = 1) = r^*(\overline{D})$. Moreover, note that

$$\frac{dT'(D;\theta)}{dD} = \pi_1 < \frac{dr^*(D)}{dD}.$$

Thus, for any $D > \overline{D}$, $T'(D; \theta = 1) < r^*(D)$. Accordingly, given $D \geq \overline{D}$, there exists a unique $\widehat{\theta}$ such that $T'(D;\theta) < r^*(D)$ for any $\theta \geq \widehat{\theta}$.

The assumption $R - \pi_1 D - r^{**} > v$ and the observation $r'(\theta = 1) = r^{**}$ imply that the client would not terminate the project when $\theta = 1$ and there is no signal about negligence. Then by continuity, the same claim holds when θ is large. Note that, when θ is sufficiently small, it is possible to have $R - \pi_1 D - r'(\theta) < v$, in which case the optimal contract does not include the termination right (as otherwise the client would always terminate the project).

The earlier analysis implies that, as long as the contracting cost δ is not large, there exists a cut-off $\overline{\theta} \geq \widehat{\theta}$ such that the optimal contract includes the termination right and indemnification clause whenever $\theta \geq \overline{\theta}$.

Second, consider the case with $\theta < \overline{\theta}$. Suppose that the contract contains the termination right. If the contract also includes an indemnification clause, the earlier analysis implies that the termination right itself cannot induce the agent to take precautions and the client would conduct monitoring with some probability. Similar to the analysis in the baseline model, both the client and agent will play mixed strategies. Let q be the probability for the agent to take precautions. If the client conducts monitoring and the agent does not take precautions, the client would not make indemnification payments and therefore would not terminate the project. If the client does not conduct monitoring but observes the non-verifiable signal of the agent's negligence, the client would terminate the project (given the assumption $v > R - \pi_0 D - r^{**}$). The client is indifferent between monitoring or not, which

implies

$$\begin{aligned} & -K + q(R - r - \pi_1 D) + (1 - q)(R - r) \\ = \; & q(R - r - \pi_1 D) + (1 - q)[(1 - \theta)(R - r - \pi_0 D) + \theta v]. \end{aligned}$$

Similar to the proof of Lemma 2 and Proposition 1, it can be shown that the optimal royalty is r^{**}, so that the client would never terminate the project when there is no signal of negligence. Accordingly, the client's expected payment is

$$\begin{aligned} T''(D;\theta) &= r^{**} + \pi_1 D + \frac{(\pi_0 - \pi_1)D - \theta(r^{**} + v + \pi_0 D - R)}{\pi_0 D - \theta(r^{**} + v + \pi_0 D - R)} K \\ &< r^{**} + \pi_1 D + \frac{\pi_0 - \pi_1}{\pi_0} K \\ &= T(D). \end{aligned}$$

Therefore, $T''(D;\theta) < r^*(D)$ whenever $T(D) \leq r^*(D)$. Thus, as long as the contracting cost δ is not large, the optimal contract includes the termination right and an indemnification clause for a larger set of parameters as compared to the case without termination rights. ■

APPENDIX B: EXTENSION WITH PARTIAL INDEMNIFICATION

In the baseline model, we focus on the client's choice between full indemnification and no indemnification. In theory, the client can use a contract with partial indemnification $s \in (0, D)$, although in practice it could be costly for the client and agent to predict potential damages or negotiate the amount of indemnification payments. In this section, we show that even when the client can use partial indemnification, the main results about monitoring stay robust.

Given a contract (r, s) where $s \in [0, D]$, the client would not conduct monitoring if $K \geq \pi_a s$, where $a = \{0, 1\}$ indicates whether the agent takes precautions or not. Accordingly, if the contract offers a positive but small indemnification s, there may exist an equilibrium

with the client and agent playing pure strategies, which is different from the analysis in the baseline model. Instead of trying to characterize all possible equilibria with pure and mixed strategies, we focus on the question of when the client's optimal contract includes full, partial, or no indemnification. As shown in the following proposition, the optimal contract includes full indemnification only when the monitoring cost is not too large and the agent's potential liability is large. But different from the results in the baseline model, the optimal contract contains partial indemnification when the potential liability is small.

Proposition 3 *If* $C < \frac{\pi_0}{1-\pi_0}u(w)$, *for any* $D > \overline{D}$, *there exists a unique cut-off* $\widetilde{K} \in (0, \overline{K}]$ *such that the client's optimal contract includes full indemnification* $s = D$ *if and only if* $K \leq \widetilde{K}$. *For all other parameter values, the optimal contract includes partial indemnification.*

Proof of Proposition 3. We first prove two claims.

Claim 1: If the client's optimal contract is $(\widetilde{r}, \widetilde{s})$, where $\widetilde{s} \in (0, D)$, then in equilibrium the agent is indifferent between taking precautions and not taking precautions. If the client employs a pure strategy under this contract, then his/her expected payment is $\widetilde{r}+\pi_1\widetilde{s}$; if the client employs a mixed strategy (i.e., randomizes between monitoring and not monitoring), his/her expected payment is $\widetilde{r} + \pi_1\widetilde{s} + \frac{\pi_0-\pi_1}{\pi_0}K$.

Proof of Claim 1: The first part of the claim holds in any equilibrium where the agent plays mixed strategies (i.e., randomizing between precautions and no precautions). Now consider any equilibrium where the agent plays a pure strategy. Suppose that the client's optimal contract is $(\widetilde{r}, \widetilde{s})$, where $\widetilde{s} \in (0, D)$, under which the agent plays a pure strategy $a = \{0, 1\}$. If $\widetilde{s} < \frac{K}{\pi_0}$, then the client does not conduct monitoring, irrespective of whether the agent takes precautions or not. Suppose that $\widetilde{s} \geq \frac{K}{\pi_0}$. If in the equilibrium the agent takes precautions for sure, then the client would not conduct monitoring; if the agent does not take precautions, then the client would conduct monitoring (given $\pi_0\widetilde{s} \geq K$), in which case an indemnification payment would not be made. In this latter case, the client could save the monitoring cost by using a contract $(\widetilde{r}, s = 0)$. To summarize, if the optimal

contract contains partial indemnification $\widetilde{s} \in (0, D)$ and induces the agent to play a pure strategy, then the client would never conduct monitoring.

Suppose that the optimal contract induces the agent to take precautions, then the client's expected payment is $\widetilde{r} + \pi_1 \widetilde{s}$, with the contract satisfying

$$(\pi_0 - \pi_1)[u(w + \widetilde{r}) - u(w + \widetilde{r} + \widetilde{s} - D)] \geq C; \tag{3}$$

$$(1 - \pi_1)u(w + \widetilde{r}) + \pi_1 u(w + \widetilde{r} + \widetilde{s} - D) - C \geq u(w). \tag{4}$$

We can show that the incentive compatibility constraint (3) is binding. To see this, suppose to the contrary that

$$\Delta \equiv (\pi_0 - \pi_1)[u(w + \widetilde{r}) - u(w + \widetilde{r} + \widetilde{s} - D)] > C.$$

Then condition (4) must be binding, as otherwise the client could reduce his/her expected payment by choosing $r < \widetilde{r}$. Given the binding condition (4), we have

$$\begin{aligned}
\frac{d\widetilde{r}}{d\widetilde{s}} &= -\frac{\pi_1 u'(w + \widetilde{r} + \widetilde{s} - D)}{(1 - \pi_1)u'(w + \widetilde{r}) + \pi_1 u'(w + \widetilde{r} + \widetilde{s} - D)} < 0; \\
\frac{d(\widetilde{r} + \widetilde{s})}{d\widetilde{s}} &= 1 - \frac{\pi_1 u'(w + \widetilde{r} + \widetilde{s} - D)}{(1 - \pi_1)u'(w + \widetilde{r}) + \pi_1 u'(w + \widetilde{r} + \widetilde{s} - D)} > 0; \\
\frac{d(\widetilde{r} + \pi_1 \widetilde{s})}{d\widetilde{s}} &= \pi_1[1 - \frac{1}{(1 - \pi_1)\frac{u'(w+\widetilde{r})}{u'(w+\widetilde{r}+\widetilde{s}-D)} + \pi_1}] < 0; \\
\frac{d\Delta}{d\widetilde{s}} &= (\pi_0 - \pi_1)\frac{-u'(w + \widetilde{r} + \widetilde{s} - D)u'(w + \widetilde{r})}{(1 - \pi_1)u'(w + \widetilde{r}) + \pi_1 u'(w + \widetilde{r} + \widetilde{s} - D)} < 0.
\end{aligned}$$

That is, the client could marginally increase the indemnification payment above $\widetilde{s}$ and reduce the royalty payment to keep condition (4) binding. Condition (3) still holds under this new contract. But this new contract strictly decreases the client's expected payment $\widetilde{r} + \pi_1 \widetilde{s}$, which is a contradiction. Therefore, given the optimal contract $(\widetilde{r}, \widetilde{s})$, where $\widetilde{s} \in (0, D)$, if the agent chooses precautions, condition (3) must be binding. Similarly, we can

show that given the optimal contract, if the agent does not take precautions, the incentive compatibility constraint must be binding as well. To summarize, if the contract contains partial indemnification, the agent is indifferent between taking precautions and not taking precautions.

Finally, if the agent plays a pure strategy under the contract ($\widetilde{r}, \widetilde{s} \in (0, D)$), the earlier analysis suggests that the client does not conduct monitoring and the agent is indifferent between taking precautions or not. Without loss of generality, assume that the agent takes precautions. Accordingly, the client's expected payment is $\widetilde{r} + \pi_1 \widetilde{s}$.

If both the agent and client play mixed strategies under the contract ($\widetilde{r}, \widetilde{s} \in (0, D)$), then the client must be indifferent between monitoring and not monitoring. Suppose that the client conducts monitoring with probability p and the agent takes precautions with probability q. Then, similar to the analysis in the baseline model, we have

$$-K - q\pi_1 \widetilde{s} = -q\pi_1 \widetilde{s} - (1-q)\pi_0 \widetilde{s},$$

which implies $q = 1 - \frac{K}{\pi_0 \widetilde{s}} \in (0, 1)$. Accordingly, the client's expected payment is $\widetilde{r} + \pi_1 \widetilde{s} + \frac{\pi_0 - \pi_1}{\pi_0} K$. This concludes the proof for Claim 1.

Claim 2: The client prefers partial indemnification to no indemnification.

Proof of Claim 2: As shown in Lemma 1, if $s = 0$, the client's optimal royalty payment is $\min\{r_0(D), r_1(D)\}$. Define $r_0(D, s)$ and $r_1(D, s)$ by

$$\begin{aligned} u(w) &= (1-\pi_1)u(w + r_1(D,s)) + \pi_1 u(w + r_1(D,s) + s - D) - C \\ &= (1-\pi_0)u(w + r_0(D,s)) + \pi_0 u(w + r_0(D,s) + s - D). \end{aligned}$$

Note that $r_0(D, 0) = r_0(D)$ and $r_1(D, 0) = r_1(D)$. Consider two scenarios.

First, if $r_0(D,0) > r_1(D,0)$, then for $s = 0$ we have

$$\begin{aligned} & (1-\pi_1)u(w+r_1(D,s)) + \pi_1 u(w+r_1(D,s)+s-D) - C \\ = \; & (1-\pi_0)u(w+r_0(D,s)) + \pi_0 u(w+r_0(D,s)+s-D) \\ > \; & (1-\pi_0)u(w+r_1(D,s)) + \pi_0 u(w+r_1(D,s)+s-D), \end{aligned}$$

which implies, for $s = 0$,

$$(\pi_0 - \pi_1)[u(w+r_1(D,s)) - u(w+r_1(D,s)+s-D)] > C.$$

In this case, similar to the proof of Claim 1, we can show that $\frac{d(r_1(D,s)+\pi_1 s)}{ds} \mid_{s=0} < 0$ and $\frac{d(r_1(D,s)+s)}{ds} \mid_{s=0} > 0$. Therefore, by using $s = \varepsilon$, where ε is positive but arbitrarily close to 0 (so $\varepsilon < \frac{K}{\pi_0}$), the client would not conduct monitoring and the agent would take precautions. Accordingly, the client's expected payment is $r_1(D,\varepsilon) + \pi_1\varepsilon < r_1(D,0)$. That is, the client strictly prefers partial indemnification to no indemnification.

Second, if $r_0(D,0) \leq r_1(D,0)$, then for $s = 0$, we have

$$\Delta' \equiv (\pi_0 - \pi_1)[u(w+r_0(D,s)) - u(w+r_0(D,s)+s-D)] \leq C;$$

Again we have $\frac{d(r_0(D,s)+\pi_0 s)}{ds} \mid_{s=0} < 0$, $\frac{d(r_0(D,s)+s)}{ds} \mid_{s=0} > 0$ and $\frac{d\Delta'}{ds} \mid_{s=0} < 0$. Therefore, by offering $s = \varepsilon$, where ε is positive but arbitrarily close to 0 (so $\varepsilon < \frac{K}{\pi_0}$), the client would not conduct monitoring and the agent would not take precautions. Accordingly, the client's expected payment is $r_0(D,\varepsilon) + \pi_0\varepsilon < r_0(D,0)$. That is, the client strictly prefers partial indemnification to no indemnification. This concludes the proof for Claim 2.

Now we proceed to show the results in Proposition 3. As shown in Proposition 1, the client prefers full indemnification to no indemnification only when $C < \frac{\pi_0}{1-\pi_0}u(w)$, $D > \overline{D}$, and $K < \overline{K}$. And the client's expected payment under full indemnification is $r^{**} + \pi_1 D + \frac{\pi_0 - \pi_1}{\pi_0}K$.

Let $(\widetilde{r}, \widetilde{s} \in (0, D))$ be the optimal contract among all contracts with partial indemnification. Given the definition of r^{**} and condition (6), we have

$$\begin{aligned} & u(w + \widetilde{r} + \pi_1 \widetilde{s} - \pi_1 D) \\ > \; & (1 - \pi_1) u(w + \widetilde{r}) + \pi_1 u(w + \widetilde{r} + \widetilde{s} - D) \\ \geq \; & u(w) + C \\ = \; & u(w + r^{**}), \end{aligned}$$

which implies $\widetilde{r} + \pi_1 \widetilde{s} > r^{**} + \pi_1 D$.

If the client plays a mixed strategy under the contract $(\widetilde{r}, \widetilde{s} \in (0, D))$, then as shown in Claim 1, the client's expected payment is $\widetilde{r} + \pi_1 \widetilde{s} + \frac{\pi_0 - \pi_1}{\pi_0} K$, which is higher than $r^{**} + \pi_1 D + \frac{\pi_0 - \pi_1}{\pi_0} K$. That is, the client prefers full indemnification to partial indemnification. In this case, define $\widetilde{K} = \overline{K}$. Proposition 1 and the above analysis suggest that the optimal contract includes full indemnification if and only if $C < \frac{\pi_0}{1 - \pi_0} u(w)$, $D > \overline{D}$, and $K < \widetilde{K}$.

If the client plays a pure strategy under the contract $(\widetilde{r}, \widetilde{s} \in (0, D))$, then as shown in Claim 1, the client's expected payment is $\widetilde{r} + \pi_1 \widetilde{s}$, which is independent of K. Define K' by

$$r^{**} + \pi_1 D + \frac{\pi_0 - \pi_1}{\pi_0} K' = \widetilde{r} + \pi_1 \widetilde{s}.$$

Since $\widetilde{r} + \pi_1 \widetilde{s} > r^{**} + \pi_1 D$, we have $K' > 0$. In this case, the client prefers the contract $(r^{**}, s = D)$ to the contract $(\widetilde{r}, \widetilde{s} \in (0, D))$ if and only if $K < K'$. Define $\widetilde{K} = \min\{K', \overline{K}\}$. Then Proposition 1 and the earlier analysis suggest that the optimal contract includes full indemnification if and only if $C < \frac{\pi_0}{1 - \pi_0} u(w)$, $D > \overline{D}$, and $K < \widetilde{K}$. ■

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Notes

[1] Aghion et al. (2001) also show that, in other industries with much less competition, competition and innovation can have a negative relationship.

[2] For example, see *Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286 (2002).

[3] Additionally, indemnification may not be necessary if agents have very limited assets and can avoid liabilities via bankruptcy, as shown by Mullin and Snyder (2010). Essentially this is the judgment-proof problem discussed by Shavell (1986).

[4] In theory but rare in practice, the client may adopt a non-contingent indemnification clause. Many state laws in the U.S impose restrictions on non-contingent indemnification. Section 2 provides more background information.

[5] To focus on this trade-off, we abstract away from the possibility that courts may make errors in imposing sanctions, a point discussed by Mullin and Snyder (2010). Adding court errors would not change the main results in this article.

[6] Winter (1991) provides an overview of the liability-insurance market and its relation to tort law. Meurer (1992) and Lemus et al. (2021) discuss how ex-post settlement bargaining affects the design of liability-insurance contracts.

[7] Friedman and Wickelgren (2017) provide a theoretical study of different liability rules for injuries caused by generic drugs. They do not consider contractual indemnification for liabilities arising during R&D projects.

[8] There are many other empirical studies on agency contracts, for example, Brickley and Dark (1987), Brickley (1999), and Elfenbein and Lerner (2003, 2012).

[9]Between 1998 and 2018, the U.S. Food and Drug Administration approved only about 30 new-molecular-entity drugs each year, even though thousands firms invested in various R&D projects. See https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019

[10]See the report at: https://www.clearwaterinternational.com/assets/pdfs/L7177-Clearwater-International-Pharma-Report-2019-FINAL.pdf

[11]Viscusi et al. (1994) documented the high liability costs in the pharmaceutical industry.

[12]Morreim (2004) and Singh (2009) investigate litigation risks for researchers, especially those conducting clinical trials.

[13]*Wright v. Fred Hutchinson Cancer Research Center*, 269 F. Supp. 2d 1286 (2002); and *Berman v. Fred Hutchinson Cancer Research Center*, No. C01-0727L (2002). For more related lawsuits and discussions, see the following sites: http://www.appliedclinicaltrialsonline.com/heading-clinical-trial-liability-lawsuit, https://www.agcs.allianz.com/insights/expert-risk-articles/watching-clinical-trials-liability/

[14]See Meurer (2017) for a review of patent litigation cases and the use of indemnification contracts in the supply chain. In particular, Meurer (2017) states that one reason why agents currently face growing patent litigation risks is that "the growth of complex and modular technology is associated with more decentralized innovation and more collaboration between parties who might participate in an infringing activity."

[15]See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (2012).

[16]See Mullin and Snyder (2010) for discussions about liability risks for company directors and executives.

[17]In other industries, there are exceptions where indemnification contracts contain caps, for example, see *Moore & Assocs., Inc. v. Jones & Carter Inc.*, 217 F. App'x 430 (2007).

[18]In *Brooks v. Judlau Contracting Inc.*, 11 N.Y. 3d 204 (2008), the Court of Appeals concluded that contracts should not attempt to indemnify a party for its own negligence.

[19]See *Widson v. Int'l Harvester Co., Inc.*, 153 Cal. App. 3d 45, 59 (1984).

[20]See *Blum v. Kauffman*, 297 A.2d 48, 49 (1972).

[21]Source: the Fifty-state Survey by Weinberg Wheeler on Agreements to Indemnify and General Liability Insurance. See https://www.wwhgd.com/assets/attachments/50%20State%20Survey%2000810220.PDF

[22]Experience has been widely used as a proxy for monitoring capabilities in the finance literature. For instance, institutional investors with more experience in investments can provide intensive monitoring and increase the effectiveness of monitoring actions (Barry et al., 1990; Nahata, 2008; Krishnan et al., 2011; Kang et al., 2018).

[23]Both on-site and off-site monitoring is important for quality management of clinical trials (Willson et al., 2014). Such monitoring actions need people who have relevant skills to review research data and

activities. A pharmaceutical client with more experience can have more established human capital and stronger capabilities to identify potential risks.

[24]Recap provides another dataset on all the clinical trials that have been filed by pharmaceutical firms with the U.S. Food and Drug Administration (FDA) since 1963. Based on this dataset, we can count how many clinical trials in which each firm had been involved.

[25]The first of these agreements was signed in 1987, and the last one was in 2004. Among the agreements with indemnification, the first one was signed in 1989, and the last one was in 2009.

[26]In particular, two of the eight agreements signed in 1992 did not offer indemnification.

[27]The Recap Dataset classifies all the R&D agreements into 21 disease types, which is almost consistent with the disease classifications employed by the World Health Organization and U.S. Food and Drug Administration (FDA). Based on the dataset of clinical trials, we can count how many other firms have conducted clinical trials of the same disease type.

[28]We abstract away from judgment-proof issues. As shown by Mullin and Snyder (2010), firms do not offer indemnification to their agents if the agents' wealth is much less than the expected liability. The results about the impact of monitoring stay robust even if the agent has limited wealth.

[29]Note that the client would never engage in monitoring if $K \geq \pi_0 D$.

[30]The results stay robust if we consider imperfect monitoring.

[31]In this paper, we focus on the risk of harming third parties and abstract away from other uncertainties, such as the probability of the R&D project being successful.

[32]Alternatively, if courts follow negligence rules (imposing less liability on an agent who has taken precautions) and the client's monitoring generates evidence that the agent has taken precautions, the client may have greater incentives to engage in monitoring. However, as long as liabilities are not reduced to zero under negligence rules, the main insights in this paper still hold.

[33]See Hay and Spier (2005) for a study about liabilities shared by manufacturers and customers when customers' use of products causes harm to third parties.

[34]We also extend the model by considering non-contingent indemnification. The analysis is available upon request.

[35]For example, termination rights can address moral hazard problems and motivate agents to exert R&D effort, as studied by Lerner and Malmendier (2010) and Guo et al. (2017).

[36]We abstract away from renegotiation over the contract. The results hold if renegotiation is feasible but very costly.

[37]The analysis of the optimal choice of e and the impact of competition is similar to that in the baseline model.

[38] Recap classifies the nature of each agreement. If an agreement is classified as "R," "D," "CoD," and/or "CoL," it involves R&D activities by the agent. We also read all the contracts to verify their nature.

[39] Agreements with three or more agents have too much heterogeneity among the agents, and therefore, are eliminated.

[40] Costs of clinical trials accounted for approximately 58.2% and 57.1% of the total R&D expenses in new drug development between the 1990s and mid-2000s and between 2000s and mid-2010s, respectively (DiMasi et al., 2003 and 2016).

[41] The disease types include allergic, autoimmune inflammatory, bone, cancer, cardiovascular, central nervous system, dental oral, dermatologic, endocrinological and metabolic, gastrointestinal, genitourinary gynecologic, hematologic, infectious-bacterial, infectious-miscellaneous, infectious-viral, ophthalmic, psychiatric, renal, respiratory, transplantation, and other miscellaneous items.

[42] The literature uses various measures of competition. For example, Goldberg and Knetter (1999), Wallsten (2003), and Guo et al. (2017) use the number of competitors to measure competition in different industries. We do not observe each firm's market share or sales related to a particular disease type and therefore cannot use other measures such as HHI.

[43] We do not control the sizes of project investments or royalty rates, as Recap hides the information for many agreements and these are choice variables in contract design.

[44] The definition of this stage variable is consistent with that in Lerner and Malmendier (2010).

[45] The expected market size can affect pharmaceutical firms' innovation incentives, as shown by Dubois et al. (2015).

[46] It would be ideal to control all of the disease-fixed effects by using 20 disease dummies. However, given the sample size, controlling too many disease-fixed effects would make the p-value of the F-test larger than 0.1, implying that the joint effects of the variables included in the regression are not significant.

[47] The *Newsmagazine for Pharmacists* publishes sales data of the top 200 branded and top 200 generic drugs between 2000 and 2010.

[48] Controlling year-fixed dummies would remove all data observations in some years and create "gaps" in the sample, as all observed agreements in these years had indemnification clauses. Moreover, most clients in our dataset did not enter into R&D alliances frequently.

[49] EBITDA stands for earnings before interest, taxes, depreciation, and amortization.

[50] All the results with OLS estimations are similar.

[51] The results are similar when we use robust standard errors or clustered standard errors at the disease-type level. Since the clients did not enter R&D alliance agreements frequently in our dataset, we could not cluster standard errors at the client and year level.

[52] We report the marginal effects under these logit regressions. The corresponding coefficients are significant as well.

[53] See Brickley (1999) and Lafontaine and Raynaud (2002).

[54] Filson and Morales (2006) investigate equity links in biotechnology alliances.