

Mind the Time: Failure Response Time, Variations in the Reasons for Failures, and Learning from Failure

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Abstract

How does a firm's response time to past failures affect its likelihood of experiencing future failures? Does this likelihood depend on the reasons for past failures? Using drug recalls during 2006-2016, we examine the effect of pharmaceutical firms' response time to their past failures on their learning from failure. Longer response times reduce the likelihood of subsequent failure. Variations in the reasons for past failures increase the potential for subsequent failure. However, a longer response time helps overcome the challenges associated with this variation. By focusing on the temporal dimension of learning from failure, we provide unique theoretical insights into when and how organizations can learn from failure.

Key words: Learning from failure; response time; variations in experiences of failure; organizational learning; pharmaceutical industry.

1. Introduction

Studies have recognized organizational failure—the deviation from desired performance outcomes—as an important source of organizational learning (Sitkin, 1992; Desai, 2011; Dahlin, Chuang and Roulet, 2018). Failure focuses a firm’s attention on imperfections in its organizational processes (Baum and Dahlin, 2007; Madsen and Desai, 2010; Maslach, 2016). Given that failure may hurt the company’s reputation and result in financial losses (Rhee and Haunschild, 2006; Thirumalai and Sinha, 2011; Haunschild, Polidoro and Chandler, 2015), managers are faced with a dilemma. Should they respond swiftly to address shareholders’ short-term concerns, or should they take the time to understand the root causes to prevent future failures? (Lei, Naveh and Novikov, 2016). As a scarce and unscalable resource, time needs to be managed effectively in response to a failure, especially given the need to identify a timely solution that fixes current issues while avoiding subsequent failures (Bluedorn and Denhardt, 1988).

Scholars offer seemingly diverging managerial advice on the appropriate response time to a failure. One school of thought suggests that a slow response may amplify the firm’s financial and reputational losses, increase the possibility of its forgetting about the failure, and, most importantly, reduce the firm’s motivation to learn from it (Haunschild et al., 2015; Desai and Madsen, 2022). A second school, however, suggests that a slower response allows the firm to deeply investigate the root causes of the failure, search for and experiment with viable solutions, and finally codify these solutions to prevent future failures (Lei et al., 2016; Avgerinos, Gokpinar and Fragkos, 2020). This scholarly discussion clearly highlights the risks and rewards associated with the time management of different response strategies.

Even though research has recognized the time involved in responding to failure as an important dimension of organizational learning (e.g., Muehlfeld, Rao Sahib, and Van Witteloostuijn, 2012; Musaji et al., 2020; Desai and Madsen, 2022), it has not directly

examined its effects. Time, however, has both theoretical and empirical importance. It directly impacts the what (i.e., temporality of learning), how (i.e., codifiability of past failures), and why (i.e., causality between failures and their prevention) elements of theory (George and Jones, 2000). Thus, adding a temporal dimension to learning from failure, such as response time, has a significant role in advancing organizational learning theory. Building on this gap, we theorize that taking longer to respond to past failures is associated with a decrease in the likelihood of subsequent failures.

Another important relationship that has been underexplored is the effect of variations in the reasons for the failure, and thus of experiences, on the likelihood of a future failure (Haunschild and Sullivan, 2002; Shah, Ball and Netessine, 2017). An examination of the broader learning from experience literature reveals a theoretical puzzle. While some scholars argue that variations in experiences increase a firm's ability to learn due to potential knowledge spillovers across experiences (Haunschild and Sullivan, 2002; Zollo and Winter, 2002; Musaji et al., 2020), others claim that these variations increase complexity and causal ambiguity, thus reducing the firm's ability to learn from its prior experiences (Fisher and Ittner, 1999; Boh, Slaughter and Espinosa, 2007; Kc and Terwiesch, 2011). While this theoretical debate is insightful, the empirical evidence on the effect of variations in experiences of failure on learning is limited to single-context studies such as airlines. In these cases, variations in the reasons for failure are closely related to each other, and so are the corrective actions. For example, a failure caused by inadequate organizational coordination may also feature errors by the flight crew and flight attendants (Haunschild and Sullivan, 2002). However, do variations in failure experiences also shape a firm's ability to learn from different reasons in contexts where they are unrelated to each other? Building on this stream of research, we theorize that variations in the reasons for past failures are associated with an increase in the likelihood of subsequent failures.

We further argue that we cannot fully evaluate the effect of these variations without a consideration of the duration of the firm's response to failures. Firms need time to identify, experiment with, and codify solutions to failures. A long response time represents an opportunity to gain in-depth knowledge, which can complement the knowledge breadth associated with variations in experience. Therefore, we hypothesize that failure response times negatively moderate the positive effect of variations in the reasons for past failures on subsequent failures. In doing so, we follow calls to further examine the extent to which organizational learning from variations in failures depends on the temporal dimension of experience (Shah, Ball and Netessine, 2017).

To examine these relationships, we use unique panel data on recalls issued by the U.S. Food and Drug Administration (FDA) to pharmaceutical firms that marketed cardiovascular drugs in the U.S. during 2006-2016. Our dependent variable, subsequent failure, measures the initiation of a drug recall in a following year. To operationalize our independent constructs, we identify drug recalls experienced by the firm in the prior five years, which we use to proxy for several dimensions of organizational experience with failure. First, we conceptualize past response time to a failure (response time, hereafter) as the average time that elapses between the identification of past drug recalls and their solution. Second, we conceptualize variations in the reasons for past failures (variations in reasons, hereafter) as an entropy-based index of the distribution of such past drug recalls across the FDA's categories of reasons.

Our findings show that a longer response time reduces the likelihood of a subsequent recall. In contrast, variations in the reasons for the failures increase this likelihood. More importantly, we find that response time reduces the positive relationship between variations in the reasons and the likelihood of a subsequent recall. We conclude that a longer response time helps overcome the challenges associated with variations in experience by exerting a negative moderating effect.

Our results contribute to the literature on organizational learning in several ways. First, by focusing on the temporal dimension of learning from failure, we provide a better assessment of when and how organizations can learn from failure (Madsen and Desai, 2010; Desai, 2015; Dahlin et al., 2018). We argue and demonstrate that, in the case of failure, on average, a longer response duration reduces the firm's likelihood of experiencing subsequent failure. These results shed fresh light on the debate between those who suggest that a fast response to a failure promotes greater performance and those who claim the opposite, that a slow response promotes greater learning. Second, we establish that variations in the reasons indeed increase the likelihood of a future failure, but a longer response time to past failures attenuates this effect. By implication, before resorting to old solutions to new problems, managers should spend the time necessary to analyze the specific root causes of new problems and codify their new knowledge to implement appropriate solutions, especially when there are numerous variations in the reasons for the past failures. Understanding the critical element of time can help managers and their organizations manage the financial, human, and reputational costs associated with failures, and prevent them in the future.

2. Theory

Time is a critical dimension in decisions about how to respond to failure (Dahlin et al., 2018). When organizations face a failure, managers are very conscious that a quick response may help reduce the short-term harm to their performance and reputation but also has long-term negative implications. In fact, a slow response is needed for managers and firm members to properly investigate and understand the issues underlying a failure, and review their prior failure experiences to find or develop a viable solution. Indeed, research has established that the time a firm spends processing information about a failure has a critical impact on its performance (Shepherd, Patzelt and Wolfe, 2011; Lei et al., 2016). As a scarce and unscalable organizational resource, time is an important asset in failure management and prevention

(George and Jones, 2000; Shi, Sun, Prescott, 2012; Brides, Smith, and Grimm, 2013) that needs to be managed prudently (Bluedorn and Denhardt, 1988).

The organizational learning literature has examined time as a multidimensional concept that includes three core dimensions: time as duration, timing (rhythm, timeliness, and synchronization of actions and events) and the temporal modalities of past, present, and future (for a review, see Berends and Antonacopoulou, 2014). In this paper, we focus on time as response duration. We recognize that it can be both an opportunity for and a threat to organizational learning from failure (Berends and Antonacopoulou, 2014). We also recognize that firms with similar levels of experience with failure may implement different response strategies to deal with the situation. Specifically, some scholars contend that the quick iteration of activities results in more learning (Bingham, Heimeriks, Schijven, and Gates, 2015; Haunschild et al. 2015; Desai and Madsen, 2022). Others suggest that a quick response does not serve the organization well when searching for the root causes of a failure, nor does it provide the organization with an opportunity to create and disseminate organizational knowledge (Weber and Berthoin Antal, 2001; Hassard, 2002; Martin and Salomon, 2003; Tucker and Edmondson, 2003). We view these seemingly contradictory arguments as complementary, as each highlights the risks and rewards associated with each temporal strategy.

Different response duration strategies may also reflect variations in a firm's experience with failure (Haunschild and Sullivan, 2002; Zeng et al., 2022). These variations can foster learning by providing rich information about the causal structure of the failure experience (Schilling et al., 2003; Zollo, 2009; Musaji et al., 2020). However, they can also impair learning by increasing causal ambiguity and complexity (Fisher and Ittner, 1999; Boh, Slaughter and Espinosa, 2007; Kc and Terwiesch, 2011). We reconcile these views by building a theoretical model that examines the direct and interactive effects of the time spent

on the resolution of past failures and the variations in the reasons for such failures on organizational learning.

3. Hypotheses

3.1 Response time and learning

Organizational learning scholars diverge in their perspectives on the role of time in learning from experience. One school of thought suggests that a faster pace may accelerate learning by providing timely information and incentivizing knowledge codification (Bingham, Heimeriks, Schijven, and Gates, 2015; Haunschild et al., 2015). Furthermore, this school of thought argues that time is a threat for organizational learning, because, over time, firms may forget the knowledge acquired from experience (Argote et al., 1990; Holan and Phillips, 2004). In addition, newly acquired knowledge may become obsolete over time due to changes in the firm's external environment (Darr, Argote and Epple, 1995; Ingram and Baum, 1997). For example, Haunschild et al. (2015) showed that organizations oscillate between periods of learning and forgetting, which are driven by the shift of attention from one focus to another. Specifically, as time passes since the last error and the organization moves into an error-free period, the firm forgets the lessons learned from experience (Haunschild et al., 2015). Similarly, Desai and Madsen (2022) demonstrated that when the organization's experiences are frequent and routinized, so they do not differ much from one iteration to another, organizational knowledge is created, codified, and disseminated more rapidly. Therefore, they concluded that a quick iteration of activities results in more learning than longer intervals between activities.

While the first school of thought emphasizes the urgency needed in learning from recent failure, the second focuses on identifying, codifying, and implementing the lessons learned from past failures. Specifically, it suggests that fast responses may help identify a rapid solution but not one that addresses and eliminates the root causes. Indeed, this approach

may result in more errors (Tucker and Edmondson, 2003; Lei et al., 2016). It also argues that the negative feedback associated with failure is inherently harder to interpret and learn from (i.e., causally ambiguous) than other forms of organizational experience (March, Sproull and Tamuz, 1991). Taking time to identify the root causes of the problems and develop potential solutions allows their proper implementation to eliminate reoccurrences (Berends and Antonacopoulou, 2014).

In many ways, the two schools complement rather than contradict each other. As highlighted by Rudolph, Morrison and Carroll (2009; p.734), “... *either acting slowly when one is unsure or generating alternatives too quickly can make it difficult to collect enough supporting information to confirm a diagnosis and resolve the crisis*”. Both schools highlight the need for urgency and the commitment to learning but have a different focus regarding the response time. Specifically, the first school suggests the need for urgency in identifying the cause of a failure as, otherwise, its lessons will be forgotten. Firm members will slide into complacency, reducing their ability to benefit from the learning opportunity. In that sense, a slow response time may reduce the likelihood of learning from failure. The second school focuses instead on learning related processes. Specifically, it argues that firms must spend time delving deeper into understanding the reasons for the failure, identifying solutions, experimenting with them, and adding them to their inventory of solutions.

Consistent with these observations, empirical research provides strong support for the argument that the time an organization spends processing information about a failure or an error has a critical impact on its performance (Shepherd, Patzelt and Wolfe, 2011; Avgerinos et al., 2020; Desai and Madsen, 2022). For instance, in their analysis of cardiac surgery operations, Avgerinos et al. (2020) argued and demonstrated that in complex, knowledge-intensive contexts, people need to take time to review the relevant information, interpret it, and internalize it. Similarly, in their study of hospital failures, Tucker and Edmondson (2003),

indicated that nurses habitually preferred a quick, short-term solution for most of the problems they experienced, but rarely took the time necessary to learn from and prevent the reoccurrence of similar issues. As a result, the organization was unable to learn broader lessons for improving its processes, routines, and structures, and preventing subsequent failures.

Based on the empirical evidence, we suggest that, on average, a longer response time helps organizations learn more from failure, for three main reasons. First, it gives the firm the opportunity to reflect on and identify the root causes of failure and avoid quick resolutions that commonly result in reoccurrences (Shepherd et al., 2011; Lei et al., 2016; Avgerinos et al., 2020). Firms can engage in deliberate, mindful learning processes that may help them avoid incorrect generalizations and superstitious learning (Levinthal and Rerup, 2006). Second, on average, a longer response time allows a firm to implement both corrective actions—to eliminate the adverse consequences of the current failure—and preventative actions—to eliminate the root causes of failures and prevent a reoccurrence (Lei et al., 2016). Finally, a longer response time allows the firm to refine and codify the routines and procedures associated with the corrective and preventive actions (Edmondson, Bohmer and Pisano, 2001; Hayward, 2002; Berends and Antonacopoulou, 2014). Accordingly, we expect:

Hypothesis 1 (H1). A longer response time to past failures reduces a firm's likelihood of a future failure.

3.2 Variations in experiences with failure and learning

Another factor that may affect the likelihood of future failure is variations in the reasons for past failures. The literature on organizational learning suggests that variations in experience both foster and impede learning (Levitt and March, 1988; Staats and Gino, 2012; Argote, 2013; Dutt and Lawrence, 2022). Specifically, some argue that varied experiences promote the emergence of multiple alternative solutions and, therefore, improve the organization's problem-solving ability (Janis and Mann, 1977; Zollo, 2009) and enhance learning (Musaji et

al., 2020). The richness of the information provides more opportunities to learn (Reason, 1997; Haunschild and Sullivan, 2002; Stan and Vermeulen, 2013). For example, Haunschild and Sullivan (2002) showed that airlines that have experienced various types of accidents are better able to reduce their subsequent errors. This result is particularly true when organizations are specialized, and the root causes of their past failures are closely related to each other.

Related research, however, reports that variations in the reasons for failure may also result in more future failures (Staats and Gino, 2012; Avgerinos et al., 2020). These variations increase causal ambiguity, which requires firms to determine which experiences are relevant to the current problem, how to derive useful insights from them, and how to apply these insights to solve the current problem and then codify new knowledge (Desai and Madsen, 2022; Zeng et al., 2022). For example, Shah, Ball and Netessine (2017) established a relationship between the variety of products in an automobile, measured by the number of options installed in it, and an increase in the number of manufacturing recalls of the model. Similarly, Thirumalai and Sinha (2011) reported that medical device firms with a broader range of products were more likely to experience product recalls. They attributed this effect to the decreased operational focus that firms with a broader portfolio have, which compromises their ability to design, develop, produce, and monitor different product lines.

The main reason for the divergence of these two views is that those who suggest that variations in experience have a positive effect do not consider the scarcity and unscalability of time in learning from experience. When the causes of multiple failures in the firm's past are related to each other—such that the firm's experience is homogeneous—it is likely that the firm spent time developing in-depth knowledge of a feasible solution that could be easily redeployed to anticipate and correct future events. However, this is possible only if these new events involved causes that are related to the firm's prior experience. In contrast, when a

firm's experiences involve multiple, unrelated reasons for its failures—meaning, the firm's experience is heterogeneous—it is likely that the firm had to dilute the time spent on resolving past failures that were idiosyncratic. Thus, it favored the development of broad knowledge at the expense of less in-depth understanding of cause and effect relationships. Such variations in the reasons for the failures limit the applicability of past solutions and past procedures for dealing with new and dissimilar problems (Zollo, 2009; Desai and Madsen, 2022; Zeng et al., 2022).

By reducing the generalizability of past cognitive lenses, solutions, routines, and procedures (March et al., 1991; Konlechner and Ambrosini, 2019; Zollo and Winter, 2002), while also increasing complexity and casual ambiguity, variations in the reasons for failure may prompt organizations to experiment with new solutions, routines, and procedures through trial-and-error methods (Stan and Vermeulen, 2013). Such experimentation and exploratory search can prove risky and may increase subsequent errors and failures (Levinthal and March, 1993; Edmondson, 1999; Katz-Navon, Naveh, and Stern, 2009; Lei et al., 2016). Accordingly, we suggest:

Hypothesis 2 (H2). Variations in the reasons for past failures increase a firm's likelihood of future failure.

3.3 *Response time and variations in the reasons for failure*

Implicit in the various arguments on learning from variations in the reasons for failure is the idea that a firm's ability to learn from it depends on the response time afforded to the firm's members. Haunschild and Sullivan (2002), for example, suggested that variations in experience prompt organizations to *“look deeper, and not focus narrowly in their analysis of causes, as a prescriptive solution to accident prevention”* (p. 614). Deeper examination requires time, which organization members need in order to investigate the root causes and make generalizations across failure events (Haunschild and Sullivan, 2002; Muehlfeld et al., 2012; Zeng et al., 2022). Time also provides firm members with an opportunity to generalize

and determine which experience is relevant for the current problem, how to derive useful insights from these experiences, and how to apply these insights to solve the current problem and then codify the new knowledge (Desai and Madsen, 2022; Zeng et al., 2022).

Accordingly, we suggest that the response time to past failures attenuates the negative relationship between variations in the reasons for past failures and subsequent failures, for three main reasons. First, a longer response time reduces the negative effect of causal ambiguity associated with variations in the reasons for the failure because it allows the firm to conduct a deeper investigation and derive useful insights. Time allows firms to process the abundance of information provided by variations in their experiences into new knowledge (Desai and Madsen, 2022). A richer understanding of the various causes reduces causal ambiguity and uncertainty, while also providing the firm with a clearer understanding of the direction for a resolution.

Second, a longer response time reduces the negative effects of experimenting with multiple solutions simultaneously. When firm members are not pressured by time during the trial-and-error stage, they are in a better position to identify the right solution for multiple unrelated causes. Furthermore, a longer response time allows the firm to experiment with new alternative solutions, deeply evaluate each one of them, and identify the most efficient solution without falling into the trap of automatically applying known solutions from past problems (Cohen et al., 1972; Prencipe and Tell, 2001, Baum and Dahlin, 2007). Finally, a longer response time gives firm members the opportunity to identify all of the processes and organizational routines that need to be changed. Such an opportunity to update organizational routines helps reduce the overall negative effect associated with variations in the reasons for the failure.

Accordingly, we expect that a longer average response time to past failures reduces the negative relationship between variations in the reasons for past failures and subsequent failures.

Hypothesis 3 (H3). The firm's response time will moderate the positive relationship between variations in the reasons for past failures and the likelihood of future failures, such that the latter will be less positive when response time is high.

4. Methods

4.1. *Research context*

We investigated the role of response time and variations in the reasons for past failures on cardiovascular drug recalls in the U.S. A pharmaceutical product recall refers to the removal or correction of marketed products that are in violation of the U.S. FDA's laws. Studies have used product recalls as examples of failures from which organizations can learn rich lessons for improving their organizational processes (e.g., Thirumalai and Sinha, 2011; Geleilate, Fainschmidt and Zollo, 2021). The recalling firm, under the monitoring of and in coordination with the FDA, conducts corrective actions—to eliminate the cause of a detected problem—and preventive actions—to prevent the recurrence of known problems or the occurrence of new potential problems (FDA, 2014). A recalling firm's ability to learn from its past recalls largely depends on the quality of its corrective and preventive actions. We suggest that the quality of these actions, in turn, depends on the amount of time the firm devotes to implementing these actions, as well as the variations in the reasons for such recalls.

4.2 *Data sources and sampling strategy*

We relied on data on product recalls initiated by pharmaceutical firms that commercialized cardiovascular drugs in the U.S. between 2006 and 2016. To build our sample, we used information provided by the U.S. FDA in the Drug Facts and Comparisons database, Thomson Reuters' SDC Platinum, ORBIS and Compustat. To sample cardiovascular drug firms, we first identified cardiovascular drug classes and the active

ingredients belonging to these classes using the classification of cardiovascular drugs in the Drug Facts and Comparisonsⁱ, a public pharmacological database providing a wealth of information about drugsⁱⁱ. We next searched for all drugs containing these ingredients using the FDA's National Drug Code Directory (NDC Directory). This registry also lists all firms that manufacture, package, label, or re-label drugs for commercial distribution in the U.S. It is important to note that firms listing products in this directory are not necessarily the original applicants of those drugs. They can also be contract manufacturers, as well as packagers, (re)labelers, or distributors. Finally, since our level of analysis is the firm, we consolidated all firms listing cardiovascular drugs at the corporate level. For this task, we relied on ORBIS, Thomson Reuters' SDC Platinum, and press releases to build the longitudinal corporate trees of the corporations to which these firms belonged.ⁱⁱⁱ We also searched for these firms in Compustat Fundamentals to obtain their standard industrial classification (SIC) codes and longitudinal financial data. We relied on their SIC code to select public firms with primary activity in "Pharmaceutical Preparations" (SIC 2834), "Drugs, Drug Proprietaries, and Druggists' Sundries" (SIC 5122), "Biological Products, except Diagnostic Substances" (SIC 2836), and "Drug Stores and Proprietary Stores" (SIC 5912). In this list, 75 corporations have manufactured, packaged, distributed, or labeled cardiovascular drugs.

Next, we identified any recalls these firms reported to the FDA. We obtained this information from Recall Enterprise System (RES).^{iv} This database contains more than 15,000 recalls registered between 2002 and 2017, of which only about 0.25% were mandated by the FDA. Following prior research (e.g., Cheah, Chan and Chieng, 2007), we thus focused on drug recalls that were voluntarily initiated by the firms.^v Despite this voluntary basis, the FDA has the overall responsibility to audit recalls. As one interviewee—an FDA official (a team leader of the Office of Enforcement Recall Team)—explained to us, the FDA monitors the firm's management of the recall and determines when the recall should be terminated. During

the recall process, the firm needs to provide the FDA with sufficient documentation on what has been corrected or removed, and on how it has addressed the reason for the recall. The FDA will then review this evidence and evaluate whether all reasonable efforts have been made by the firm. The FDA will terminate a recall only when it estimates that all necessary corrective and preventive actions have been implemented. Specifically, it occurs when the FDA determines “... *that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard*” (FDA, 2021, Regulatory procedures manual, Chapter 7 Recall Procedures: 26). The FDA relies on recall audit checks, the recalling firm’s status reports, and product disposition records to make termination decisions.

Even though the recalling firm does not have agency in terminating a recall, it has significant discretion on the speed at which it provides such evidence to the FDA. Indeed, another interviewee—a chief operating officer of a large pharmaceutical company—confirmed to us that firms are generally under pressure to terminate a recall. Even though doing so largely depends on the scope and complexity of the recall, firms can strategize on the timing of the response. Some may compromise the quality of post-recall investigations and solutions by speeding up the provision of necessary evidence to the FDA. Drug recalls at the FDA are, therefore, particularly relevant for studying the role of time in organizational learning from failure.

From this database we extracted information about the recalling firms, the recalled products, the reasons for the recalls, their severity class (based on the magnitude of the hazard associated with the affected products, i.e., Class I, Class II, Class III—Class I being the most severe), the dates of the recalls’ initiation and termination, and the geographical scope of the drugs’ distribution. In this list, 46 firms reported at least one recall during 2002-2017. These firms accounted for about 93% of cardiovascular drug registrations in the FDA’s NDC

directory over our study period. Given that having a past recall is a necessary condition for measuring our main independent constructs—recall response time and variations in the reasons for the failure—for the purposes of this study, we focused on these 46 firms.

We consolidated the data on an annual basis. The start and end years of our panel were dictated by data availability. As recall data were available from 2002-2017, and we used moving windows of time up to $[t-4, t]$ for the independent constructs and a time lag of $t+1$ for our dependent construct, our final dataset consisted of a balanced panel from 2006 to 2016, which included 394 firm-year observations.

4.3 Measures

For each firm-year observation in our dataset, we measured the following variables (see Table 1 for a detailed description of each measure and data sources).

[Insert Table 1 here]

4.3.1 Dependent variable

We built a theory that predicts the likelihood of a future recall. Accordingly, our dependent variable, *drug recall* _{$t+1$} , is a dummy variable equal to 1 if the firm had at least one recall during the following year. For a robustness check, not reported in the paper, we also measured the yearly count of recalls the firm initiated in the following year.

4.3.2 Independent variables

Response time. To operationalize our main construct, the response time to past failures, we first listed all the recalls the firm initiated and terminated in $[t-4, t]$ and calculated their duration as the number of months that elapsed between the recall's initiation and termination dates. Next, we calculated the *response time* _{$[t-4, t]$} variable as the average duration (in months) of recalls the firm initiated and terminated in the five-year moving window. It is important to note that a recall is considered to enter the firm's experience pool only after it has been already terminated. Given that knowledge extracted from experience may decay over

time due to forgetting and antiquation (Ingram and Baum, 1997; Argote et al., 1999; Haunschild and Rhee, 2004), learning studies often use some depreciation method to account for this possibility. The theory does not provide clear guidelines about the choice of appropriate discounting specification. The best specification depends on the specific context. Studies examining learning from experiences that are relatively frequent (e.g., product recalls, airline incidences, acquisitions) but still different from routine operating activities generally apply three-year to five-year moving windows to construct experience related measures (Haunschild and Sullivan, 2002; Haunschild and Rhee, 2004; Muehlfeld et al., 2012). We followed common practice and used five-year moving windows for all variables related to firm experience (Baum and Ingram, 1998; Haunschild and Sullivan, 2002). In a robustness check, not reported in the paper, we also tried three-year moving windows. Overall, our results (not reported here, but available upon request) were consistent with our main estimations.

Variations in the reasons. Recalls registered with the FDA provide a text description of the reasons for the recall. We used this description to establish categories of the reasons. We then measured our second dependent variable, the variations in the reasons for past failure, as an entropy-based index of the distribution of the firm's drug recalls in these categories in $[t-4, t]$. First, we reviewed the text descriptions of the entire dataset of recalls (containing more than 15,000 recalls). Using keyword clustering, we identified 280 different categories. With this list, we then consulted an industry expert, a chief operating officer of a large pharmaceutical company, who helped us aggregate them into 14 higher-order reasons for recalls in our data. Then, we consulted another industry expert, who confirmed these 14 categories. Firms in our sample have recalls belonging to 11 of these 14 categories. These causes are not related to each other, nor are the required corrective actions, which is

particularly important for the purposes of our study. Table 2 reports these 11 categories and their definitions.

[Insert Table 2 here]

With this information, we then followed prior research (Jehn, Northcraft and Neale, 1999; Haunschild and Sullivan, 2002) and used an entropy-based index to construct the variable *variations in the reasons* $_{[t-4, t]}$, which estimates the distribution of a firm's recalls across these categories in $[t-4, t]$. Specifically,

$$\text{Variations in the reasons}_{i[t-4, t]} = \sum_{i=1}^{11} -P_{i[t-4, t]} (\ln P_{i[t-4, t]}), \quad (1)$$

where P_i denotes the proportion of the firm's recalls initiated and terminated in each category i in $[t-4, t]$. The higher this index, the greater the variations in the reasons for the firm's failures.

4.3.3 Control variables

We controlled for several factors that might affect the probability of a subsequent recall. Consistent with prior studies, we accounted for the number of firm's past failures by including a variable, *past recalls* $_{[t-4, t]}$, that counts the number of recalls the firm issued over the past five years. Next, to account for the complexity in the firm's distribution system, we included a dummy variable, *international recalls* $_{[t-4, t]}$, that is equal to 1 if the firm had at least one recall that involved international distribution in the past five years. The geographical distribution of the firm's recalls can also impact the transfer of knowledge of past recall resolutions and, thus, organizational learning from them. Therefore, we controlled for *past recalls' geographical dispersion* $_{[t-4, t]}$, which is a Herfindahl index of the U.S. states' distribution of the firm's drug recalls initiated and terminated in $[t-4, t]$. Then, to account for the tendency of firms to oscillate between periods when the focus is on safety and periods when the focus is on innovation (Haunschild et al., 2015), we controlled for *new drugs approved* $_{[t-4, t]}$, the number of new drug applications (NDA) awarded to the firm in the five-

year window.

In addition, we controlled for the inspections that the FDA made in the pharmaceutical firms' manufacturing facilities^{vi}. The FDA inspects all manufacturing plants that commercialize drugs in the U.S. on average every two years. At the end of each inspection, the FDA provides an evaluation of the state of the facility's compliance with the FDA's rules and regulations. It also indicates if the firm is required to make a correction, termed "official action indicated" (OAI). OAI implies that the FDA has identified severe violations and forces the firm to take corrective measures. Given that such inspections may feature warnings, the firm's likelihood of issuing a subsequent recall may correlate with them. Accordingly, we controlled for *FDA inspections*_[t-1, t] (the number of FDA inspections at the firm during [t-1, t]) and the *FDA OAI ratio*_[t-1, t] (the ratio of FDA inspections with OAI outcomes during [t-1, t]). As these inspections occur every two years, on average, we used two-year windows for these controls. However, a robustness check with five-year windows (not shown in the paper, for the sake of conciseness) produced similar results.

As large firms (relative to small) tend to be more bureaucratic, which may influence their ability to provide a fast response, we controlled for *firm size*_t (the number of firm's employees in year t) and for *drug portfolio size*_t (the number of firm's drugs commercialized in year t). Then, to account for the effect of competitive dynamics, we controlled for the firm's *market share*_t in pharma-related SIC codes in the focal year. Finally, studies have established that corporate restructuring activities, such as M&As, have a disruptive effect on an organization's operational routines and procedures (Haunschild et al., 2015). Therefore, we included a dummy variable *M&A*_t, which indicates if the firm has at least one M&A in the focal year.

4.4 Statistical Methods

We measured the main dependent variable, *drug recall*, as a dummy variable. Therefore, our

main regression model is a logistic regression. Formally:

$$\text{Drug recall} = f(\text{response time, variations in the reasons, response time} \times \text{variations in the reasons}, \mathbf{X}; \beta), \quad (2)$$

where $\mathbf{X}$ is a vector of the control variables, and β is a vector of the parameters to be estimated. The Hausman statistic indicated no significant differences between fixed and random effect parameter estimates, so we included inventor random effects. As a robustness check, we also adopted a count specification of our dependent variable. Doing so showed overdispersion, so we used a panel negative binomial regression model (Cameron and Trivedi, 1998).

5. Results

Table 3 provides the descriptive and correlation statistics. The variance inflation factors (VIFs) are less than 10 and the mean VIF is 1.68, indicating that multicollinearity is not present in the data set^{vii}.

[Insert Table 3 here]

We present the results of our main estimation in Table 4. An inspection of the control variables reported in Model 1 reveals that the firm's *past recalls* increase the likelihood of a subsequent failure. Thus, prior failures do not necessarily lead to a reduction in future failures and may be associated with more future failures (Haunschild and Rhee, 2004). This finding highlights the importance of accounting for the characteristics of the failure experience and its context for understanding the subsequent learning processes (Baum and Dahlin, 2007; Madsen and Desai, 2010). Firms with a larger *FDA OAI ratio* were the most likely to recall a drug in the following year.

[Insert Table 4 here]

Model 2 in Table 4 tests Hypothesis 1. The negative and slightly significant coefficient ($\beta = -0.033$, $p < 0.05$) of *response time* suggests that the average duration of past recalls

reduces the likelihood of future *drug recalls*, in line with Hypothesis 1. An increase in the recall *response time* by one standard deviation results in a 40% decrease in the likelihood of a future recall ($[e^{-0.033} - 1] * 12.51 = -40.60\%$). Figure 1 illustrates this relationship.

[Insert Figure 1 here]

In Model 3, we test Hypothesis 2 suggesting that variations in the reasons for past failures increase the likelihood of a drug recall. As the model indicates, the coefficient is positive and slightly significant ($\beta = 0.882, p < 0.1$), in line with Hypothesis 2. An increase in the *variations in the reasons* by one standard deviation results in an increase of 59% in the likelihood of a recall ($[e^{0.882} - 1] * 0.42 = 59.46\%$). Accordingly, firms that experienced many variations in the reasons for their recalls are far more likely to experience subsequent recalls than those with more homogeneous reasons for past recalls. Figure 2 illustrates this relationship.

[Insert Figure 2 here]

When included together in Model 4, the coefficients of *response time* and *variations in the reasons* retain their signs, and the latter also increases its significance ($p < 0.05$), thus providing robust support for our arguments.

To test Hypothesis 3, we examined the interaction between *response time* and *variations in the reasons*. Model 5 in Table 4 shows a significant negative interactive effect ($\beta = -0.146, p < 0.001$), such that firms with more variations in the reasons for past recalls benefited the most from a long response time to those recalls. To interpret this effect, we plotted the interactive effect of *response time* and *variations in the reasons*. As Figure 3 illustrates, when firms have numerous variations in the reasons for their recalls, those with a longer response time are less likely to experience a future drug recall than firms that respond more quickly. As expected, a quicker average response time reduces the positive relationship

between variations in the reasons for the recall and subsequent drug recalls, supporting Hypothesis 3.

[Insert Figure 3 here]

In a supplemental analysis, reported in Model 6 of Table 4, we interacted *response time* with *past recalls* to test whether a firm's ability to learn from its cumulative failure experience is contingent on the amount of time it takes to respond to these failures. Results show that the interactive term is negative and significant ($\beta = -0.007$, $p < 0.01$), implying that firms learn more from their cumulative failure experience, measured in terms of the reduced likelihood of subsequent failures, when they take a longer time to respond to these failures. This analysis is in line with findings from recent studies, which argue that the attributes of experience and its context largely shape learning processes and outcomes (Haunschild et al., 2015; Musaji et al., 2020; Desai and Madsen, 2022).

5.1 Robustness checks

About 50% of the firm-year observations in our sample show a zero level of variations in the reasons for past failures. To interpret the robustness and economic significance of the interactive effect between *response time* and *variations in the reasons* more in depth, we transformed the latter variable into a dummy, *variations in the reasons (dummy)_[t-4, t]*, which is equal to 1 if the firm had variations in the reasons for its past recalls, and 0 otherwise. We then re-ran the logit model with this new specification. The results in Table 5 are consistent with our main estimate, providing additional support to Hypothesis 3.

[Insert Table 5 here]

Noting the non-linearity of our estimation model, we then followed Hilbe (2009) to interpret the interactions as odds ratios. In particular, we categorized *response time* into quartiles and computed the odds ratios of interactions with the following formula (Hilbe, 2009):

$$\begin{aligned} \text{Odds Ratio}_{\text{ResponseTime} \times \text{Variations in the reasons(dummy)}} &= \\ &= \exp[\beta_{\text{ResponseTime}} + \beta_{\text{ResponseTime} \times \text{Variations in the reasons (dummy)}} \times (\text{response time} - \text{Mean}(\text{response time}))], \end{aligned} \quad (3)$$

Table 6 contains the odds ratios, corrected standard errors, and confidence intervals (95%) for the quartile values of *response time*. The lower bound of the ratio for the last quartile of *response time* was less than 1, which suggests that the *variations in the reasons* effect might not be consistently negative and significant for firms with a long *response time*. In contrast, the lower bound of the ratios for the lower quartiles of *response time* was systematically greater than 1 ($p < 0.01$), which confirms the higher estimates for high values of *variations in the reasons*. When firms had a score greater than zero on this variable, those with a *response time* of 5.5 months (first quartile) were 10.26 times more likely to have a drug recalled than those with no *variations in the reasons*. In addition, a *response time* of 12.9 months (second quartile) increased this likelihood by 5.2 times, and a *response time* of 19.6 months (third quartile) increased it by only 2.8 times, compared to those with no *variations in the reasons*. Thus, the results provide robust support for our argument that the response time of a firm to its prior failures attenuates the effects of variations in the reasons for prior failures on the likelihood of subsequent failures, further supporting Hypothesis 3.

[Insert Table 6 here]

Next, in Table 7, we re-ran our main estimation model by weighting the *response time* measure by the average recall duration in the industry. Doing so allowed us to account for systematic differences between the firm's response strategy and the industry benchmarks. The results reported in Table 7 are consistent with our main models, providing additional support to our hypotheses.

[Insert Table 7 here]

Finally, to test the robustness of our specification, we ran our models with a count specification of our dependent variable (i.e., the number of recalls in year $t+1$). The results of a negative binomial regression reported in Table 8 are consistent with our main estimates.

[Insert Table 8 here]

6. Discussion and conclusion

This paper aims to improve our understanding of how the amount of time a firm takes to respond to a failure affects its subsequent failures. We argued and demonstrated that, on average, a longer response time reduces the likelihood of subsequent failure. In contrast, variations in the reasons for previous failures increase this likelihood. However, the response time moderates this relationship, reducing the positive effect of variations in prior experiences. Overall, our paper reveals the multifaceted nature of learning from failure. These results have interesting implications for theories of learning from failure, as well as for understanding how firms learn from varied experiences with the reasons for failure. Our study thus contributes to the literature on organizational learning in several ways.

First, to the best of our knowledge, this study is among the first to test the role of time in preventing subsequent failures. In focusing on the temporal dimension of learning from failure, we follow calls to consider the impact of the temporal dimension of time on organizational learning (Bridges, Smith and Grimm, 2013; George and Jones, 2000; Shi Sun and Prescott, 2012), and to provide a better assessment of when and how organizations can learn from failure (Madsen and Desai, 2010; Desai, 2015; Dahlin et al., 2018). We underscored the need to invest sufficient time to conduct deep learning that significantly improves organizational processes and performance in the long run. Our results also provide fresh insights into the debate between those who suggest that a faster response promotes greater learning and those who claim that the opposite is true in the case of failure. We argued and demonstrated that, on average, taking a longer time to respond to past failures reduces the

likelihood of the firm's experiencing subsequent failures. As such, our study complements existing explanations about why different organizations derive different lessons from their failures (Kim et al., 2009; Desai, 2010), suggesting that these differences depend, in part, on the amount of time they take to respond to their failures.

Second, we also contribute to the debate on the impact of variations in experience on learning. Prior research has posited both positive and negative relationships between the level of variations in experience and learning (Haunschild and Sullivan, 2002; Schilling et al., 2003; Zollo, 2009). Resolution of these apparently competing claims is particularly important in the context of operational failures that have significant financial and safety implications, where the failure to learn or learning the wrong lessons can be a frequent organizational outcome. Our findings suggest that, in general, firms find it harder to learn from failures resulting from various reasons due to their inherent causal ambiguity, which complicates the identification of casual links between actions and outcomes. However, firms that take the time to conduct the necessary investigations are more likely to benefit from these variations than those that respond more quickly. As such, our results underscore the benefits of taking time to learn from dissimilar failures to avoid making preventable mistakes in the future.

By adding time as a critical factor in learning from variations in the reasons for failures, our study reconciles the seemingly competing theoretical perspectives about learning from failure. By showing how the joint effect of variations in the reasons and average response time to past recalls reduces the likelihood of subsequent recalls, our study improves our understanding of the conditions under which firms can learn from failure (Kim et al., 2009; Desai, 2010; Madsen and Desai, 2010). In doing so, we provide a more holistic picture of learning in organizations (Kim et al., 2009; Musaji et al., 2020).

Our results also broaden inquiries into the role of time in strategy and organizational studies. Prior research has highlighted the benefits of a sufficient interval between strategic

initiatives to allow organizations the time to extract reliable knowledge that can be useful for future decision making (Hayward, 2002; Laamanen and Keil, 2008; Musaji et al., 2020). In parallel, other studies emphasize the benefits of speed and rapid iteration for competitive activities as well as for repetitive iterations of operational activities (Bakker and Shepherd, 2017; Desai and Madsen, 2022). We contribute to this conversation by arguing that, in cases of failure involving a great deal of causal ambiguity, speed may hinder systemic improvements in organizational processes and, thus, can harm organizational performance in the long run.

Our findings also offer relevant insights for managers and policy makers. By highlighting the benefits of devoting the time needed to examine the various reasons for previous recalls, our results inform managers about the ways in which they can improve the quality of their post-recall corrective and preventive actions to enhance learning. Notably, by raising awareness about the negative consequences of speeding up the management of the recall, our analysis warns managers about the dangers of accelerating their response to the recall and running the risk of future non-compliance. From a regulatory perspective, our study suggests that FDA investigators consider additional scrutiny of firms that have a shorter average recall response time and more variations in the reasons for their recalls compared to industry peers.

Finally, our study makes an important empirical contribution. To the best of our knowledge, this is one of the rare management studies investigating product recalls in the context of pharmaceutical products (Cheah, Chan and Chieng, 2007). Prior research has extensively examined automobile recalls (e.g., Haunschild and Rhee, 2004), toy recalls (e.g., Hora, Bapuji and Roth, 2011) and medical device recalls (e.g., Thirumalai and Sinha, 2011). Our analysis of recalls in the pharmaceutical industry enriches our knowledge about the specifics of recalls in different sectors. Furthermore, given the damages that defective drugs

may cause to patients, studying this setting is particularly important for firms, regulatory bodies, healthcare professionals, and patients.

Like any study, this research has several limitations that provide opportunities for future inquiry. First, our study is limited to a specific context—product recalls reported with the FDA—where failures are not exceptionally rare events. Therefore, one might question the extent to which our findings apply to other contexts. Our results thus call for future research to examine the generalizability of these effects. We believe that our theory and conclusions are relevant in other contexts where negative feedback from very frequent tasks and pressure to respond quickly to the disruptions caused by failures are of paramount importance for a firm's performance. Second, although we theorized about organizational learning in the face of failures, we were unable to observe how the firms searched for solutions, implemented them, and then codified the knowledge. This limitation is shared by most studies on organizational learning, given the challenge of obtaining information on the internal organizational processes of a firm (Baum and Dahlin, 2007; Desai and Madsen, 2022). Third, given that we used secondary data, we might have missed important insights into the extent to which the firm's culture and strategy affected the response time to the recall (Wowak and Boone, 2015). Such limitations open up opportunities for qualitative investigations to examine whether and how firms strategically decide on the amount of time they are going to spend on responding to recalls.

Notwithstanding these limitations, our findings enrich theory and practice by shedding light on the dynamics of organizational learning from failure. Our results should encourage managers to refrain from responding to failures quickly at all costs. Instead, they should understand the strategic importance of taking the time to identify root causes, experiment with solutions, and codify the resulting knowledge to avoid having more failures in the future.

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Tables and Figures

Table 1. Descriptions of the main measures and data sources.

Variable	Measure	Data Source
1. <i>Drug recall</i> $_{t+1}$	1 {the firm initiated at least one drug recall with the FDA in year $t+1$ }; 0 otherwise.	FDA
2. <i>Response time</i> $_{[t-4, t]}$	Average duration (in months) of recalls the firm initiated and terminated in $[t-4, t]$.	FDA
3. <i>Variations in the reasons</i> $_{[t-4, t]}$	Entropy-based index of distribution of reasons for a firm's drug recalls into categories in $[t-4, t]$.	FDA
4. <i>Past recalls</i> $_{[t-4, t]}$	Number of recalls the firm initiated and terminated in $[t-4, t]$.	FDA
5. <i>International recalls</i> $_{[t-4, t]}$	1 {the firm initiated at least one drug recall outside the US in $[t-4, t]$ }; 0 otherwise.	FDA
6. <i>Past recalls' geographical dispersion</i> $_{[t-4, t]}$	Herfindahl index of firm's prior drug recalls distribution in $[t-4, t]$ across US states.	FDA
7. <i>New drugs approved</i> $_{[t-4, t]}$	Number of firm's new drug applications (NDA) granted by the FDA in $[t-4, t]$.	FDA
8. <i>FDA inspections</i> $_{[t-1, t]}$	Number of FDA inspections in the firm's establishments in $[t-1, t]$.	FDA
9. <i>FDA OAI ratio</i> $_{[t-1, t]}$	Ratio of FDA inspections in the firm's establishments in $[t-1, t]$ where objectionable conditions were found, and regulatory action was recommended	FDA
10. <i>Firm size</i> $_t$	Number of firm's employees [in thousands] in year t .	Compustat
11. <i>Drug portfolio size</i> $_t$	Number of firm's drugs commercialized in year t .	FDA
12. <i>Market share</i> $_t$	Firm's market share in pharmaceutical industry in year t .	Compustat
13. <i>M&A</i> $_t$	1 {the firm has at least one M&A involving any of its drug labeler facilities in year t }; 0 otherwise.	Thompson

Table 2. Categories of the reasons for the recall.

Reason	Category's definition
Contamination/Cross-contamination	Lack of (assurance of) sterility. This may lead to the contamination of the drug or the presence of any substance present other than the drug or another drug present (e.g., glass, rubber, bacteria, foreign particulate matter, unusual odor). This includes suspected or confirmed contamination.
Mislabeling	Incorrect or missing information on product label, or dispensing product not mentioned on label. This includes undeclared drugs dispensed as dietary supplements.
Adverse reaction	Product is found to cause an adverse reaction.
Defective product	Failed uniformity specifications, such as: ○ wrong color, viscosity or pH, or particle size ○ failed dissolution or particulates present, crystallization, failed stability test ○ standard compression, tablet erosion, broken tablets, numbers on tablet rubbed off, excess moisture ○ placebo and active drug misplaced in oral contraceptives.
Incorrect potency	Subpotent, hyper potent, or low fill volume in vial.
Defective delivery system	Damage to the container (e.g., warped cap, punctured i.v. bag, leaking port, missing tamper-resistant seal).
Miscellaneous: CGMP deviations	Imprecise or miscellaneous CGNP deviations.
Inadequate/defective raw materials used in manufacturing	Active pharmaceutical ingredients (API) or other raw materials used during manufacturing were defective, expired, contaminated, etc.
Deviations from Monograph	Noncompliance with FDA monograph for over the counter (OTC) products.
Failure to validate manufacturing processes	Failure to validate manufacturing processes (e.g., incorrect stability test method, inadequate documentation and in-process controls).
Unapproved NDA	Product contains undeclared ingredients, substances making it an unapproved product, or manufacturer is not registered as an approved site for manufacturing the product.

Table 3. Descriptive statistics and correlations.

Variable	Mean	SD	Min	Max	1	2	3	4	5	6	7	8	9	10	11	12
1. <i>Drug recall</i> $t+1$	0.50	0.50	0.00	1.00												
2. <i>Response time</i> $[t-4, t]$	13.98	12.51	0.00	79.13	.06											
3. <i>Variations in the reasons</i> $[t-4, t]$	0.45	0.42	0.00	1.00	.41	.42										
4. <i>Past recalls</i> $[t-4, t]$	8.74	17.19	0.00	140.00	.29	.22	.42									
5. <i>International recalls</i> $[t-4, t]$	0.47	0.50	0.00	1.00	.32	.38	.63	.40								
6. <i>Past recalls' geographical dispersion</i> $[t-4, t]$	0.28	0.37	0.00	1.00	.34	.25	.62	.26	.52							
7. <i>New drugs approved</i> $[t-4, t]$	3.74	5.25	0.00	32.00	.25	.03	.32	.21	.33	.46						
8. <i>FDA inspections</i> $[t-1, t]$	9.66	10.73	0.00	73.00	.24	.20	.44	.10	.37	.48	.39					
9. <i>FDA OAI ratio</i> $[t-1, t]$	0.03	0.09	0.00	0.67	.16	-.02	.14	.31	.12	-.01	.00	.01				
10. <i>Firm size</i> t	31.81	39.34	0.01	135.70	.23	.15	.39	.13	.29	.36	.47	.49	.04			
11. <i>Drug portfolio size</i> t	229.98	401.72	0.00	2864.00	.18	.22	.32	.19	.23	.32	.18	.54	-.02	.27		
12. <i>Market share</i> t	0.06	0.10	0.00	0.45	.11	.16	.07	-.01	-.02	.00	-.04	.24	-.07	.28	.46	
13. <i>M&A</i> t	0.08	0.27	0.00	1.00	.13	.02	.09	.11	.13	.20	.07	.11	-.03	.00	.17	-.02

Note. N = 394. All correlations above $|\text{.01}|$ are significant at $p < 0.01$.

Table 4. Results of random effects logit models.

DV:	Drug recall $t+1$					
	1	2	3	4	5	6
<i>Response time</i> $_{[t-4, t]}$		-0.033* (0.017)		-0.043* (0.018)	-0.007 (0.018)	-0.016 (0.018)
<i>Variations in the reasons</i> $_{[t-4, t]}$			0.882 [†] (0.535)	1.301* (0.570)	3.378*** (0.867)	0.902 (0.594)
<i>Response time</i> $_{[t-4, t]}$ <i>X Variations in the reasons</i> $_{[t-4, t]}$					-0.146*** (0.043)	
<i>Response time</i> $_{[t-4, t]}$ <i>X Past recalls</i> $_{[t-4, t]}$						-0.007** (0.002)
<i>Past recalls</i> $_{[t-4, t]}$	0.045* (0.022)	0.049* (0.024)	0.041* (0.020)	0.043* (0.021)	0.053* (0.024)	0.215** (0.068)
<i>International recalls</i> $_{[t-4, t]}$	0.588 (0.397)	0.806 [†] (0.423)	0.402 (0.404)	0.613 (0.423)	0.621 (0.440)	0.363 (0.444)
<i>Past recalls' geographical dispersion</i> $_{[t-4, t]}$	0.793 (0.558)	0.810 (0.573)	0.507 (0.569)	0.398 (0.583)	0.372 (0.621)	0.531 (0.618)
<i>New drugs approved</i> $_{[t-4, t]}$	0.032 (0.049)	0.023 (0.052)	0.041 (0.046)	0.033 (0.048)	0.003 (0.054)	0.003 (0.052)
<i>FDA inspections</i> $_{[t-1, t]}$	-0.009 (0.022)	-0.004 (0.023)	-0.014 (0.022)	-0.010 (0.023)	0.000 (0.024)	-0.005 (0.023)
<i>FDA OAI ratio</i> $_{[t-1, t]}$	4.697* (1.932)	4.505* (1.966)	4.581* (1.899)	4.284* (1.936)	4.602* (2.025)	4.608* (2.031)
<i>Firm size</i> $_t$	0.009 (0.007)	0.009 (0.007)	0.006 (0.007)	0.006 (0.007)	0.006 (0.007)	0.007 (0.007)
<i>Drug portfolio size</i> $_t$	0.001 (0.001)	0.001 (0.001)	0.001 (0.001)	0.001 (0.001)	0.001 (0.001)	0.000 (0.001)
<i>Market share</i> $_t$	2.786 (2.201)	2.945 (2.299)	3.041 (2.053)	3.391 (2.121)	3.541 (2.264)	3.722 [†] (2.243)
<i>M&A</i> $_t$	0.571 (0.561)	0.509 (0.565)	0.652 (0.557)	0.607 (0.560)	0.673 (0.591)	0.680 (0.582)
Year dummies (10)	Included	included	included	included	included	included
Firm's RE	Included	included	included	included	included	included
Constant	-1.858*** (0.503)	-1.791*** (0.516)	-1.919*** (0.491)	-1.863*** (0.501)	-2.297*** (0.548)	-2.102*** (0.530)
Log likelihood	-197.2	-195	-195.9	-192.5	-185.7	-187.5

Note. N = 394. Standard errors (in parentheses) estimated from the observed information matrix (OIM).

*** $p < .001$; ** $p < .01$; * $p < .05$; [†] $p < .1$

Table 5. Robustness check: Results of random effects logit models.

DV: <i>Drug recall</i> $_{t+1}$	
	1 2
<i>Response time</i> $_{[t-4, t]}$	-0.049* -0.014 (0.020) (0.018)
<i>Variations in the reasons (dummy)</i> $_{[t-4, t]}$	1.514** 2.748*** (0.490) (0.679)
<i>Response time</i> $_{[t-4, t]}$ X <i>Variations in the reasons (dummy)</i> $_{[t-4, t]}$	-0.094** (0.033)
<i>Past recalls</i> $_{[t-4, t]}$	0.042* 0.048* (0.021) (0.023)
<i>International recalls</i> $_{[t-4, t]}$	0.476 0.494 (0.431) (0.440)
<i>Past recalls' geographical dispersion</i> $_{[t-4, t]}$	0.247 0.194 (0.585) (0.612)
<i>New drugs approved</i> $_{[t-4, t]}$	0.029 0.012 (0.046) (0.051)
<i>FDA inspections</i> $_{[t-1, t]}$	-0.009 -0.004 (0.022) (0.023)
<i>FDA OAI ratio</i> $_{[t-1, t]}$	4.114* 4.450* (1.916) (1.992)
<i>Firm size</i> $_t$	0.005 0.005 (0.007) (0.007)
<i>Drug portfolio size</i> $_t$	0.001 0.001 (0.001) (0.001)
<i>Market share</i> $_t$	3.215 3.458 (2.063) (2.171)
<i>M&A</i> $_t$	0.642 0.689 (0.565) (0.587)
Year dummies (10)	included Included
Firm's RE	included Included
Constant	-1.901*** -2.239*** (0.500) (0.537)
Log likelihood	-190.3 -186

Note. N = 394. Standard errors (in parentheses) estimated from the observed information matrix (OIM).

*** $p < .001$; ** $p < .01$; * $p < .05$; † $p < .1$.

Table 6. Interpretation of interaction effects.

<i>response time X variations in the reasons (dummy)</i>					
Value of <i>response time</i>	Percentiles	Odds Ratios	SE	95% C.I.	
5.5 months	25%	10.256	0.696	2.620	40.141
12.9 months	50%	5.153	0.788	1.099	24.168
19.6 months	75%	2.764	0.922	0.453	16.844

Table 7. Robustness check: Industry weights

	DV: <i>Drug recall</i> _{<i>t</i>+1}	
	1	2
<i>Response time (weighted by industry mean)</i> [<i>t</i> -4, <i>t</i>]	-0.550 [†] (0.29)	-0.038 (0.29)
<i>Variations in the reasons</i> [<i>t</i> -4, <i>t</i>]	1.205* (0.57)	3.194*** (0.88)
<i>Response time (weighted by industry mean)</i> [<i>t</i> -4, <i>t</i>] X <i>Variations in the reasons</i> [<i>t</i> -4, <i>t</i>]		-2.166** (0.71)
<i>Past recalls</i> [<i>t</i> -4, <i>t</i>]	0.041* (0.02)	0.044 [†] (0.02)
<i>International recalls</i> [<i>t</i> -4, <i>t</i>]	0.547 (0.43)	0.589 (0.44)
<i>Past recalls' geographical dispersion</i> [<i>t</i> -4, <i>t</i>]	0.439 (0.59)	0.402 (0.61)
<i>New drugs approved</i> [<i>t</i> -4, <i>t</i>]	0.092 (0.23)	0.032 (0.25)
<i>FDA inspections</i> [<i>t</i> -1, <i>t</i>]	-0.010 (0.02)	-0.002 (0.02)
<i>FDA OAI ratio</i> [<i>t</i> -1, <i>t</i>]	4.348* (1.94)	4.545* (2.01)
<i>Firm size</i> _{<i>t</i>}	0.007 (0.01)	0.005 (0.01)
<i>Drug portfolio size</i> _{<i>t</i>}	0.001 (0.00)	0.001 (0.00)
<i>Market share</i> _{<i>t</i>}	3.210 (2.15)	3.411 (2.22)
<i>M&A</i> _{<i>t</i>}	0.595 (0.56)	0.647 (0.59)
Year dummies (10)	included	included
Firm's RE	included	included
Constant	-1.742*** (0.52)	-1.884*** (0.54)
Log likelihood	-194.0	-188.9

Note. N = 394. Standard errors (in parentheses) estimated from the observed information matrix (OIM).

*** $p < .001$; ** $p < .01$; * $p < .05$; [†] $p < .1$.

Table 8. Robustness check: Negative binomial regression on the count of total drug recalls

DV:	<i>Drug recalls (count)</i> $t+1$				
	1	2	3	4	5
<i>Response time</i> $[t-4, t]$		-0.013 (0.010)		-0.027* (0.011)	0.005 (0.011)
<i>Variations in reasons</i> $[t-4, t]$			0.601* (0.279)	0.900** (0.298)	1.452*** (0.377)
<i>Response time</i> $[t-4, t]$ <i>X Variations in reasons</i> $[t-4, t]$					-0.053** (0.019)
<i>Past recalls</i> $[t-4, t]$	-0.001 (0.005)	-0.001 (0.005)	0.000 (0.005)	-0.001 (0.005)	-0.000 (0.005)
<i>International recalls</i> $[t-4, t]$	-0.015 (0.203)	0.048 (0.212)	-0.045 (0.202)	0.064 (0.210)	0.035 (0.205)
<i>Past recalls' geographical dispersion</i> $[t-4, t]$	0.275 (0.228)	0.306 (0.230)	0.104 (0.242)	0.077 (0.243)	0.083 (0.240)
<i>New drugs approved</i> $[t-4, t]$	0.047* (0.020)	0.046* (0.020)	0.052** (0.019)	0.050* (0.019)	0.043* (0.020)
<i>FDA inspections</i> $[t-1, t]$	0.001 (0.012)	0.003 (0.012)	-0.001 (0.011)	0.001 (0.011)	-0.002 (0.011)
<i>FDA OAI ratio</i> $[t-1, t]$	1.310 [†] (0.671)	1.289 [†] (0.659)	0.985 (0.683)	0.830 (0.667)	0.943 (0.672)
<i>Firm size</i> t	0.000 (0.004)	0.000 (0.004)	0.000 (0.003)	0.001 (0.003)	0.001 (0.003)
<i>Drug portfolio size</i> t	0.000 (0.000)	0.000 (0.000)	0.000 (0.000)	0.000 (0.000)	0.000 (0.000)
<i>Market share</i> t	2.554 (1.604)	2.114 (1.594)	2.232 (1.473)	1.719 (1.338)	2.462 [†] (1.463)
<i>M&A</i> t	0.279 (0.174)	0.270 (0.172)	0.273 (0.177)	0.253 (0.174)	0.257 (0.174)
Year dummies (10)	included	included	included	included	included
Firm Random Effects	included	included	included	included	included
Constant	-0.928* (0.394)	-0.807* (0.411)	-1.208** (0.401)	-1.109** (0.410)	-1.331** (0.415)
Log likelihood	-620.8	-619.8	-618.5	-615.4	-612.5

Note. N = 394. Standard errors (in parentheses) estimated from the observed information matrix (OIM).

*** $p < .001$; ** $p < .01$; * $p < .05$; [†] $p < .1$

Figure 1. Response time and the predicted probability of a drug recall

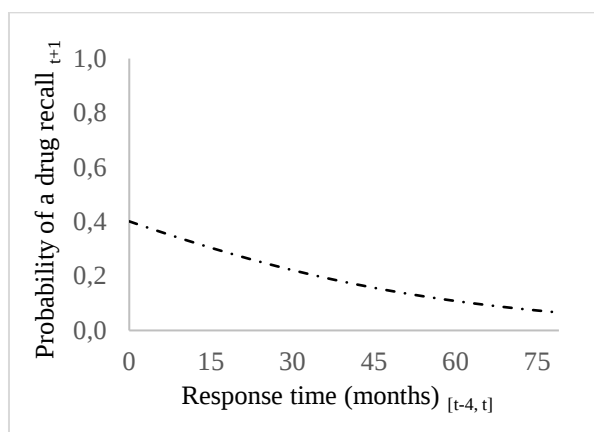


Figure 2. Variations in reasons and the predicted probability of a future drug recall

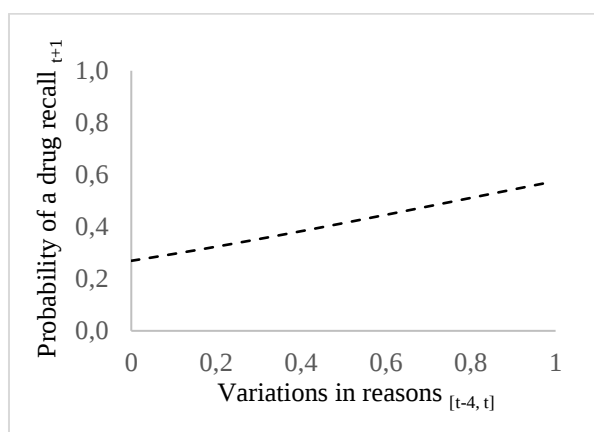
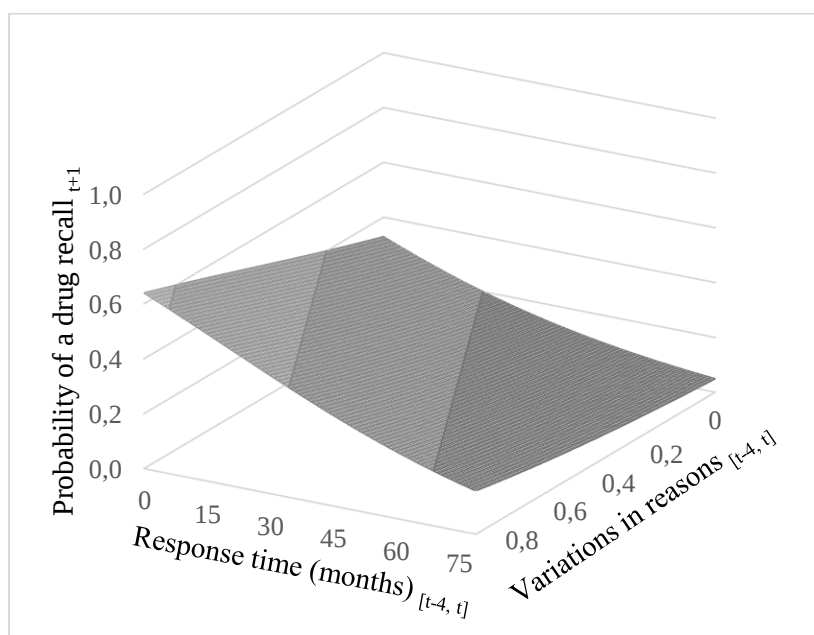


Figure 3. The combined effects of response time and variations in reasons



Endnotes

ⁱ “Cardiovascular agents are medicines that are used to treat medical conditions associated with the heart or the circulatory system (blood vessels), such as arrhythmias, blood clots, coronary artery disease, high or low blood pressure, high cholesterol, heart failure and stroke” (Drug Facts and Comparisons, 2019). According to the classification provided by the Drug Facts and Comparisons, 2019, cardiovascular agents that are used in cardiovascular drugs can be divided into 24 classes. We used these classes to extract the active ingredients that belong to these classes from Drug Facts and Comparisons. In total, we identified 197 active ingredients or combinations of active ingredients (as many drugs are composed of more than one ingredient).

ⁱⁱ <https://www.drugs.com/drug-class/cardiovascular-agents.html>

ⁱⁱⁱ Note that the corporate trees we built include only the subsidiaries that have cardiovascular drugs registered with the FDA and are 100% owned by the corporate parent.

^{iv} The data were collected through a Freedom of Information Act (FOIA), submitted to the FDA in April 2017.

^v Most recalls in this industry are voluntarily initiated by the firm, rather than being mandated by the FDA. The FDA may also recommend that the firm recall a drug after identifying some deviations from good manufacturing practices during an investigation of the firm’s manufacturing facility. In this case, the firm may initiate a voluntary recall following an inspection to address the concerns raised by the FDA. The few other existing studies on pharmaceutical product recalls assert that most recalls are carried out voluntarily by firms.

^{vi} Inspection’s data were also obtained through a FOIA submitted to the FDA.

^{vii} Nonetheless, the high correlation of some of our independent variables may be alarming. To make sure that they were not biasing our results, we performed further robustness checks. First, by following common practice, we ran our main regression model by excluding the highly correlated variables one at a time. Results (not reported in the paper) confirm our prior estimates and indicate that the high correlation between variables is not biasing our results. Next, as a further check, we also transformed these variables by mean centering them and then re-running our estimation models. Results (not reported in the paper) did not change, thus confirming our prior estimates.