

**Quality Compliance Following Near-Failures. Evidence From FDA Investigations In
Drug Manufacturing Plants**

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Abstract

Near-failures—situations where an accident or a failure is avoided by chance—are frequent organizational phenomena (e.g. airline incidents). Interpreting near-failures as signs of vulnerability fosters organization's ability to learn from such experiences. Conversely, when near-failures are interpreted as signs of resilience (i.e. near-success), organizational learning is limited. We question in this study—what is the effect of prior near-failures in compliance on the likelihood of future near-failures? We argue that *ceteris-paribus*, prior near-failure experience will increase the likelihood of future near-failures as risky behaviors become normalized in the absence of salient adverse consequences. We further predict that a firm's prior failure experience and industry near-failure experience will moderate this relationship. We employ data on inspections conducted by the US Food and Drug Administration (FDA) in pharmaceutical plants to test our hypotheses. The expected contributions of this study to research on organizational learning and change are discussed.

Theory and hypotheses

Near-failures—situations where a failure or an adverse outcome could have happened but was avoided due to chance or prevention (Dillon and Tinsley, 2008; Madsen, Dillon and Tinsley, 2016)—are frequent organizational phenomena (e.g. airline incidents). Yet, organizations and individuals often fail to learn from them (Tamuz, 2001; Dillon and Tinsley, 2008). A failure to notice, act upon and learn from such weak cues may lead to serious adverse events in the future (Ansoff, 1975; Vaughan 1996; Dillon and Tinsley, 2008; Rerup, 2009). To learn from near-failure experience, the organization needs to identify near-failure events, investigate their root causes and implement appropriate corrective and preventive actions. Near-failures and near-misses have been studied extensively in risk management, healthcare and operations research (e.g. Dillon, Tinsley and Cronin, 2011; Cui, Rosoff and John, 2018; Phimister et al., 2003) and, to a lesser extent, in management literature (e.g. Dillon and Tinsley, 2008; Dillon, Tinsley, Madsen, and Rogers, 2016; Kim and Miner, 2007). Moreover, from empirical standpoint, this prior work has mainly focused on high-reliability, high-hazard industries (i.e. nuclear power plants, airlines). More scarce is research on near-failures in other highly regulated industries where compliance remains nonetheless critical. Given the proliferation of disruptions and sustainability imperatives imposed on firms nowadays, organizations need to swiftly recognize and attend to near-failures as such weak cues may alert about future discontinuities. Thus, our study aims to enhance our knowledge about the mechanisms and factors that can inhibit and/or improve organization's ability to learn from near-failure events and engage in timely transformation. We examines near-failures in the context of pharmaceutical firm's operations.

An organization's ability to extract valuable lessons from their near-failures depends on the way in which near-failures are interpreted inside the firm. Near-failures may be interpreted as signs of system's resilience (i.e., near-success) or vulnerability (Tamuz, 2001; Dillon and Tinsley, 2008; Dillon and Tinsley, 2016). Prior research suggests that in most situations individuals and organizations are more likely to interpret near-misses as almost successes and evidence of resilience than as an near-failure (Tamuz, 2001; Dillon and Tinsley, 2008; Dillon, Tinsley and Cronin, 2011; Dillon and Tinsley, 2016). Dillon and Tinsley (2008) show that when managers' decisions result in near-miss or success, they are evaluated more positively than when their decisions result in failures. This inclination of focusing on the apparent outcomes of a decision or an event by underestimating the (quality of) processes and mechnaisms leading to these outcomes is often referred to as 'outcome bias' in decisions sciences (Baron and Hershey, 1988; Soyer and Hogarth, 2015; Dillon et al. 2016). This bias is likely to push the organization to make riskier decisions over time (Dillon and Tinsley, 2008; Madsen et al. 2016). As a result, risky behaviors become normalized at the absance of salient adverse consequences—'normalization of deviance' (Vaughan 1996; Tamuz, 2001). Such behaviors may, however, lead to negative consequences in the future (Vaughan 1996; Tamuz, 2001; Dillon and Tinsley, 2008; Madsen et al. 2016). In the same line, Tong et al. (2020) mobilize normalized deviation and social contagion perspectives and show that the focal organization's and other organization's minor operational incidents incerase the hazard of experiencing a future serous accident for the focal organization. Building upon these arguments, we posit our first hypothesis:

Hypothesis 1: An organization's prior near-failure in compliance increases the likelihood of future near-failure in compliance.

We further attempt to uncover factors that influence organizations' interpretation of near-failure experience and subsequent learning potential. We start by arguing that whether the firm will perceive its near-failure experience as a failure or success depends on its prior failure experience. Madsen, Dillon and Tinsley (2016) found that airlines learn from near-miss events when these events belong to a category of event that has previously resulted in a serious accident. By building upon and extending this work, we argue that if the organization has experienced failures in the past, it is more likely to perceive the focal near-failure event as a failure that almost occurred. The reason behind this prediction is that prior experience with failures helps to distinguish near-failures from successful outcomes and reduces, therefore, the outcome bias. As a result, the positive effect of prior near-failures on future near-failures will be attenuated given the firm's incentives to attend to weak cues and engage in mindful learning in order to prevent the hazard of future failure.

Hypothesis 2: An organization's prior failure experience weakens the positive relationship between prior near-failure in compliance and likelihood of future near-failure.

Learning literature asserts that organizations learn also vicariously from the experience of others. Thus, we examine whether the near-failures of other firms in the industry influence the firm's propensity of experiencing near-failures following prior near-failure experience. Near-failures and near-misses of peer organizations may have two different contradicting effects on focal organization's response to and subsequent learning from their own near-failures. On the one hand, near-failures of peer organizations provide opportunities for additional information gathering and processing concerning compliance deviations across the industry. Such knowledge spillovers may improve the focal firm's ability to interpret and extract accurate inferences from its own near-failures (Ingram and Baum, 1997; Kim and Miner, 2007). Furthermore, industry near-failures may also serve as signals of systematic problems within the industry and, therefore, incentivize the focal firm to conduct more systemic investigation of its prior near failures and review its internal quality systems (Hall and Johnson-Hall, 2017). On the other hand, when near-failures are widespread in the industry, they may be perceived as acceptable deviations and become normalized generating no learning effect (Vaughan 1996; Tong, Linderman, Lo, Lai and Cheng, 2020). As a result, firm may perceive their own near-failures as non-alarming and equivalent to success. Because existing scarce research on this question provides support for both mechanisms, we propose competing hypotheses.

Hypothesis 3A: The industry near-failure experience weakens the positive relationship between prior near-failure in compliance and likelihood of future near-failure.

Hypothesis 3B: The industry near-failure experience strengthens the positive relationship between prior near-failure in compliance and likelihood of future near-failure.

Methodology

The empirical setting for this study involves pharmaceutical firms manufacturing drugs in the United States (US). We identify a sample of firms using the data on drug listings in the

Food and Drug Administration (FDA) National Drug Code (NDC) Directory. This registry reports in yearly bases all the firms that manufacture, package, label or re-label drugs designated for commercial distribution in US. We then relied on information about inspections conducted by the FDA in these firms' manufacturing facilities to operationalize near-failures in compliance. The FDA inspects regularly all manufacturing plants that manufacture drugs for commercial distribution in the US. The objective of these inspections is to assess the facility's state of compliance with the rules and regulations (FDA, 2023). Data from the FDA inspections have been used in the prior research to limited extent (Anand, Gray and Siemsen, 2012; Macher, Mayo and Nickerson, 2011). While much research on plant inspections has been conducted in areas such as safety science and operations management, inspections present a relevant empirical setting for investigating broader organizational issues (Anand et al., 2012; Macher et al., 2011; Ball et al., 2019).

At the end of an inspection, if some objectionable conditions have been identified, the inspector will issue a FDA Form 483 in which the observed deviations will be listed (FDA, 2023). Companies are encouraged to provide a written response (within 15 working days) to the FDA Form 483 by describing the corrective and preventive actions they plan to implement (or have already implemented) to address each observations indicated in the Form 483 (FDA, 2023). The The Form 483, however, does not constitute the Agency's final evaluation of the facility's compliance. After reviewing all relevant information (including the firm's response to Form 483 if any), the FDA District Office determines the inspection outcome. There are three possible outcomes. Official action indicated (OAI) is the most severe outcome and it is issued when the FDA has identified severe violations and enforces the firm to implement corrective actions. No action indicated (NAI) implies that no violations were found. Voluntary action indicated (VAI) is issued when some violations have been identified and need to be addressed by the firms but the agency does not enforce any action. Most inspections with VAI outcomes had received a Form 483. Therefore, we believe that inspections receiving Form 483 but resulting in VAI outcome constitute fine near-failures.

We use drug recalls to operationalize product failures. The data on drug recalls and plant inspections has been obtained from the FDA through a Freedom of Information Act (FOIA). We complemented this data with the information on new drug approvals from the FDA Orange book, the financial records from Compustat, the mergers and acquisitions involving sample firms from the SDC Platinum and the information on firm ownership from ORBIS and press releases.

Conclusion and contributions

We suggest in this study that organizations struggle to learn from their prior near-failures. In particular, we predict that prior near-failure experience in compliance will increase the likelihood of future near-failures in compliance. We further investigate the moderating effect of prior failure experience and industry near-failure experience on this relationship. Investigating whether an organization operates in a state of near non-compliance following its near-failures and identifying contingences that can alleviate this effect would provide significant contributions to research and practice. Specifically, this study aims to contribute, first, to research on near-failures in management science. We highlight the challenges of

learning from near-failures and the dangers of complacency and drift after a near failure. We further investigate how a firm's prior failure experience and industry near-failures impact the firm's interpretation of and behavior following near-failures. The proliferation of disruptions and the sustainability imperatives imposed to the firms nowadays requires organizations to recognize and attend to weak cues that may alert about future discontinuities. In this context, our study seeks to enhance our knowledge about the mechanisms and factors that can impede an organization's ability to learn from near-failures and engage in timely transformation. This study also informs managers in organizations about the need of making mindful efforts following near-failures in order to prevent future near non-compliance. Finally, our study provides several insights for regulatory bodies concerning the surveillance of pharmaceutical industry.

The next steps for developing this research are twofold. First, the theoretical framing and arguments will be streamlined and strengthened. Second, the data analysis will be completed to establish robust findings. Finally, the contributions of the study will be elaborated more in order to better highlight the contributions of our work for organizational learning and transformation research.

References

- Anand, G., Gray, J. and Siemsen, E. (2012) 'Decay, shock, and renewal: Operational routines and process entropy in the pharmaceutical industry', *Organization Science*, 23(6), pp. 1700–1716. doi: 10.1287/orsc.1110.0709.
- Ansoff, H. I. (1975) 'Managing Strategic Surprise by Response to Weak Signals', *California Management Review*, 18(2), pp. 21–33. doi: 10.2307/41164635.
- Ball, G., Macher, J. T. and Stern, A. D. (2019) Recalls, Innovation, and Competitor Response: Evidence from Medical Device Firms, *SSRN Electronic Journal*. doi: 10.2139/ssrn.3251630.
- Baron, J., & Hershey, J. C. (1988). Outcome bias in decision evaluation. *Journal of personality and social psychology*, 54(4), 569.
- Cui, J., Rosoff, H. and John, R. S. (2018) 'Public Response to a Near-Miss Nuclear Accident Scenario Varying in Causal Attributions and Outcome Uncertainty', 38(5). doi: 10.1111/risa.12920.
- Dillon, R. L. and Tinsley, C. H. (2008) 'How near-misses influence decision making under risk: A missed opportunity for learning', *Management Science*, 54(8), pp. 1425–1440. doi: 10.1287/mnsc.1080.0869.
- Dillon, R. L. and Tinsley, C. H. (2016) 'Near-miss events , risk messages , and decision making', *Environment Systems and Decisions*, 36(1), pp. 34–44. doi: 10.1007/s10669-015-9578-x.
- Dillon, R. L., Tinsley, C. H. and Cronin, M. (2011) 'Why Near-Miss Events Can Decrease an Individual's Protective Response to Hurricanes', *Risk Analysis*, 31(3), pp. 440–449. doi: 10.1111/j.1539-6924.2010.01506.x.
- Dillon, R.L., Tinsley, C.H., Madsen, P.M. and Rogers, E.W., (2016). Organizational correctives for improving recognition of near-miss events. *Journal of Management*, 42(3), pp.671-697.
- Hall, D. C. and Johnson-Hall, T. D. (2017) 'Learning from Conformance Quality Failures That Triggered Product Recalls: The Role of Direct and Indirect Experience', *Journal of Supply Chain Management*, 53(4), pp. 13–36. doi: 10.1111/jscm.12143.
- Ingram, P. and Baum, J. (1997) 'Chain Affiliation and the Failure of Manhattan Hotels , 1898-1980 Author (s): Paul Ingram and Joel A . C . Baum Published by : Sage Publications , Inc . on behalf of the Johnson Graduate School of Management , Cornell University Stable URL : <https://www>', 42(1), pp. 68–102.
- Kim, J.Y. and Miner, A.S., (2007). Vicarious learning from the failures and near-failures of others: Evidence from the US commercial banking industry. *Academy of Management Journal*, 50(3), pp.687-714.
- Macher, J. T., Mayo, J. W. and Nickerson, J. A. (2011) 'Regulator heterogeneity and endogenous efforts to close the information asymmetry gap', *Journal of Law and Economics*, 54(1), pp. 25–54. doi: 10.1086/658484.
- Tamuz, M. (2001). Learning disabilities for regulators: The perils of organizational learning in the air transportation industry. *Administration & Society*, 33(3), 276-302.
- Madsen, P., Dillon, R. L. and Tinsley, C. H. (2016) 'Airline Safety Improvement Through Experience with Near-Misses: A Cautionary Tale', *Risk Analysis*, 36(5), pp. 1054–

1066. doi: 10.1111/risa.12503.

Phimister, J. R., Oktem, U., Kleindorfer, P. R., & Kunreuther, H. (2003). Near-miss incident management in the chemical process industry. *Risk Analysis: An International Journal*, 23(3), 445-459.

Rerup, C. (2009) 'Attentional triangulation: Learning from unexpected rare crises', *Organization Science*, 20(5), pp. 876–893. doi: 10.1287/orsc.1090.0467.

Soyer, E., & Hogarth, R. M. (2015). Fooled by experience. *Harvard Business Review*, 93(5), 72-77.

Tong, X., Linderman, K., Lo, C.K., Lai, K.H. and Cheng, T.C.E., (2020). Anti-Learning Behavior Toward Safety Risk: The Roles of Internal Context and Social Contagion. *Decision Sciences*.

Vaughan, D., (1996). *The Challenger launch decision: Risky technology, culture, and deviance at NASA*. University of Chicago press.