

# Medical device managers rely on physicians to screen out defects rather than issue recalls

August 22 2018

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George Ball. Credit: Indiana University Kelley School of Business

Results of a new behavioral study into what influences the decision to recall a defective product found that medical device firm managers may rely on their physician-customers to screen out detectable defects, in lieu of issuing a recall.

The study also found that some managers appear to hesitate to recall a product until the root cause of the defect is clearly understood, because this can reduce recall costs to the firm.

The study, performed by professors at the Indiana University Kelley School of Business and the University of Minnesota's Carlson School of Management, has led to changes at the medical device firms that participated in the study and has attracted interest from leadership at the Food and Drug Administration. The FDA expressed interest in using this research to improve how they oversee medical device product quality.

Their research, published in the *Journal of Operations Management*, is the first behavioral study using actual industry managers to study what influences voluntary product recall decisions, an important new field of study considering the prevalence and customer safety impact of product recalls across multiple industries.

"The [decision](#) to recall a product can significantly affect an operations manager's career, the credibility and financial performance of the firm, and the safety of customers," the authors wrote. "Surprisingly, the FDA does not clearly specify how a manager should integrate the multiple, and potentially conflicting, criteria influencing whether or not to recall a product. Consequently, managers use individual judgment in arriving at recall decisions."

George Ball, the lead author and an assistant professor of operations and decision technologies at the Kelley School of Business, and his two co-authors performed a randomized behavioral experiment with medical device industry managers who make recall decisions in practice.

A key finding of the study is that "medical device industry managers appear to trust physicians to screen out defects on behalf of the firm, meaning that when the defect is detectable to the physician, managers

are less likely to recall," Ball said. "This is because of a perception of increased patient safety when defects are detectable."

Ball and his colleagues—Rachna Shah, associate professor of supply chain and operations; and Karen Donohue, Board of Overseers Professor of supply chain and operations, both at the Carlson School—also found that managers often hesitated to recall until they first understand the root cause of the product defect.

After working closely with these managers, Shah said they observed that, "most of these managers are very technically oriented, and they want to know 'why' before they take an action that could be very costly both in direct financial consequences and in reputational harm. Waiting to understand root cause before choosing to recall, however, is not required by the FDA."

The researchers also found a relationship between a manager's cognition and their recall decision. In particular, managers with high cognitive reflection issued fewer recalls. The ability to first reflect, before making a quick, intuitive decision, may lead to fewer recalls because such reflective individuals have a tendency to seek out more information before reaching a decision. Non-reflective, intuitive managers, conversely, were influenced by relational factors such as their gender, work experience and perception of their firm's relationship with the FDA.

While the paper focuses on operations at [medical device](#) manufacturers, the authors believe that the findings have broader applications. "Any industry in which the [supply chain](#) has multiple stages where quality can be observed and controlled may be susceptible to the study's conclusions," said Donohue. "For example, auto firms may trust their dealers to catch their mistakes before selling their cars to the final customer."

**More information:** George P. Ball et al, The decision to recall: A behavioral investigation in the medical device industry, *Journal of Operations Management* (2018). [DOI: 10.1016/j.jom.2018.07.003](https://doi.org/10.1016/j.jom.2018.07.003)

Provided by Indiana University

Citation: Medical device managers rely on physicians to screen out defects rather than issue recalls (2018, August 22) retrieved 6 May 2024 from <https://medicalxpress.com/news/2018-08-medical-device-physicians-screen-defects.html>

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