Price competition for generic drugs linked to increase in manufacturing-related recalls

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Researchers from three universities have found that extreme price competition in the generic pharmaceutical market—designed to make medications more affordable—may be putting more patients at serious health risk, as evidenced by a higher number of product recalls caused

by manufacturing-related problems.

The same research, published online today in the *Journal of Operations Management*, also raises concerns that generic drug makers may be underreporting discretionary recalls due to competitive pressures.

"Extreme price competition in the generic pharmaceutical market has some unexpected risks that regulators and lawmakers may not have foreseen when pushing for cheaper drugs," said George Ball, assistant professor of operations and decision technologies at the Indiana University Kelley School of Business and the study's lead author.

"There's a downside to cheaper drugs: You can't guarantee that they're going to be of the exact same quality," Ball said. "This research demonstrates that regulators and insurers may want to temper their intense public pressure placed upon pharmaceutical companies to bring prices down. Such pressure may come at a cost: poorly manufactured drugs."

Other authors of the paper are Rachna Shah, associate professor of supply chain and operations at the University of Minnesota's Carlson School of Management, and Kaitlin Wowak, assistant professor in the Department of Information, Analytics and Operations at the University of Notre Dame's Mendoza College of Business.

The researchers assessed the impact of the Drug Price Competition and Patent Term Restoration Act—commonly called the Hatch-Waxman Act—which was intended to increase competition in the pharmaceutical industry and lower drug prices by expediting the approval process for generic drugs. The process has led to a considerable increase in the number of generic drugs entering the marketplace since its passage in 1984.

It's generally believed that generic drugs are of equivalent quality to the original pioneer drug because they have the same formulation and because generic manufacturers are audited by FDA regulators to the same manufacturing quality standards. But the authors' study of 939 recalls at 64 firms over a 12-year period found that generic drug companies facing more product competition have more serious Class 1 and 2 manufacturing recalls. These are the recall classes designated by the FDA that may cause death or medically reversible harm to the customer.

While generic drug makers are not allowed to change the design of the product, they have considerable leeway regarding manufacturing decisions.

"This may explain why firms producing a higher proportion of generic products may have higher rates of recalls," Shah said. "These decisions may include reducing labor costs, hiring less experienced employees or lowering maintenance costs by servicing manufacturing equipment less often. Firms may also respond to intense competition by purchasing lower-cost ingredients."

Ball, Shah and Wowak used data from the FDA's annual Orange Book, which contains all approved pharmaceutical products for sale in the U.S. and classifies whether a drug is a new drug application (NDA) or an abbreviated new drug application (or a generic). They compared its information with recall data from 2002 to 2014.

"Our results demonstrate that as product competition increases, manufacturing-related recalls increase," Wowak said. "This is particularly evident when firms are encouraged to compete on product price, are free to set prices, and the design of the product is unalterable."

The professors also found that the relationship between product

competition and manufacturing-related recalls is not universal but is contingent upon managerial discretion. This finding may indicate that while price competition via more generic drugs leads to more serious manufacturing problems in the production process, it may also encourage managers not to announce recalls when they have discretion.

They believe that their findings suggest the need for changes in processes used by the Food and Drug Administration. These include requiring more detailed and precise documentation about how the generic drug will be produced and how stringently the manufacturing plants that product generic pharmaceuticals are inspected.

More information: George P. Ball et al, Product competition, managerial discretion, and manufacturing recalls in the U.S. pharmaceutical industry, *Journal of Operations Management* (2018). DOI: 10.1016/j.jom.2018.04.003

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