Quality problems more likely in offshore drug plants, study finds

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Drugs produced in offshore manufacturing plants -- even those run by U.S. manufacturers -- pose a greater quality risk than those prepared in the mainland United States, a new study suggests.

Researchers found that drugs produced in Puerto Rican plants owned and operated by U.S. pharmaceutical firms were more likely to have quality problems than those produced by the same firm in a matched plant on the United States mainland.

The results show how difficult it is to transfer world-class quality control to an offshore plant, even under the best of conditions, said John Gray, lead author of the study and assistant professor of operations at Ohio State University's Fisher College of Business.

"Many people, including some pharmaceutical executives, think offshore plants can produce drugs at significantly less cost but with the same quality risk as plants in the U.S. But we found that may not always be the case," Gray said.

"We believe the quality differences we found in Puerto Rican plants were driven by challenges in transferring knowledge from headquarters to the plant, due to cultural differences, primarily differences in language and values."

The study findings accounted for many of the alternative explanations about why offshore plants may have lower quality than those on the U.S.

mainland.

The Puerto Rico plants in this study were compared to plants on the U.S. mainland owned by the same companies, and manufacturing the same or similar drugs, so the conditions were very similar. The researchers found that quality was not related to the distance between the plant and the company headquarters, the education of the local population near the plant, or the number of similar drug manufacturing plants in the area. That left knowledge transfer challenges due to cultural differences as the most likely explanation for the results, Gray said.

Before getting his PhD, Gray worked as an operations manager for eight years for Proctor & Gamble. He conducted this study with Aleda Roth of Clemson University and Michael Leiblein, associate professor of business and corporate strategy at Ohio State's Fisher College. The results appear in the November 2011 issue of the *Journal of Operations Management,* now available online.

For the study, the researchers used inspection data that the U.S. Food and Drug Administration compiled on Puerto Rican and mainland U.S. pharmaceutical manufacturing plants. These plants produced both over-the-counter and prescription drugs.

These inspection reports listed any deviations that the FDA inspectors found from "good manufacturing practices." These are practices that, if not followed, increase the likelihood of defective products. Each of these inspection reports indicate one of three possible actions required of the plant: no action, voluntary action (minor problems found) or official action (major problems that must be corrected under threat of government sanctions). The protocols for the inspections were the same between the U.S. mainland and Puerto Rico, and there is no evidence of a difference in inspection quality that may bias the results.

The researchers matched 30 plants in Puerto Rico with plants owned and operated by the same pharmaceutical companies on the U.S. mainland. These plants were matched on a variety of measures to ensure that were as similar as possible.

Armed with the FDA inspection reports from 1994 to 2007, the researchers asked four independent experts to create a scoring system based on possible inspection outcomes. This system allowed the researchers to create a quantitative measure of quality risk for each plant in the study. One of the experts worked in the FDA for 34 years, and the other three had extensive experience working in quality control for major U.S. manufacturers.

After the experts scored all the plants, the results clearly showed that the quality risk was higher in the Puerto Rico plants when compared to their matched mainland facilities, Gray said.

From a consumer standpoint, the results don't mean that drugs manufactured in Puerto Rico are unsafe, he said. Not all the quality risk problems that the FDA found would necessarily lead to unsafe drugs.

"There is a very low probability that you will get a bad drug manufactured in a mainland U.S. plant and, based on these results, we assert that there is a slightly greater, but still very low probability that you will get a bad drug manufactured in Puerto Rico," Gray said.

"It is a small practical difference for consumers. But for companies, even a slightly higher probability of a quality error can be a substantial problem. Just one quality error that hurts consumers or leads to a recall can be extremely costly to the company responsible."

Gray said the results suggest that knowledge transfer challenges created by differences in language and culture are the best explanation why the

offshore plants in the study had a higher quality risk. But he said the researchers can't rule out the possibility that there is something unique about Puerto Rico that would explain the results.

If – as the researchers suspect –cultural differences are the primary reasons for the differences in quality risk found here, the risks may actually be lower in Puerto Rico than they would be elsewhere.

Gray noted that Puerto Rico is a U.S. territory and the manufacturing plants there share much in common with similar mainland facilities.

"Facilities in more distant, less developed countries may face even greater obstacles to quality control than what we found in Puerto Rico," he said.

Gray said he and his colleagues are conducting studies that compare other headquarter country - plant country pairs to try to disentangle the drivers of the differences found in this study.

The results should serve as a caution to pharmaceutical executives who want to cut costs by producing drugs offshore.

"It is difficult for many executives to fully appreciate the day-to-day discipline required to operate with low quality risk. And that is something harder to monitor and ensure when plants are offshore," he said.

The most effective way to improve quality standards in offshore plants may be to rotate managers and line employees from mainland plants with well-established quality programs.

"One of the managers I spoke to currently in a Puerto Rican plant said it best: No one here knows what it looks like to run a world-class operation

in terms of quality control," Gray said.

This kind of knowledge can't just come from books and manuals, he said, especially when you're dealing with workers who speak another language and come from another culture.

Provided by The Ohio State University

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