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Drug maker [Pfizer](#) Inc. recalled about a million packs of birth-control pills that weren't packaged correctly, which raised the risk of unplanned pregnancies among women who relied on the pills.

Pfizer Inc. is recalling about a million packages of two types of birth-control pills because they might not contain enough pills with active ingredients, Jennifer Corbett-Dooren reports on the News Hub.

Photo: AP.

Pulled from shelves were Lo/Ovral-28 pills and their Norgestrel generic versions, which doctors have been prescribing for years to tens of thousands of women. The pills come in blister packs containing a mix of 21 active tablets and seven that are inert. As guided by the packs, women are supposed to take a certain pill each day in order to prevent pregnancy, taking the inert pills at the end of a monthly cycle.

Pfizer said Wednesday that it believes only 30 packs had packaging problems, including having the active and inert tablets out of order, or lacking the proper amount of each kind of pill. The company said it recalled a million packs in the U.S. to be safe.

The Food and Drug Administration hasn't received any reports of adverse events, such as unintended pregnancies, and the agency is investigating, according to an agency spokeswoman. Pfizer said it hadn't received reports either, while noting that it had only just alerted the public.

The pills were made and shipped last year by a Pfizer plant in upstate New York, on the Canadian border. To encourage proper use, active pills in the packs are colored white, while the inert tablets are pink. An alert customer noticed that her pack had a pink pill where a white one should have been, and complained to the company on Oct. 19, a Pfizer spokeswoman said.

Investigating the complaint, Pfizer discovered that some blister packs of pills had an extra active pill at day 22 or 28, one pack lacked an active tablet at day 10 and another pack lacked a placebo tablet at day 24, the FDA spokeswoman said.

Pfizer identified three glitches in its production of the packs that could, on rare occasion, result in improper packaging, a Pfizer spokeswoman said. The problems: The design of the packaging line could allow for incorrect placement of the pills; a mechanical system for detecting defective packs could miss one in "very, very infrequent" times; and plant workers could also miss problem packs. The company said it has since fixed the problems.

Pfizer notified pharmacies and distributors on Dec. 28 that it was recalling the pills, according to an FDA spokeswoman. The company believed, based on the "low defect rate and our health-hazard assessment," that providing public notice wasn't necessary, but then went public late Tuesday following an FDA request, a Pfizer spokeswoman said.

Women who miss birth-control pills—say, by taking an inert pill when they should take an active one—are at risk of an unintended pregnancy because they may ovulate in the absence of the hormonal medicines meant to prevent it. Carolyn Westhoff, a professor of obstetrics and gynecology at Columbia University, cautioned that the risk from missing one or two pills is likely low. "Usually the women who ovulate have missed a larger number," said Dr. Westhoff, who has studied the ovarian effects of missing birth-control pills.

Yet Eve Espey, an obstetrics and gynecology professor at the University of New Mexico, said the risk could be compounded because women also tend to miss pills on their own.

It was unclear how many of the pills were already used and how many remain in the hands of women. Pfizer said it didn't know. The expiration dates on the affected products range from July 31, 2013, to March 31, 2014. A list of the affected lots is available at www.pfizer.com.

The company is advising women who have used the pills "over the last several months" to consult with their doctors.

"We understand that this news can be very concerning and confusing for any woman who takes birth-control pills to protect against unintended pregnancies. We share their concerns," the company said in a statement.

Last year, doctors wrote 64,000 prescriptions for Lo/Ovral-28 in 2011, and another 453,000 prescriptions for its generic version, Norgestrel and Ethinyl Estradiol tablets, according to IMS Health, a health-care data firm. The tablets were manufactured and packaged by Pfizer, but are labeled and sold under the Akrimax Pharmaceuticals brand.

"This is one of the pills that are commonly used, and patients depend on it to be efficacious," said Jennifer Wu, an ob-gyn doctor at Lenox Hill Hospital in New York City. Neither Dr. Wu nor Dr. Westhoff said they had heard from patients taking Lo/Ovral, but would switch their prescriptions to another product and recommend partners use condoms. Lo/Ovral-28 is a small product for Pfizer, the world's largest drug maker with \$67.4 billion in world-wide sales last year. The product had \$7.6 million in sales in 2011, according to IMS Health. But the recall could dent Pfizer's reputation for quality manufacturing, a selling point in competing with rival products.

Through Nov. 3 of last year, the FDA had notified Pfizer 12 times of "objectionable" manufacturing conditions requiring correction, up from nine each of the previous two years, according to FDAzilla, a business intelligence firm that analyzes FDA data. Since 2008, Pfizer had received 38 of the letters, which can result in official warning letters if serious problems go unaddressed.

The Pfizer spokeswoman said, "A review of our complete inspection records shows consistently strong performance for the past three years."

The FDA has been issuing more of the letters. In 2010, it sent 1,500 to pharmaceutical companies, up from 1,068 in 2007, according to FDAzilla.