U.S. Pharma Accused of Delaying FDA Adverse Event Reports

July 30, 2015

Pharmaceutical companies in the United States often delay reports of drug-related illness or death to federal regulators, a move that could be putting patient's lives at risk in the interest of public relations, alleges a new analysis published in JAMA Internal Medicine and reported by HealthDay.

The research letter, which was written by public health analysts at the University of Minnesota, reviewed more than 1.6 million bad drug interactions submitted to the U.S. Food and Drug Administration (FDA) Adverse Event Reporting System between 2004 and 2014.

Researchers found that during this 10-year period, drug-makers delayed reporting nearly 10 percent (about 120,000) of adverse drug effects to the FDA until after the required 15-day period. The study further revealed that pharmaceutical companies also delayed reporting more than 40,000 patient deaths.

One example cited in the letter outlines an FDA warning sent to Pfizer in 2010 for a series of reporting delays ranging from nine months to more than three years. Another letter sent to Actelion Pharmaceuticals cited the drug-maker's failure to report nearly 3,500 patients who died on their medications that same year.

"If adverse event reports are getting filed late, that means safety warnings are delayed and more people are taking dangerous drugs without knowing it," wrote Rita Redberg, MD, chief editor of JAMA Internal Medicine and professor of medicine at the University of California, San Francisco.

Redberg added that the analysis is likely just the tip of the iceberg when it comes to big pharma's reporting problem, noting that it's estimated only about 2 percent of all adverse medication events ever get reported to the FDA.

Consumers and physicians can take matters into their own hands by reporting adverse medication events or deaths directly to the FDA, rather than going through a drug company. For more information on how to do this, click here.

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