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Bad medicine: The awful drug reactions Americans report

BY DAN KEATING AND JASON MILLMAN June 6

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New data released by the U.S. Food and Drug Administration on bad reactions to drugs show men and women having vastly different experiences.

The most commonly reported adverse reaction to bad drugs for men is death, according to a new database of reports spanning from 2004-2013. Women had a fairly similar number of deaths, just more than 60,000, but that was only the ninth-most common reaction suffered.

The FDA data provide an incomplete picture, but the information underscores serious challenges in

delivering safe care and reducing waste in the health-care system. A 2006 Institute of Medicine **report** estimated that 1.5 million preventable adverse drug events occur each year, and the committee said the number may be much higher.

Here are the most common reactions experienced by women, according to the new FDA data:

(U.S. Food and Drug Administration)

And the most common adverse reactions for men:

(U.S. Food and Drug Administration)

The FDA unveiled a new access project as part of this week's Health Datapalooza intended to create more transparency and help developers find ways to improve health care. The FDA initiative compiles about 3.5 million adverse drug event reports from patients, medical providers and pharmaceutical firms over the past decade.

However, the disclosures cannot be considered a comprehensive account of drug reactions. There are limitations on what actually gets reported to FDA, and just the existence of a report doesn't necessarily

mean a drug actually caused a bad reaction. Still, the complaint database can help detect problems with various drugs.

There are many more reactions listed for women – more than 2 million reaction records compared to less than 1.3 million for men. The women's records are more likely to list more than one bad reaction to a drug. And almost half of the reported events for women actually came from the patient, while more than 60 percent of reports for men came from care providers, the drug manufacturer or lawyers.

Dr. Michael Carome, director of the health research group at Public Citizen, said the data don't make clear why more adverse events were reported for women. The FDA data, he added, probably undersell how frequently people suffered an adverse reaction to a drug.

"Much of this is voluntary, so there's likely very

significant under reporting," Carome said. "There's likely many more adverse events occurring than you get from this database."

The FDA has promised to release more data on adverse drug events, so perhaps there will be some more clarity to come on why there's a stark difference in the reports from men and women.

Jason Millman covers all things health policy, with a focus on Obamacare implementation. He previously covered health policy for Politico.