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**ISMP Advocates for Improvement of
FDA's Adverse Event Reporting System**

Horsham, Pa—The majority of drug manufacturer reports to the US Food and Drug Administration (FDA) about serious adverse events lack essential information, according to a new ISMP-authored article in the peer reviewed literature. The Institute for Safe Medication Practices (ISMP) is urging the FDA to launch a new initiative to modernize its most important tool to monitor safety of approved drugs—the MedWatch program, also called the FDA Adverse Event Reporting System (FAERS).

“As our published analysis shows, a majority of reports from drug manufacturers lack one or more items of basic information such as age, gender and event date,” says lead author Thomas J. Moore, ISMP Senior Scientist. “FAERS serves as the primary source of evidence for new warnings about drugs after approval, and FDA reporting requirements for industry have not been updated for more than a decade. In addition, growing industry contact with individual patients through the internet and social media provide new opportunities to improve postmarket surveillance at a modest cost.”

The paper, which appears in *Pharmacoepidemiology and Drug Safety*, examines the completeness of serious adverse drug event reports submitted to FAERS in 2014. Moore and the three coauthors are the project team for ISMP's QuarterWatch drug safety publication, which monitors all adverse drug events received by the FDA. For more on QuarterWatch, visit: <http://www.ismp.org/QuarterWatch/default.aspx>.

For a copy of the paper, visit: <http://onlinelibrary.wiley.com/doi/10.1002/pds.3979/abstract> or contact Renee Brehio, ISMP, at: rbrehio@ismp.org.

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.

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