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DRUG SIDE EFFECTS STUDY PUBLISHED, DEBUNKS PREVIOUSLY ACCEPTED LIMITATION IN THE USE OF FAERS DATA FOR MONITORING DRUG SAFETY:

"Stimulated Reporting: The Impact of US Food and Drug Administration-Issued Alerts on the Adverse Event Reporting System (FAERS)" Published In *Drug Safety Journal*

SANTA ROSA, Calif., September 30, 2014 – AdverseEvents, Inc., a healthcare informatics company, that analyzes post-approval drug side effect data collected by the FDA, has overturned long-held conventional wisdom with its report: "**Stimulated Reporting: The Impact of US Food and Drug Administration-Issued Alerts on the Adverse Event Reporting System (FAERS)** (http://info.adverseevents.com/stimulated-reporting) in the premier drug risk assessment journal, ***Drug Safety***. This report refutes a widely held assumption that FAERS data are significantly influenced by the issuance of FDA alerts.

The Adverse Event Reporting System (FAERS) is a database maintained by the FDA that contains over five million side effect case reports (also known as adverse events) that are linked to FDA-approved drugs. "Stimulated reporting," is the concept that public disclosure of a safety issue by the issuance of an FDA alert or warning will result in substantially increased reporting rates for the affected drug, thereby negating the reliability of the FAERS database.

AdverseEvents' report analyzed both overall and adverse event-specific reporting before and after 100 FDA alerts, and found no discernable pattern of increased reporting. The report clearly demonstrates that modern FAERS data does not suffer from the biases that would be introduced by significant shifts in reporting owing to the issuance of FDA alerts.

"Since its establishment, AdverseEvents has been redefining drug safety by systematically debunking traditionally held assumptions that underlie misunderstanding and distrust of FAERS data, thereby resulting in missed opportunities in improving patient outcomes and lowering healthcare costs," said Brian Overstreet, CEO of AdverseEvents.

AEI's "Stimulated Reporting" study is the second in a series of reports that addresses purported FAERS limitations. The first installment was published April 2, 2014, titled ***"The Weber effect and the United States Food and Drug Administration's Adverse Event Reporting System (FAERS): Analysis of sixty-two drugs approved from 2006-2010."*** This study contradicted the "Weber Effect" – the belief that after regulatory approval of a drug, adverse event reporting increases over the first two years, peaks near the end of year two, and then reliably, and rapidly, diminishes with further time on the market. Overstreet continued, "the publishing of these reports in premier drug safety journals, continues to bolster our convictions and substantiates our evidence that FAERS data is not only relevant but vital in determining the overall safety profile of all FDA approved prescription drugs."

Keith Hoffman, the primary author of the report and AEI's VP of Scientific affairs, stated "the only way to fully understand a drug's true safety profile is to track and monitor real world side effect profiles that emerge after the general population uses a given medication. Eradicating misconceptions and misinformation regarding the significance and validity of FAERS data is a necessary step in ensuring that the healthcare community will embrace

and utilize these data to effect positive drug safety changes. With approximately one million new side effect case reports being submitted to FDA each year we believe FAERS data are vital to drug safety analyses."

As studies have estimated the systemic cost of drug side effects at $27 billion per year, the healthcare industry has readily acknowledged the need for information that can drive improved patient outcomes and lower avoidable medical costs. Meeting this need through its' proprietary technology, analytics, and product platform designed for health insurers, health systems, hospitals, and related service providers, AdverseEvents, has been recognized for its game-changing analytical tools: RxScore®, the first drug safety scoring system that compiles available drug information and quickly summarizes comprehensive post-approval drug safety issues and RxSignal®, a predictive algorithm that alerts users to emerging and/or previously unidentified side effect threats that may prompt a future FDA regulatory action (warnings, Black Box designations, product withdrawal or recalls, etc).

To view the report in its entirety click http://info.adverseevents.com/stimulated-reporting

ABOUT DRUG SAFETY

Drug Safety is the premier international journal covering the disciplines of pharmacovigilance, pharmacoepidemiology, benefit-risk assessment, risk management and medication error prevention.

Drug Safety specializes in definitive reviews on the epidemiology, clinical features, prevention and management of adverse effects of individual drugs and drug classes. Benefit-risk assessments provide an in-depth review of adverse effect and efficacy data for a drug in a defined therapeutic area. Drug Safety is the official journal of the International Society of Pharmacovigilance.

ABOUT ADVERSE EVENTS, INC.

AdverseEvents, Inc. (AEI) is a California-based healthcare informatics company that improves patient safety and reduces systemic healthcare costs through the comprehensive analysis of post-marketing drug side effect data. Utilizing data-mining and analysis technology, AEI makes post-marketing drug safety data accessible, actionable, and predictable. AEI is one of the foremost research authorities on drug side effects – publishing comparative drug studies, industry white papers, topical special reports, and platform validating research papers in leading academic journals.