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SPECIAL DRUG SAFETY REPORT DETAILS 49,000 PREVIOUSLY UNDISCLOSED SIDE EFFECT REPORTS

REPORT AT TEDMED 2014 HIGHLIGHTS DATA MINING'S ROLE IN IMPROVING PUBLIC SAFETY

SANTA ROSA, Calif., September 10, 2014 – AdverseEvents Inc., a healthcare informatics company, released today at TEDMED 2014 in San Francisco, CA a Special Report: **Expediting Drug Safety Using FOIA: An Analysis of 48,971 Unreleased FAERS Reports.**

In response to the continued delayed release by the FDA of drug safety data from the FDA Adverse Event Reporting System, AdverseEvents has been filing Freedom of Information Act (FOIA) requests for high profile individual drugs that are of the most concern to healthcare decision makers.

In response to the FOIA requests on 152 drugs through June 2014, the FDA provided **88,922 pages of unstandardized data**, in PDF format. Incorporating this data into the AdverseEvents Explorer platform resulted in the extraction of **48,971 new primary suspect cases yet to be seen outside of FDA and drug manufactures.**

AdverseEvents released the report to coincide with its' participation in TEDMED 2014, a conference dedicated to the idea that technology will radically alter the healthcare landscape. The release highlights the power of AdverseEvents proprietary data mining capabilities and more importantly the analytics and insight that enables healthcare decision makers to drive safer prescribing behavior that improves patient outcomes and reduces the estimated \$27 billion burden that avoidable side effects have on the healthcare system.

AEI's FOIA request and processing methods revealed significant safety concerns that have yet to be communicated by FDA or drug manufacturers. The drug safety information revealed in this report provides not only the data, but AdverseEvents' analytics and accompanying insight that cannot be found from any other source.

AdverseEvents' FOIA Report contains the following:

- **Drugs that have experienced significant increased serious side effects that are not currently being communicated to healthcare providers and the general public**
- **12 drugs with an Active RxSignal¹ that have shown an increased likelihood that the FDA will take future regulatory action**
- **20 drugs with large increases in RxScore², indicating a dramatic negative shift in the post market safety profile**

In addition, the report also provides insight on the marketplace battle between the obesity drugs **Qsymia** and **Belvig**, with new side effect data that potentially will play a role in determining a

marketshare winner. Also featured, are new alternatives to statins and a review of the sudden spike in deaths associated with **Zemplar**, a now generic drug whose safety profile went from average to risky during this period.

- To view the report in its entirety please [click here](#).

¹ RxScore® is the first drug safety scoring system that compiles available drug information and quickly summarizes comprehensive post-approval drug safety issues.

² RxSignal® is 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).

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, through its proprietary RxSuite™ of analytics, AEI makes post-marketing drug safety data accessible, actionable, and predictable.

In addition to managed care organizations, AEI also provides services to enterprise markets including the pharmaceutical industry and financial institutions.

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