AdverseEvents Debunks Previously Accepted Limitation in the use of FAERS Data for Monitoring Drug Safety

Broad Research Study Published in *DRUG SAFETY* Refutes the 'Weber Effect"'

Santa Rosa, Calif. April 2, 2014… AdverseEvents, Inc., a healthcare informatics company, today published a modern analysis that debunks the so-called 'Weber Effect', a widely cited limitation regarding the use of the data collected by the FDA for post-approval drug safety monitoring.

The research study, "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," was published in the Wednesday, March 19, 2014 edition of ***Drug Safety***, a premier international journal that specializes in risk assessment and the prevention and management of adverse effects of individual drugs and drug classes (http://link.springer.com/journal/40264).

The 'Weber Effect' was first described in 1984 (Weber, Advances in Inflammation Research, Rave Press, New York, 1984, Pages 1-7). In modern publications, the 'Weber Effect' is often summarized as "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." In the thirty-year period since the publication of Weber's study, drug safety professionals have relied upon the 'Weber Effect' and cited it as a reason why the FAERS database should not be used for comparable post-approval drug studies.

The results of AdverseEvents' study contradict these objections by demonstrating that most of the modern adverse event reporting into FAERS does not follow the pattern described by the 'Weber Effect.' Factors that contribute to these findings include large increases in the volume of adverse events reports since the 'Weber Effect' was described, as well as a concerted effort by the FDA to increase awareness regarding the utility of post-approval adverse event reporting.

334,984 FAERS case reports from sixty-two drugs approved by the FDA between 2006 and 2010 were included in AdverseEvents' analysis. While a few of the drugs demonstrated what could be considered 'Weber Effect' curves, a majority of the drugs showed little evidence of the effect. In fact, the general adverse event reporting pattern observed in this study appears to consist simply of increasing case counts over the first three quarters after approval (consistent with market roll-out) followed by relatively constant counts thereafter. The study followed the adverse event reporting pattern for up to a four year period following each drug's approval date.

Brian M. Overstreet, president of AdverseEvents said, "Drug Safety's acceptance and publication of this study is a major milestone in AdverseEvents' mission to unravel the misinformation that has built up around the FAERS dataset. For far too long, these data have been vastly underutilized due to a lack of understanding and a general distrust over what these data can and cannot do. Clinical trials are so limited in scope that the true safety profile of a particular drug can only be determined once it reaches the public market. Therefore, the only way to fully review a drug's safety is to track and monitor side effects as the general population begins utilizing the drugs on an ongoing basis in real world circumstances. Debunking the 'Weber Effect' is only our first step in the process of redefining the dogmatic – and, we believe, incorrect - limitations that the drug safety industry assumes and assigns to these data."

AEI's study has demonstrated the quality and usefulness of FAERS data, thereby giving managed care companies an opportunity to look at unbiased data regarding side effects from approved drugs (which are costing over $27B in avoidable costs to the healthcare system).. Managed care companies are employing AEI tools that utilize FAERS datasets in order to lower their costs and improve patient outcomes by making decisions based on real-world side effect data.

Overstreet added, "It is clear that there is a movement afoot to recognize the importance of FAERS data and its importance as a drug safety monitoring tool, by the push for the FDA to introduce "OpenFDA" – a program to provide easy to use, high value data collected by the FDA, so that developers such as ourselves can analyze these data and provide it to the healthcare industry and the general public at large. The more reliable the information, the better the prescribing decisions that will be made."

Keith Hoffman, VP of Scientific Affairs said, "This study of modern reporting trends into FAERS was made possible by the application of our various analytic tools to sort through over 300,000 case reports. It was this broad access to so many reports, over so many newly approved drugs that enabled one of the most comprehensive analyses of FAERS reporting trends that we are aware of. The results of this study underscore the fact that modern FAERS reporting has improved greatly over the last decade."

Side effects from FDA-approved drugs cause over $27B in avoidable costs to the healthcare system every year. To try to limit those side effects, the FDA collects and maintains a vast repository of side effect data in its FDA Adverse Event Reporting System (FAERS). FAERS is a collection of over five million post-approval safety events across all demographic groups and is used by the FDA to monitor real world drug safety issues. The 'Weber Effect' has often been cited as a primary reason to discard FAERS as a valuable safety tool in regards to FDA approved prescription drugs.

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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