



## IMMEDIATE RELEASE

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### **JOURNAL OF MANAGED CARE AND SPECIALTY PHARMACY (JMCP) PUBLISH REPORT ON HOW SIDE EFFECTS CONTRIBUTE TO A DRUG'S TOTAL FINANCIAL IMPACT**

*Advera Health Analytics, Inc. and Columbia University Author Study: Impact Drug Safety Rating System Based On Post-Marketing Costs Associated With Adverse Events and Patient Outcomes*

**SANTA ROSA, CALIFORNIA – December 6, 2015** – [Advera Health Analytics, Inc.](#) and Columbia University's Dr. Nicholas Tatonetti joint study, [A Drug Safety Rating System Based on Postmarketing Costs Associated with Adverse Events and Patient Outcomes](#), was published today in the Academy of Managed Care Pharmacy's (AMCP's) *Journal of Managed Care & Specialty Pharmacy (JMCP)*. The study provides a method to estimate the true total financial impact of prescription drugs by incorporating downstream medical costs incurred as a result of side effects and poor patient outcomes.

In order to better monitor, control and mitigate patient risks and systems costs, managed care companies are seeking to utilize broad datasets that provide actionable intelligence and meaningful conclusions regarding the inclusion in their formularies of one drug over another. The effort undertaken by Advera Health Analytics and Nicholas Tatonetti, Assistant Professor of Biomedical Informatics at Columbia University, was to develop the first of its kind drug safety statistic that estimates the downstream medical costs associated with serious adverse events (AEs) and patient outcomes associated with the use of FDA-approved drugs.

There is an enormous gap in quality data regarding drug safety. Pre-approval clinical trials are conducted in relatively homogeneous patient populations and this oftentimes leads to unexpected safety issues after FDA approval. Additionally, during a drug's marketing phase inadequate data disclosures, slow reaction times from regulatory bodies, and deep rooted bias against disclosing and publishing negative results further complicate the analysis of drug safety in real world usage. Accordingly, there is an acute need for the development of analytics that reflect drug safety in heterogeneous, real world, populations.

The system developed by Advera Health and Columbia's Dr. Tatonetti demonstrates that post-marketing AE reports can be assigned direct medical costs in order to estimate a drug's downstream financial impact, and thereby provide a needed window into drug safety after the drugs are used broadly.

This is the first study regarding side effects financial impact. It considered over 5 million AE case reports from 1997-2014 imported from FDA's post-marketing AE database known as the Adverse Event Reporting System (FAERS). All "primary suspect" case reports for each drug were collected from FAERS. Serious AEs and outcomes were MedDRA coded and tallied for each case report. Non-serious AEs and outcomes were not included. All costed cases were aggregated for each drug and divided by the number of patients exposed to obtain a downstream estimated direct medical cost burden per exposure. Each drug was assigned a corresponding 1-100 point total.

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“This study definitively reveals that it is possible to factor in the rate of drug adverse events when calculating the total financial impact of FDA approved prescription drugs,” said Brian Overstreet, President of Advera Health. “This system takes into account downstream safety consequences and enables hospitals, health systems and payers, as well as pharmaceutical companies, for the first time to see a complete picture of how much drugs really cost when real world safety data are reviewed.”

To learn more about this report: <http://www.amcp.org/JMCP/2015/December/20477/1033.html>

#### **ABOUT ADVERA HEALTH ANALYTICS**

Advera Health Analytics is a health informatics company that improves patient safety and reduces systemic healthcare costs through the comprehensive analysis of real world outcomes data. Advera Health Analytics makes these data accessible, actionable, and predictable. For more information visit [adverahealth.com](http://adverahealth.com) and connect with us on [LinkedIn](#), [Twitter](#) and [Facebook](#).

#### **ABOUT NICHOLAS TATONETTI, PhD**

Assistant Professor of Biomedical Informatics, [Columbia University](#)

The Tatonetti Lab is in the [Department of Biomedical Informatics](#) at Columbia University as well as the [Department of Systems Biology](#), and the [Department of Medicine](#) and is a member of the [Data Science Institute](#) at Columbia.

#### **ABOUT JMCP**

*JMCP* publishes peer-reviewed original research manuscripts, subject reviews, and other content intended to advance the use of the scientific method, including the interpretation of research findings in managed care pharmacy. JMCP is under the auspices of the trade association The Academy of Managed Care Pharmacy (AMCP).