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New Studies Show Popular Heartburn Medications Raise Significant Cardiovascular Event Risks and Costs for Patients Taking Widely Prescribed Heart Drug

- *Four of the most commonly used proton pump inhibitors raise risk of heart attack and stroke for patients taking Plavix®*
 - *Drug interaction increases annual hospital costs by nearly 40 percent*

FRANKLIN LAKES, NJ, May 6, 2009 – Four of the most commonly prescribed heartburn medications substantially raise the risk of a major adverse cardiovascular (CV) event in patients taking clopidogrel, a widely used antiplatelet medication also known by its brand name, Plavix. These findings by researchers at Medco Health Solutions, Inc. (NYSE:MHS) and the Indiana University School of Medicine were presented today at the annual scientific meeting of the Society for Cardiovascular Angiography and Interventions (SCAI).

The study found that using any one of several different proton pump inhibitors (PPIs) in conjunction with clopidogrel increases the risk of hospitalization for a CV event by 51 percent, and that individual PPIs each significantly raise that risk as well, ranging from 39 percent to 61 percent. The four PPIs included in the study were pantoprazole (Protonix®), esomeprazole (Nexium®), omeprazole (Prilosec®) and Lansoprazole (Prevacid®), which together accounted for about 96 percent of PPI use in the study. Other PPI’s, including rabeprazole (Aciphex®), were not included in the study due to the patient count for these agents being insufficient to yield reliable results.

Clopidogrel is one of the world’s most prescribed drugs, and ranked third in US pharmaceutical sales in 2008. PPIs are often taken along with clopidogrel to prevent against serious gastrointestinal bleeding, a possible side-effect of the antiplatelet drug. While 41 percent of patients in the study were prescribed a PPI, a negligible number of them had experienced a severe bleeding problem.

“There’s a growing body of evidence that PPIs decrease the effectiveness of clopidogrel and put cardiovascular patients at a much higher risk – a huge concern given the large number of patients affected,” said Dr. Robert Epstein, Medco’s chief medical officer and one of the study researchers. “While this study confirms prior research in this area, it brings us a step further in our understanding by showing that this is a problem associated with each of the four most popular PPIs.”

The adverse cardiovascular events that were measured in the study include myocardial infarction, unstable angina, transient ischemic attack/stroke, coronary revascularization or cardiovascular death.

The analysis is one of a series by Medco and Indiana University researchers known as The Clopidogrel Outcomes Study that is examining factors impacting the effectiveness of clopidogrel and the associated clinical outcomes and costs. An additional study conducted as part of this research effort found that the

use of PPI therapy in conjunction with clopidogrel increases related hospital costs by at least 38 percent; the annual cost for patients on both a PPI and clopidogrel was \$6,061 as compared to \$4,400 for patients only taking clopidogrel. These findings will be presented this month at the annual meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

Study details

The Clopidogrel Outcomes Study investigated medical and pharmacy claims data of 16,690 patients who were taking clopidogrel following a stent procedure and tracked the study subjects for a 12-month period from 2005 to 2006. The study compared a group of 6,828 patients who were concurrently taking a PPI and clopidogrel to a group of 9,862 patients who were only taking clopidogrel. When PPIs were examined individually, all of the associations were highly statistically significant.

To address a related issue that has raised questions about the PPI/clopidogrel interaction, the researchers also looked at whether or not PPIs independently increase the risk of a CV event. The results of this study found that there was no independent effect from taking a PPI in the absence of clopidogrel. The study included 1,641 patients who had undergone a stent procedure but were not taking clopidogrel and compared CV event hospitalizations of patients on a PPI to those not taking a PPI. These findings were recently presented at the American Heart Association's Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular and Stroke (QCOR).

“Our study, along with a 2007 FDA review and other researchers’ work, provides strong evidence that PPIs do not independently raise cardiovascular risks for stent patients and further strengthens the observation that this interaction exists between PPIs and clopidogrel and impairs the effectiveness of the antiplatelet drug,” said Epstein. “Given the totality of the evidence generated on this interaction and the known benefits of clopidogrel in reducing the risk of death, heart attack and stroke after coronary stenting, patients and their physicians should continue to trust in the use of this medication and consider a PPI only when clearly indicated.”

About Medco

Medco Health Solutions, Inc (NYSE: MHS) is a leading health care company, serving the needs of more than 60 million people. *Medco, the world's most advanced pharmacy*®, provides clinically driven pharmacy services designed to improve the quality of care and lower total health care costs for private and public employers, health plans, labor unions and government agencies of all sizes, and for individuals served by Medicare Part D Prescription Drug Plans. Through its unique *Medco Therapeutic Resource Centers*® and the Accredo Health Group, Medco's Specialty Pharmacy, the company is creating innovative models for the care of patients with chronic and complex conditions. Medco is a leader in the emerging field of personalized medicine and in applying evidence-based protocols to elevate the practice of pharmacy – a key element in reforming America's health care system. Medco is ranked number 45 on the Fortune 500 list, with 2008 revenues of more than \$51 billion. For more information about Medco, go to <http://www.medcohealth.com>.

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