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Nighttime Heartburn's Impact on Workplace Productivity Costs the Nation More Than \$1.9 Billion Each Week

Resolving Nighttime Heartburn Improves Sleep Quality and Boosts Daytime Productivity According to New Study Published in *American Journal of Gastroenterology*

Bethesda, MD, August 31, 2005 – The first major multi-center, randomized, double-blind, placebo-controlled trial addressing therapy for gastroesophageal reflux disease (GERD) related sleep disorders was published today in the September issue of the *American Journal of Gastroenterology*. An estimate based on findings from this study reveals that U.S. workers who frequently suffer from moderate-to-severe nighttime heartburn symptoms cost the U.S. economy \$1,920,528,315 per week in paid hours of lost productivity.

This study demonstrated that effective acid suppression therapy with a proton pump inhibitor (PPI), either 20 mgs or 40 mgs of esomeprazole, relieved nighttime heartburn symptoms and GERD-related sleep disturbances and significantly improved sleep quality and thereby improved work productivity.

"Sleep problems are extremely common in patients with GERD and are often unrecognized," said lead author David A. Johnson, M.D., FACG, Professor of Medicine and Chief of Gastroenterology at Eastern Virginia Medical School who serves as the Vice President of the American College of Gastroenterology. For those with frequent and moderate-to-severe symptoms, GERD has a significant negative impact on sleep. "Anyone who's had a poor night's rest knows how much that impacts their performance the next day. We found that nighttime heartburn is a treatable condition, that responds to effective, acid-suppressive medical therapy such as esome-prazole."

Dr. Johnson and his colleagues designed the first large-scale study to look at relief of nighttime heartburn, as well as resolution of sleep disturbances and improvements in sleep quality. Using validated questionnaires, they also measured work productivity. The researchers found that nighttime heartburn was relieved in 53.1 percent, 50.5 percent and 12.7 percent of patients who received esomeprazole 40 mg, esomeprazole 20 mg and placebo, respectively. Additionally, GERD-related sleep disturbances resolved in significantly more patients who received therapy than those who received placebo. The high percentage of patients with resolutions of sleep disturbances in the current trial was both statistically and clinical significant.

"Many people mistakenly believe that heartburn is a trivial condition, but this study reveals that nighttime heartburn has a dramatic impact on daytime productivity," explained Dr. Johnson. "Our study found that improvements in sleep were associated with improvements in patients' daily activities including work productivity, which could have profound economic benefits."

Patients in the study lost 16 work hours of workplace productivity per week due to GERD related sleep disturbances when measured at the beginning of the study. After treatment, significantly more productive work hours

were saved in the patients who received acid suppression/PPI therapy compared with those who got a placebo (11.6 to 12.3 hours saved per week for treatment group compared to 6.2 hours saved per week for placebo.) Dr. Johnson explained the implications of this finding: "GERD has a more significant impact on work productivity than it does on absenteeism. Those who suffer from GERD-related sleep disorders may not stay home from work, but our findings reveal they are less productive, and that has cost implications for employers."

The study authors used an average hourly total employee compensation cost of \$24.59 from the U.S. Bureau of Labor Statistics (BLS) for the fourth quarter of 2003, the cost of productive hours saved per patient per week by employers was in the range of \$286 to \$301 for the treatment arms of the study.

According to the American College of Gastroenterology, approximately 20 percent of U.S. adults suffer from weekly heartburn symptoms. The ACG, using data from a Gallup poll, estimates that 79 percent of heartburn sufferers have nighttime symptoms, of whom 50 percent have symptoms that are moderate to severe. Narrowing this population to reflect the study population of frequent nighttime heartburn sufferers with moderate to severe symptoms, the College included in its calculation that 62.8 percent of the U.S. population is in the workforce (according to the U.S. BLS.) With the average savings of 5 hours per week of workplace productivity found by Dr. Johnson and his colleagues among the treatment groups, this translates into a potential overall economic impact of over \$1.9 billion per week compared to untreated patients.

According to Dr. Johnson, "Physicians treating patients with acid reflux therefore need to ask about sleep problems and furthermore to ask how patients feel when they wake up the next day. Daytime fatigue, irritability, concentration problems may all suggest a problem with restful sleep. Appropriate recognition of this will lead to appropriate therapy." He continued, "Sleep quality should be included as an important goal for optimal disease management of GERD. Even more so in a time of emphasis on quality management and achieving the best outcomes in medical care, this study demonstrates that appropriate treatment for GERD is an investment which has profound quality benefits for patients and economic benefits for employers."

More About Nighttime Heartburn

Heartburn affects as many as 40 percent of adults in economically developed countries.

Heartburn and other gastroesophageal reflux disease (GERD) symptoms experienced during the night commonly cause sleep disturbances, including arousal from sleep, increased wakefulness, and overall poor sleep quality.

In a U.S. study of patients with GERD, 69 percent responded that they "experienced GERD symptoms when laid down to sleep at night;" 54 percent responded that they were "awakened at night by GERD symptoms;" and 29 percent responded that they were "awakened at night by coughing or choking because of fluid or an acid or bitter taste, or food in the throat." (Farup C, et al., "The impact of nocturnal symptoms associated with gastroesophageal reflux disease on health-related quality of life." *Arch Int Med* 2001; 161:45-52.)

A survey of patients with heartburn found that 79 percent reported nighttime heartburn, and of those, 75 percent had symptoms that affected their sleep, and 40 percent believed that nighttime heartburn impaired their ability to function the next day. (Shaker R, et al., "Nighttime heartburn is an under-appreciated clinical problem that impacts sleep and daytime functions: the results of a Gallup survey conducted on behalf of the AGA. *AmJGastroenterol* 2003; 98:1487-1493.)

Full-text of the Johnson study can be accessed through the American Journal of Gastroenterology at http://www.blackwell-synergy.com/doi/full/10.1111/j.1572-0241.2005.00285.x
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