Institute for Safe Medication Practices 200 Lakeside Drive, Suite 200, Horsham, PA 19044

www.ismp.org

FOR IMMEDIATE RELEASE 7-17-18

CONTACT: Renee Brehio, Media Relations, ISMP 614-376-0212, rbrehio@ismp.org

Majority of Ambien Users May Not be Using the Drug Safely

Horsham, Pa. — A study published as an online first in *JAMA Internal Medicine* shows that **77%** of patients taking zolpidem (known by the brand names of Ambien, Edluar and Zolpimist), the most widely used prescription sleep medication, were not observing two or more U.S. Food and Drug Administration (FDA) recommendations to promote safe use. Safety issues surveyed included combining two or more drugs that depress the central nervous system, sustained instead of short-term use, and a higher than recommended dose or starting dose for women and older patients.

"The FDA has made clear how to reduce risks of next-day impairment, abnormal behavior, and dependence, but the instructions for safe use are widely ignored," said Thomas J. Moore, the lead study author, and ISMP senior scientist, drug safety and policy. The co-author was Donald R. Mattison, MD, Risk Sciences International, who also serves as a medical advisor to ISMP's *QuarterWatch*TM drug safety publication.

The research letter focuses on patient reports regarding zolpidem and was based on data from the Medical Expenditure Panel Survey, a government-sponsored annual survey of medical care.

Potential increased risk of adverse effects for zolpidem if safe use instructions are not followed include next-day impairment, abnormal behavior, and dependence. Next day impairment is of particular concern because many are not aware of it, and it can lead to preventable falls, motor vehicle accidents, and other serious injury. The study was not able to measure whether users were also following the recommendation to abstain from alcohol, another nervous system depressant that could contribute to next-day impairment.

Women are at greater risk than men, since they are twice as likely to be taking zolpidem and have blood concentrations that are 45%-50% higher. Nevertheless, approximately 68% of women are still taking the highest dose.

To access the research letter, visit JAMA's website at:

https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2687525?resultClick=1.

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.