

# Congress: Long-Term SGR Fix Unlikely This Year

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WASHINGTON — Physicians can look for another short-term update to the sustainable growth rate this year as lawmakers struggle under substantial fiscal constraints, members of Congress told physicians at the American Medical Association's national advocacy conference.

"What would be best for me, for everyone in this room and for the older Amer-

icans under the Medicare system is to do a permanent fix. What my gut is telling me is that, at best, we will do an 18-month fix," said Rep. Shelley Berkley (D-Nev.).

Congress passed a 6-month update to the Medicare physician payment rate late last year and has until July 1 to avert a 10.6% cut for the remainder of the year. However, under current federal spending rules, lawmakers will have to offset any increases to physician pay by cutting another program or raising taxes.

"If under the law, the physicians are set to receive a 10% cut, if we restore that 10%, we have to come up with the money somewhere. That's why the solutions generally tend to be short term," said Sen. Jon Kyl, (R-Ariz.), who serves on the Finance Committee.

For example, the proposed 18-month fix that would keep physician pay steady through 2008 and raise it 1% in 2009 would cost \$37.5 billion over 5 years. By comparison, a 6-month fix, like the one passed last

year, would cost \$8.4 billion, saving lawmakers nearly \$30 billion in offsets.

That's the easier solution, Sen. Kyl said. "It's not an ideal situation. However, our priority has been and must continue to be averting scheduled cuts and securing a positive update. So we are very short-term oriented." He added that, while there is currently enough wiggle room in the budget to pay for the 18-month approach, some lawmakers had other priorities for the money. ■

## Patients are not likely to feel sedated, become dependent, or feel "hungover"

- Rozerem is the only prescription insomnia medication that works with the body's sleep-wake cycle to promote sleep and has not been associated with sedation<sup>3-8</sup>
- Clinical studies have shown no evidence of potential abuse, dependence, or withdrawal<sup>†</sup>
- Across several studies, no clinically relevant next-day residual effects were seen with respect to memory (Word List Memory Test), psychomotor performance (DSST), mood and feelings (VAS), or alertness and concentration (Post-sleep Questionnaire) when Rozerem was compared to placebo<sup>‡10</sup>

\*Sustained efficacy has been shown over 5 weeks in clinical studies in adults and older patients.<sup>1,2</sup>

†Rozerem is not a controlled substance. A clinical abuse liability study showed no differences indicative of abuse potential between Rozerem and placebo at doses up to 20 times the recommended dose (N=14). Three 35-day insomnia studies showed no evidence of rebound insomnia or withdrawal symptoms with Rozerem compared to placebo (N=2082).<sup>3,9</sup>

‡Patients should be advised to avoid engaging in hazardous activities (such as operating a motor vehicle or heavy machinery) after taking Rozerem.<sup>3</sup>

Please visit [www.rozerem.com](http://www.rozerem.com)

Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. Rozerem can be prescribed for long-term use.

### Important Safety Information

Rozerem should not be used in patients with hypersensitivity to any components of the formulation, severe hepatic impairment, or in combination with fluvoxamine. Failure of insomnia to remit after a reasonable period of time should be medically evaluated, as this may be the result of an unrecognized underlying medical disorder. Hypnotics should be administered with caution to patients exhibiting signs and symptoms of depression. Rozerem has not been studied in patients with severe sleep apnea, severe COPD, or in children or adolescents. The effects in these populations are unknown. Avoid taking Rozerem with alcohol. Rozerem has been associated with decreased testosterone levels and increased prolactin levels. Health professionals should be mindful of any unexplained symptoms which could include cessation of menses or galactorrhea in females, decreased libido or problems with fertility that are possibly associated with such changes in these hormone levels. Rozerem should not be taken with or immediately after a high-fat meal. Rozerem should be taken within 30 minutes before going to bed and activities confined to preparing for bed. The most common adverse events seen with Rozerem that had at least a 2% incidence difference from placebo were somnolence, dizziness, and fatigue.

Please see adjacent Brief Summary of Prescribing Information.

**References:** 1. Zammit G, Erman M, Wang-Weigand S, Sainati S, Zhang J, Roth T. Evaluation of the efficacy and safety of ramelteon in subjects with chronic insomnia. *J Clin Sleep Med.* 2007;3:495-504. 2. Roth T, Seiden D, Sainati S, Wang-Weigand S, Zhang J, Zee P. Effects of ramelteon on patient-reported sleep latency in older adults with chronic insomnia. *Sleep Med.* 2006;7:312-318. 3. Rozerem package insert, Takeda Pharmaceuticals America, Inc. 4. Kato K, Hirai K, Nishiyama K, et al. Neurochemical properties of ramelteon (TAK-375), a selective MT<sub>1</sub>/MT<sub>2</sub> receptor agonist. *Neuropharmacology.* 2005;48:301-310. 5. Sieghart W, Sperk G. Subunit composition, distribution and function of GABA<sub>A</sub> receptor subtypes. *Curr Top Med Chem.* 2002;2:795-816. 6. Rudolph U, Crestani F, Benke D, et al. Benzodiazepine actions mediated by specific  $\gamma$ -aminobutyric acid<sub>A</sub> receptor subtypes. *Nature.* 1999;401:796-800. 7. Rowlett JK, Platt DM, Lelas S, Atack JR, Dawson GR. Different GABA<sub>A</sub> receptor subtypes mediate the anxiolytic, abuse-related, and motor effects of benzodiazepine-like drugs in primates. *Proc Natl Acad Sci U S A.* 2005;102(suppl 3):915-920. 8. Landolt HP, Gillin JC. GABA<sub>A</sub> receptors: involvement in sleep regulation and potential of selective agonists in the treatment of insomnia. *CNS Drugs.* 2000;13:185-199. 9. Johnson MW, Suess PE, Griffiths RR. Ramelteon: a novel hypnotic lacking abuse liability and sedative adverse effects. *Arch Gen Psychiatry.* 2006;63:1149-1157. 10. Data on file, Takeda Pharmaceuticals North America, Inc.

Visit [www.rxrozerem.com/safetyconcerns](http://www.rxrozerem.com/safetyconcerns) to learn how Rozerem may be appropriate for a variety of patients with insomnia who have difficulty falling asleep.

**Rozerem**<sup>™</sup>  
ramelteon 8-mg tablets

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