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## FDA: Sleeping pills can cause 'sleep-driving'

- FDA orders 13 sleep-disorder drugs to carry stronger warnings
- Drugs include the popular Ambien and Lunesta
- Risks include driving, eating and talking while asleep with no recollection later
- Ambien manufacturer: Fewer than one in 1,000 patients reported somnambulism

**WASHINGTON (AP)** -- All prescription sleeping pills may sometimes cause sleep-driving, federal health officials warned Wednesday, almost a year after the bizarre side effect first made headlines when Rep. Patrick Kennedy crashed his car after taking Ambien.

It's a more complicated version of sleepwalking, but behind the wheel: getting up in the middle of the night and going for a drive -- with no memory of doing so.

The Food and Drug Administration wouldn't say exactly how many cases of sleep-driving it had linked to insomnia drugs, but neurology chief Dr. Russell Katz said the agency uncovered more than a dozen reports -- and is worried that more are going uncounted.

Given the millions of prescriptions for insomnia drugs, Katz called the problem rare, and said he was unaware of any deaths. But because sleep-driving is so dangerous -- and there are precautions that patients can take -- the FDA ordered a series of strict new steps Wednesday.

First, the makers of 13 sleep drugs must put warnings on their labels about two rare but serious side effects:

- sleep-driving, along with other less dangerous "complex sleep-related behaviors" -- like making phone calls, fixing and eating food, and having sex while still asleep.
- and life-threatening allergic reactions, as well as severe facial swelling, both of which can occur either the first time the pills are taken or anytime thereafter.

Next, doctors this week will begin getting letters notifying them of the new warnings.

Later this year, all prescription sleeping pills will begin coming with special brochures called "Medication Guides" that spell out the risks for patients in easy-to-understand language.

Sleep-driving made headlines last May when Kennedy crashed his car into a security barrier outside the U.S. Capitol after taking Ambien and a second drug, Phenergan, which also acts as a sedative. He has said he had no memory of the event.

Ambien isn't the only insomnia drug that can cause sleep-driving -- any of the class known as "sedative-hypnotics" can, FDA's Katz stressed Wednesday.

To lower the risk of a sleep-driving episode, he advised patients to never take any prescription insomnia drug along with alcohol or another sedating drug, or take higher-than-recommended doses of the pills.

"We really want people to know these things can occur, and these sleep behaviors can be perhaps to a large extent mitigated by behaviors the patients can control," he said.

Some of the insomnia drugs may be riskier than others, so FDA also recommended that manufacturers conduct clinical trials to figure that out.


The drugs are: Ambien; Butisol sodium; Carbrital; Dalmane; Doral; Halcion; Lunesta; Placidyl; Prosom; Restoril; Rozerem; Seconal; Sonata.

Fewer than one in 1,000 patients in studies of Ambien reported somnambulism -- a scientific term that includes the sleep behaviors flagged by the FDA -- said Lisa Kennedy, a spokeswoman for manufacturer Sanofi-Aventis SA, who is not related to the congressman. The side effect has remained similarly rare since widespread sales began, she said.

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