

New class of insomnia drugs to hit market

BOSTON - Terri Bagley spent nearly two decades searching for a way to get a good night's sleep.

She toyed with keeping her bedroom pitch black and sniffing in the soothing smell of lavender. But neither those tricks nor over-the-counter and prescription medications made much of a difference.

Bagley, a 44-year-old operator of a small cleaning service in Pelham, N.C., is typical of the millions of Americans believed to suffer from chronic insomnia who until recently had mostly short-term solutions available. She found help in a clinical trial for Lunesta, one of a new generation of prescription sleep medications, and continued taking the drug after it hit the market in April.

"If you're tired for 20 years, you don't realize how much better you can feel until you start getting a full night's sleep again," she said.

New class of sleep medications

An emerging class of sleep aids is spurring an advertising effort that industry watchers say could rival the saturation campaign for erectile dysfunction drugs.

"I would expect this to become a very active category of drugs in consumer advertising," said Judy Franks, of Starcom Worldwide, a Chicago-based ad buying agency.

U.S. advertising for prescription and over-the-counter insomnia drugs totaled nearly \$68 million last year, according to TNS Media Intelligence, a media research firm. But spending in the first four months of this year alone was already \$48.7 million; at that rate, it could top \$146 million this year.

The total is still far less than the \$382 million spent last year to advertise erectile dysfunction drugs. But advertising industry officials expect spots encouraging insomniacs to talk to their doctor will become more frequent in coming months as more sleep aids hit the market.

“When a new competitor comes into the marketplace, it usually heightens spending on the part of all the competitors, because they need to defend their positions in the marketplace,” said Michael Guarini, managing director of the New York City-based Ogilvy Healthcare.

Long-term help for insomnia

Lunesta is so far the only prescription sleep aid approved by the Food and Drug Administration for long-term use, in contrast with more established short-term medications such as Ambien and Sonata. While most of the eight FDA-approved sleep aids tend to lose their effectiveness after a week or so of use, Lunesta has been shown in Sepracor-funded clinical studies to remain effective for up to six months.

Some of the emerging new insomnia medications are believed to enhance the action of so-called GABA receptors within the brain believed to promote sleep, while minimizing the side effects more common to older drugs.

The short-term indication labeling on older drugs put doctors “into a very difficult double-bind,” said Dr. John Winkelman, medical director of the Sleep Health Center at Brigham and Women’s Hospital in Boston. “Patients complaining of chronic nightly sleeplessness were being treated with medicines that were only for short-term use. Now that double-bind has been lifted.”

At least two other medications could win U.S. regulatory approval later this year or early next year: Pfizer Inc. and San Diego-based Neurocrine Biosciences Inc. are teaming up to

develop indiplon, a GABA-receptor drug which hasn't yet been given a brand name, and Japan-based Takeda Pharmaceuticals is developing Rozerem, a drug that interacts with the natural hormone melatonin.

Like the heavily marketed erectile dysfunction drugs, the new insomnia medications are aimed at people who have gone largely untreated and may be unaware of new treatment options.

An estimated 126 million adult Americans experience at least one insomnia symptom a few nights a week, according to the National Sleep Foundation, a group which receives some of its funding from drug companies. Only about a third of sufferers are actually diagnosed with insomnia, and a small fraction of those are treated with prescription medication.

Concerns about addiction

Drug makers are trying to overcome concerns about addiction that were related partly to older barbiturate sleep aids, as well as lingering drowsiness associated with over-the-counter antihistamines.

"A lot of doctors have been historically somewhat reticent to prescribe these drugs, so a patient-driven marketing approach makes sense," said analyst David Steinberg of Deutsche Bank North America.

Sepracor Inc., the Marlborough, Mass.-based manufacturer of Lunesta, has nearly tripled the size of its sales staff to 1,250 and is spending \$60 million this year on ads for the drug.

Lunesta averaged about 60,000 new prescriptions per week after its launch, and Sepracor reported on Tuesday that the drug posted \$83.5 million in second-quarter sales. Because of the quick sales pickup, the company increased its forecast of Lunesta sales for the full year from \$160 million to \$220

million. Several analysts forecast Lunesta sales will eventually reach \$1 billion a year.

The new drugs are gunning to topple Sanofi-Aventis's Ambien, which accounts for about \$1.9 billion of a \$2.1 billion U.S. prescription sleep aid market. Sepracor Chief Financial Officer David Southwell said he expects the market to eventually grow to \$5.5 billion because of the new drugs and large number of insomniacs who go untreated.

Sanofi-Aventis's patent for the current version of Ambien is set to expire in October 2006, and the company is rolling out a new version called Ambien CR. That formulation is expected to win approval soon, leading to ads touting its ability to keep patients asleep longer than the original formulation.

The predicted marketing wars are raising alarms among critics who say ads touting medications for common problems — from heartburn to shyness — too often unnecessarily steer patients to prescription drugs.

"We've already started to see an enormous marketing push for these drugs, with insomnia now labeled the latest 'epidemic' threatening the health of America," said Dr. Jerry Avorn, a Harvard Medical School professor and author of the book "Powerful Medicines."

Avorn says many insomnia patients could find restful sleep by simply avoiding stimulants like caffeine and nicotine or getting enough exercise.

"There's no money to be made advertising those simple lifestyle solutions, but there are billions to be made getting patients onto lifelong use of expensive medications," Avorn said.