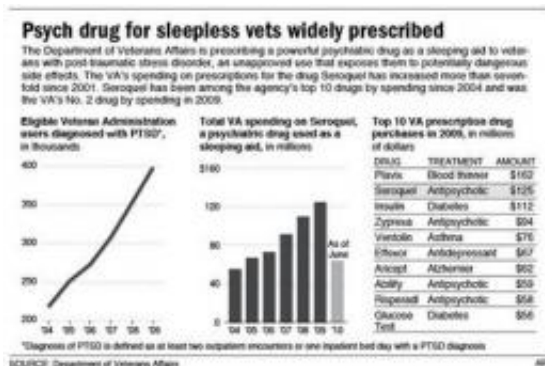


# Questions loom over drug given to sleepless vets

August 30 2010, By MATTHEW PERRONE , AP Health Writer



Graphic shows the prevalence of PTSD in veterans and spending on the drug

(AP) -- Andrew White returned from a nine-month tour in Iraq beset with signs of post-traumatic stress disorder: insomnia, nightmares, constant restlessness. Doctors tried to ease his symptoms using three psychiatric drugs, including a potent anti-psychotic called Seroquel.

Thousands of soldiers suffering from PTSD have received the same medication over the last nine years, helping to make Seroquel one of the Veteran Affairs Department's top drug expenditures and the No. 5 best-selling drug in the nation.

Several soldiers and veterans have died while taking the pills, raising concerns among some military families that the government is not being up front about the drug's risks. They want Congress to investigate.

In White's case, the nightmares persisted. So doctors recommended progressively larger doses of Seroquel. At one point, the 23-year-old Marine corporal was prescribed more than 1,600 milligrams per day - more than double the maximum dose recommended for [schizophrenia](#) patients.

A short time later, White died in his sleep.

"He was told if he had trouble sleeping he could take another (Seroquel) pill," said his father, Stan White, a retired high school principal.

An investigation by the Veterans Affairs Department concluded that White died from a rare [drug interaction](#). He was also taking an antidepressant and an anti-anxiety pill, as well as a painkiller for which he did not have a prescription. Inspectors concluded he received the "standard of care" for his condition.

It's unclear how many soldiers have died while taking Seroquel, or if the drug definitely contributed to the deaths. White has confirmed at least a half-dozen deaths among soldiers on Seroquel, and he believes there may be many others.

Spending for Seroquel by the government's military medical systems has increased more than sevenfold since the start of the war in Afghanistan in 2001, according to documents obtained by The Associated Press under the Freedom of Information Act. That by far outpaces the growth in personnel who have gone through the system in that time.

Seroquel is approved to treat schizophrenia, bipolar disorder and depression, but it has not been endorsed by the Food and Drug Administration as a treatment for insomnia. However, psychiatrists are permitted to prescribe approved drugs for other uses in a common practice known as "off-label" prescribing.

But the drug's potential side effects, including diabetes, weight gain and uncontrollable muscle spasms, have resulted in thousands of lawsuits. While on Seroquel, White gained 40 pounds and experienced slurred speech, disorientation and tremors - all known side effects.

Last year, researchers at Vanderbilt University published a study suggesting a new risk: sudden heart failure.

The study in the January 2009 edition of the New England Journal of Medicine found that there were three cardiac deaths per year for every 1,000 patients taking anti-psychotic drugs like Seroquel. Seroquel's unique sedative effect sets it apart from others in its class as the top choice for treating insomnia and anxiety.

AstraZeneca PLC, maker of the drug, said it is reviewing the study. The FDA is conducting its own review, citing the limited scope of the Vanderbilt study.

According to the Veterans Affairs Department, Seroquel is only prescribed as a third or fourth option for patients with difficult-to-treat insomnia stemming from PTSD.

Marine Cpl. Chad Oligschlaeger, 21, was being treated for PTSD when he died in his sleep at Camp Pendleton, Calif., in May 2008. Oligschlaeger was taking six types of medication, including Seroquel, to deal with anxiety and nightmares that followed two tours of duty in Iraq.

The military medical examiner attributed the death to "multiple drug toxicity," indicating that Oligschlaeger, too, died from a drug interaction. Because of the complex reactions between various drugs, medical examiners do not attribute such deaths to any one medication.

After consulting with physicians, parents Eric and Julie Oligschlaeger

now believe their son died of sudden cardiac arrest caused by Seroquel.

"Right now, I'm so angry, and I believe someone needs to be held accountable," said Julie Oligschlaeger, of Austin, Texas. "The protocol absolutely has to change."

The Defense Department's deputy director for force health protection, Dr. Michael Kilpatrick, said the government has not seen any increase in dangerous side effects from Seroquel and other drugs.

Physicians interviewed by the AP said they began prescribing Seroquel because it was the only drug that offered relief from the nightmares and anxiety of PTSD.

"By accident, some people were giving them Seroquel for anxiety or depression, and the veterans said, 'This is the first time I have slept six or seven hours straight all night. Please give me more of that.' And the word spread," said Dr. Henry Nasrallah of the University of Cincinnati, who has treated PTSD patients for more than 25 years.

Most of the soldiers and veterans seeking treatment for PTSD do so at hospitals run by the VA or the Defense Department.

The VA's spending on Seroquel has increased more than 770 percent since 2001. In that same time frame, the number of patients covered by the VA increased just 34 percent.

Seroquel has been the VA's second-biggest prescription drug expenditure since 2007, behind the blood-thinner Plavix. The agency spent \$125.4 million last fiscal year on Seroquel, up from \$14.4 million in 2001.

Spending on Seroquel by the Department of Defense, has increased nearly 700 percent since 2001, to \$8.6 million last year, according to

purchase records.

Nasrallah and others said they use drugs like Seroquel off-label because so few treatments are approved for PTSD. The FDA has only cleared two drugs for the condition, the antidepressants Paxil and Zoloft, and they do not always work.

The only published study on use of Seroquel for PTSD-related insomnia involved just 20 patients who were followed for six weeks at a VA medical center in South Carolina. The study, which showed moderate improvement in sleep, was funded by AstraZeneca at the request of VA psychiatrist Dr. Mark Hamner, who has studied the use of Seroquel for PTSD.

In his written conclusion, published in 2003, Hamner urged caution in interpreting the results because of the study's small size and short duration.

Hamner is working on larger, federally funded studies of Seroquel. For now, he acknowledges, there is little published research on the use of the drug for PTSD.

"Clinical judgment is really the best we can use at this time because there isn't really a good database to facilitate decision-making," said Hamner, who works at the Ralph H. Johnson Medical Center in Charleston, S.C.

He stressed that VA guidelines require doctors to monitor patients for dangerous side effects with drugs like Seroquel.

The drug, approved in 1997, is AstraZeneca's second-best-selling product, with U.S. sales of \$4.2 billion last year. But that success has been marred by allegations that the company illegally marketed the drug

and minimized its risks. AstraZeneca agreed to pay \$520 million in April to settle federal allegations that its salespeople pitched Seroquel for numerous off-label uses, including insomnia.

Pharmaceutical companies are prohibited from marketing drugs for unapproved uses. AstraZeneca also faces an estimated 10,000 product liability lawsuits, most alleging that Seroquel caused diabetes.

Since White died, his family has been searching for an explanation - and for a way to prevent other deaths.

"We trusted the knowledge of the physicians, that they weren't going to do any harm," White's father said. "And we also trusted the drug companies because that's who provides the research for the physicians. That's what our battle is now: trying to get changes made."

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