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## Military continues off-label drug use, despite concerns

By [Bob Brewin](#) 09/28/11

The U.S Central Command continues to back the use of Seroquel, a powerful antipsychotic, to treat insomnia in [troops deployed to combat zones](#) despite an expert panel's recommendation six months ago to cease the practice. The drug, known generically as quetiapine, has been linked to adverse effects, including heart failure.

In May, the Defense Pharmacy and Therapeutics Committee at its semiannual meeting said that the Food and Drug Administration had not approved any drugs in the class known as atypical antipsychotics, which includes Seroquel, for treatment of insomnia. Nonetheless, CENTCOM has approved the use of Seroquel in low, 25-milligram doses to treat sleep disorders.

In minutes of that meeting signed Aug. 5 by Dr. Jonathan Woodson, assistant secretary of Defense for Health Affairs, and [posted](#) to its website the same day, the committee said, "the use of low-dose AAPs [atypical antipsychotics] should be discouraged due to the lack of supportive evidence, risk of adverse events (metabolic and cardiac) and lack of monitoring (e.g. EKG) for adverse events in theater."

The Defense Health Board, a federal advisory group chartered to provide independent advice to the secretary of Defense, recommended in a [draft report](#) last month that Defense review its current guidance on the off-label or non-FDA-approved use of drugs, including Seroquel.

The pharmacy committee urged CENTCOM to use less dangerous drugs to treat insomnia. It said, "Other drug options to treat insomnia are available on the CENTCOM formulary, which have a lower risk of adverse events than the AAPs." Researchers at Vanderbilt University and the Nashville Veterans Affairs Medical Center [reported](#) in a January 2009 *New England Journal of Medicine* article that patients prescribed atypical antipsychotics, including Seroquel, had a significantly higher risk of sudden death from cardiac arrhythmias and other cardiac causes than patients who did not take these medications.

### Cost Issues

Besides treatment questions, the Military Health System also faces financial questions regarding its increasing reliance on atypical antipsychotics, the pharmacy committee reported. "The AAP drug class is a significant cost within MHS; expenditures exceed \$200 million annually . . . quetiapine is the most utilized AAP, followed by the generic risperidone," the committee said. From 2001 through June of this year, the Veterans Affairs Department told *Nextgov* it spent more than \$600 million on Seroquel.

Sleep medications, the Defense Health Board said in its draft report, are the predominant psychotropic drugs used in CENTCOM, although the board previously [acknowledged](#) Defense lacks a unified pharmacy database to track prescription drug use.

This lack of data is compounded when it comes to off-label drug use, the board said in its draft report. The Military Health System's [Theater Data Medical Store](#), a "central location for all medical data generated" in the CENTCOM theater of operations, does not include data on medications prescribed for off-label use, the board said.

Despite the recommendations from the Pharmacy Committee, CENTCOM plans to continue prescribing Seroquel to treat insomnia. Army Maj. T.G. Taylor, a CENTCOM spokesman, told *Nextgov* in an email that the command has "no plan at this time to remove 25-milligram Seroquel from the theater formulary. Seroquel at this dose can still be safely and effectively used as a sleep aid, and is particularly useful for patients with insomnia who do not respond to conventional sleep aids."

Taylor added, "Providers should fully evaluate patients with sleep disorders for other, concurrent issues and the potential for any side effects, and reserve Seroquel for those patients who cannot tolerate, or who aren't helped with other medications for insomnia."

An Army doctor who declined to be identified for publication, said he found it "quite remarkable that despite clear opposition to the continued use of the antipsychotics by [Office of the Assistant Secretary of Defense for] Health Affairs, and the [Pharmacy and Therapeutics] Committee, CENTCOM and the services continued to defend their use, all the while without anything but weak anecdotal evidence of efficacy."

Dr. Peter Breggin, an Ithaca, N.Y., psychiatrist who has studied psychotropic drugs extensively, said Seroquel is not a sedative and could dim mental acuity needed to deal with combat. "It induces sleep by blunting the emotions and reducing frontal lobe activity. Soldiers taking Seroquel will not be able to recognize that their higher mental functions and judgment have been impaired," Breggin said.

In addition to cardiac problems, Seroquel has been linked to diabetes, acute pancreatitis, elevated cholesterol levels and obesity, he said. "It is irresponsible to give 180-day supplies of any psychoactive substances to young men and women under extreme stress and with little or no supervision," Breggin said, citing the quantities of drugs deployed troops may receive.

Stan White, a retired high school teacher in Cross Lanes, W.Va., who has led a campaign against the military's use of Seroquel, hailed the decision by the pharmacy committee to discourage the use of Seroquel.

But he questioned CENTCOM's continued endorsement of the drug in low doses to treat insomnia. VA started treating his son Andrew, who served with the Marines in Iraq, with 25 milligrams of Seroquel in the summer of 2007. Doctors had increased the dosage to 1,600 milligrams a day by February 2008, when Andrew died in his sleep. White said, "My concern is that every case [of an adverse reaction] that I know of, the patient starts with a low dosage but the dosage will increase because the symptoms do not go away."