

Controversial Drug Receives Military Restrictions and FDA Warnings as Its Patent Expires

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By [Martha Rosenberg, Truthout / News Analysis](#)

There is good news and bad news about the popular antipsychotic Seroquel. The good news is, after years of pleas from military families, the US Central Command removed the powerful drug from its approved formulary list in March. Doctors now need a waiver to write a prescription for Seroquel in combat zones, reported [Military Times](#), and the Army, The Navy Department and the Air Force are tightening use. The military blew millions of dollars only to discover that antipsychotics are [not effective against post-traumatic stress disorder](#) (PTSD).

The bad news is [Seroquel's patent has just run out](#), so AstraZeneca got its money's worth anyway, before new regulations set in.

In fact, the Department of Veterans Affairs (VA) spent \$125.4 million and the Pentagon \$8.6 million on Seroquel in 2009. By way of comparison, the [cost of a F/A-18 Hornet](#) is \$94 million.

Last summer, after reports of arrhythmia (irregular heart beat) in 17 people who took more than the recommended doses of Seroquel, the Food and Drug Administration (FDA) warned that Seroquel and Seroquel XR "should be avoided" in combination with at least 12 other medications because of heart risks, reported [The New York Times](#). The drugs included synthetic opioids like methadone; other antipsychotics, including Geodon and Thorazine; some antibiotics; anti-infectives; and heart rhythm drugs. Seroquel should not be used at all by the elderly or by people with heart disease, warned the FDA, said the Times.

Two years earlier, the FDA approved Seroquel for the new use of depression, despite testimony at the [advisory committee hearing](#) by Vanderbilt University's Wayne Ray Ph.D. that patients on drugs like Seroquel showed double the risk of a "sudden, fatal, pulseless condition, or collapse." Ray had just published an article in the New England Journal of Medicine called "[Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death](#)."

In the two years in which the FDA changed its mind about the heart risks, Seroquel manufacturer AstraZeneca made from [\\$2 billion](#) to [\\$7 billion](#) on the pill.

Seroquel is not the only over-hyped, expensive antipsychotic that turned out not to be the wonder drug it was billed to be. Risperdal, Abilify, Zyprexa and Geodan have also been aggressively marketed despite studies that suggest the drug class [works no better](#) than older drugs for specific conditions. The VA spent \$717 million on Risperdal to treat PTSD in troops in Afghanistan and Iraq over nine years, only to discover it worked no better than a placebo, said a [Journal of the American Medical Association study](#) last year. Less than two weeks after the damning study, the VA awarded a contract for two million generic Risperdal pills, [reported Nextgov](#). Why let science get in the way of established prescribing habits?

Still, Seroquel has a [corruption trail](#) that few other pills can match:

An original backer, psychiatrist Richard Borison, was sentenced to a 15-year prison sentence in 1998 for a pay-to-play Seroquel research scheme involving veterans.

Seroquel's US Medical Director Wayne MacFadden had sexual affairs with two different women involved with Seroquel research, said published reports.

A continuing medical education course that promoted Seroquel "taught" by AstraZeneca staff and psychiatrist [Charles Nemeroff](#) (who left Emory University in disgrace after a [Congressional investigation](#) for unreported Pharma income) was scrapped by the Accreditation Council for Continuing Medical Education for [lacking "sufficient information"](#) about adverse effects and alternative treatments.

Chicago psychiatrist Michael Reinstein prescribed Seroquel for over 1,000 Chicago-area Medicaid patients per year, while subsidized by AstraZeneca, at a total cost of \$7.6 million to taxpayers, said The Chicago Tribune and [ProPublica](#).

Florida child psychiatrist Jorge Armenteros was chairman of the FDA committee responsible for recommending Seroquel approvals while a paid AstraZeneca speaker himself, said the [Philadelphia Inquirer](#) in 2009. University of Minnesota psychiatry chief and AstraZeneca consultant Charles Schulz termed Seroquel "significantly superior" to older antipsychotics at an American Psychiatric Association meeting though data revealed it was actually inferior, charged [City News](#).

Many safe drug and military activists are happy to see Seroquel's new restricted status hoping the services follow suit. The US Central Command still stocks Seroquel for special uses and emergencies on a case-by-case approval, but prescriptions now requires the explicit permission of the Command's surgeon.

But like other controversial drugs like Fosamax, Zyprexa, Lipitor and Singulair, warnings and restrictions have come soon before and even after patent expiration. Fosamax is linked to throat, [jaw and heart abnormalities](#); [Zyprexa](#) to diabetic problems; the asthma drug [Singulair](#) to suicidal thinking; and [statins](#) like Lipitor to memory loss and high blood sugar.

Nor is it clear that new Seroquel warnings and precautions concerns are even affecting sales. Despite last year's FDA heart warnings, the military services issued 54,581 prescriptions for Seroquel last year, [reported Military Times](#).

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