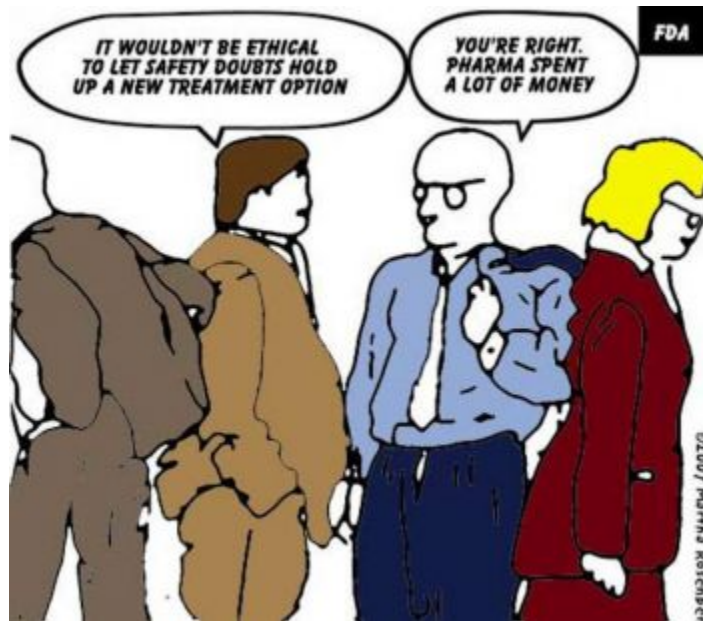


Despite Scandals and Troop Deaths, Seroquel Now Marketed for Depression

By Martha Rosenberg

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(Martha Rosenberg)

Even though AstraZeneca's antipsychotic [Seroquel](#) is the fifth best-selling medication in the United States according to drugs.com, exceeded only by Lipitor, [Nexium](#), Plavix, and [Advair Diskus](#), its safety, effectiveness, clinical trials, and promotion records are highly checked.

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

Its U.S. medical director Wayne MacFadden had

sexual affairs with two different women involved with Seroquel research, say published reports.

Chicago psychiatrist Dr. Michael Reinstein received \$500,000 from AstraZeneca and wrote 41,000 prescriptions for Seroquel, reports the Chicago Tribune and ProPublica.

Psychiatrist Dr. Charles Nemeroff, who left Emory University in disgrace after a congressional investigation for unreported pharma income, promoted Seroquel in continuing medical-education courses, according to the [website](#) of psychiatrist Dr. Daniel Carlat.

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Florida child psychiatrist Dr. 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.

- [Are Prescription Drugs Behind Troop Suicides?](#)
- [Truth of Psychiatry Revealed](#)

Psychiatrist Dr. Charles Schulz's high-profile, pro-Seroquel presentations are suspected of being colored by his AstraZeneca income, says the Minneapolis Star Tribune.

Unexplained Iraq and Afghanistan troop deaths are linked to Seroquel, reported the Associated Press in August.

Originally approved for schizophrenia in 1997, Seroquel has subsequently been approved for bipolar disorder, for some groups of kids, and for depression as an add-on drug. This "indications creep" has mostly flown below the public's radar. Seroquel expansion to treat children in late 2009, for example, was noted as a mere "label change" on the FDA website.

Now, as AstraZeneca rolls out its "Still Trying to Get Ahead of Your Depression" campaign, there are new questions about Seroquel's safety and effectiveness.

According to an FDA warning letter, an AstraZeneca [sales representative](#) during an unsolicited sales call on Jan. 3, 2008, sold Seroquel as a treatment for major depressive disorder (MDD) to a physician before it was approved for MDD, which is illegal.

Once Seroquel was approved for depression (as an add-on treatment to an antidepressant for patients with MDD who do not have an adequate response to antidepressant therapy), its leave-behind sheets drew another FDA warning letter.

AstraZeneca implied patients would achieve "remission" from depression with Seroquel XR (extended release) as opposed to an antidepressant alone, says FDA—a claim not backed up by clinical experience.

FDA further said that Seroquel's effect on depression has only been demonstrated in two, six-week trials, and six weeks is "not a long enough time period to adequately assess remission." (It was approved—why?)

Also the case study of "Catherine F." depicted in leave-behind sheets is inaccurate, says FDA, because it suggests Seroquel alleviates "symptoms of sadness and loss of interest when this has not been demonstrated by substantial evidence or substantial clinical experience." (Again, it was approved—why?)

Even AstraZeneca's own briefing to the FDA committee in 2009 admits a "failed study" in which both Seroquel and Lexapro "failed to differentiate from placebo," which is clinical trial language for "didn't work."

Nor did AstraZeneca adequately disclose Seroquel risks, says FDA, which include increased mortality in elderly patients with dementia-related psychosis, suicidal tendency, neuroleptic malignant syndrome, hyperglycemia, diabetes mellitus, hyperlipidemia, weight gain, and other serious [side effects](#).

In fact, in addition to risks like cataracts, seizures, and increases in blood pressure in children and adolescents, already on the Seroquel label, FDA asked AstraZeneca to add the "risk of EPS [extrapyramidal symptoms] and withdrawal syndrome in neonates" a few months ago. EPS are movement disorders that can affect mothers' babies if the mothers are taking Seroquel and stop.

Even without its depression indication, Seroquel is big business for AstraZeneca, earning \$4.9 billion in sales in 2009. It is the drug that North Carolina's Medicaid spends the most on: \$29.4 million per year, reports the Charlotte News and Observer.

But adding the new indication to a drug whose dangers and effectiveness have already been so misrepresented and occluded is just, well, depressing.

Martha Rosenberg is a journalist who lives in Chicago.