States Taking Pharma to Court for Risky Antipsychotic-Prescribing Spree

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Some state legislators are mad as hell and not going to take it anymore.

They've seen state outlays for controversial antipsychotics like Zyprexa grow as much as twelvefold since 2000, with a corresponding growth in side effects like weight gain, blood sugar changes and cholesterol problems.

In March, Alaska won a $15 million settlement from Eli Lilly in a suit to recoup medical costs generated by Medicaid patients who developed diabetes while taking Zyprexa.

Last year Bristol-Myers Squibb settled a federal suit for $515 million charging that it illegally hawked the antipsychotic Abilify to children and the elderly, bilking taxpayers.

Now Idaho, Washington, Montana, Connecticut, California, Louisiana, Mississippi, New Mexico, New Hampshire, Pennsylvania, South Carolina, Utah, West Virginia, Arkansas and Texas are taking pharma to court over its antipsychotic *prescrib-athon* that has left the poor and mentally ill in even worse health and legions of children and elderly in chemical straightjackets for treatment of conditions they didn't even have.

The atypical antipsychotics Zyprexa, Risperdal, Seroquel, Abilify and Geodon can be thought of as the credit swaps of the pharmaceutical world.

New with no track record, risky, barely understood and capable of making a lot of money before their long-term effects are apparent, atypical antipsychotics, like credit swaps, could only be sold with friends in high regulatory places and the help of the U.S. taxpayer.

Though atypical antipsychotics were developed to treat schizophrenia and later approved for bipolar disorder (Risperdal is also approved for autism-related irritability in children), pharma lost no time in marketing them for *non-FDA-approved uses* like ADHD and conduct disorders, dementia, sleep disorders, depression and simple mood swings, netting $8,000 a year per person, usually from state coffers.

When the second-generation atypical antipsychotics debuted in the 1990s, they seemed to lack the "typical" side effects of first-generation antipsychotics like Thorazine and Haldol, such as the movement disorder tardive dyskinesia. But soon

further "clinical testing," known as selling it to the public while the patent is hot, revealed that atypicals cause the same side effects as first-generation antipsychotics and more: increased mortality in elderly patients, suicide risk, hyperglycemia, diabetes mellitus and the hematological disorders leukopenia, neutropenia and agranulocytosis.

In fact, Seroquel and Abilify have not one black box warning but two.

Nor do the atypical antipsychotics work better than predecessors.

A National Institute of Mental Health study of 119 children ages 8 to 19 with psychotic symptoms published in September found Risperdal and Zyprexa were no more effective than the older antipsychotic Moban -- but caused such obesity that a safety panel ordered the children off the drugs.

In just eight weeks, children on Risperdal gained 9 pounds while those on Zyprexa gained 13; children on Moban gained less than a pound.

"Kids at school were making fun of me," study participant Brandon Constantineau, 18, of Wilmington, N.C., told the *New York Times*. Constantineau put on 35 pounds on Risperdal.

Other studies -- like one on Risperdal in the Jan. 4, 2008, issue of *Lancet* and one on Zyprexa, Seroquel and Risperdal in Alzheimer's patients in the Oct. 12, 2006, issue of the *New England Journal of Medicine* -- find that atypicals work no better than a placebo.

But it gets worse.

A study of Seroquel in the Feb. 19, 2005, issue of the *British Medical Journal* found the drug ineffective in relieving agitation in Alzheimer's patients -- a non-FDA-approved use that JP Morgan analysts say constitutes 29 percent of all Seroquel sales (hello? regulators?) -- but "was associated with significantly greater cognitive decline" than a placebo. Oops.

Whatever happened to first no harm?

But it was Eli Lilly's own discovery of elevated stroke and death numbers in five of its Zyprexa clinical trials and subsequent letter to doctors in 2004 that led the FDA to impose a black-box warning of "increased mortality in elderly patients with dementia" on atypical antipsychotics in 2005 after reviewing 17 clinical studies with four different drugs.

"The problem with these drugs are that we know that they are being used extensively off-label in nursing homes to sedate elderly patients with dementia and other types of disorders," testified FDA safety expert Dr. David "Vioxx" Graham last year at a congressional hearing. "But the fact is, is that it increases mortality perhaps by 100 percent. It doubles mortality. So I did a back-of-the-envelope calculation on this, and you have probably got 15,000 elderly people in nursing homes dying each year from the off-label use of antipsychotic medications. ... With

every pill that gets dispensed in a nursing home, the drug company is laughing all the way to the bank."

No kidding.

A third of the nation's estimated 2.5 million nursing home patients have taken atypical antipsychotics, estimates the *New York Times,* and the overall atypical antipsychotic tab for Medicare and Medicaid -- including children -- in the United States is $2 billion a year.

In 12 states, the pharmaceutical industry has actually written the guidelines that specify atypicals for schizophrenia and discourage older drugs. And two dozen states have hired the Lilly-backed Comprehensive Neuroscience to show them how to, not a joke, lower their drug costs.

That sounds like Wall Street too.

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