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Drug Company to Pay Half a Billion Dollar Fine for ILLEGAL Marketing

Posted by Dr. Mercola | May 20 2010 | 23,431 views

Drugmaker AstraZeneca has agreed to pay \$520 million to settle federal investigations into marketing practices for its schizophrenia drug Seroquel. This makes AstraZeneca the fourth big drug company in the last three years to admit to federal charges of illegal marketing of antipsychotic drugs.

The company was accused of misleading doctors and patients by spotlighting favorable research while failing to adequately disclose studies showing that Seroquel increases the risk of diabetes.

The *New York Times* reports that:

“AstraZeneca still faces more than 25,000 civil lawsuits filed on behalf of patients contending that the company did not disclose the drug’s risks. “

Dr. Mercola's Comments:

The illegal and unsafe actions of drug companies make headlines yet again as AstraZeneca agrees to pay a \$502 million fine to settle the federal charges of using illegal marketing tactics to drive up sales of its blockbuster drug Seroquel.

Although this sounds like a lot of money, it’s little more than a symbolic slap on the wrist when you consider how much money they’ve made from the drug already. According to the *New York Times*, the antipsychotic drug Seroquel pulled in \$4.9 BILLION in sales last year!

You see from the company’s perspective it’s merely another cost of doing business. For every dollar they are fined they are making ten. While not all of their profit was due to their illegal marketing practices, the fine was only a one-time fine, while revenues have poured in over many years and will continue to do so in the future, as a result of these illegal activities.

How Did Potent Antipsychotics Become the Top Selling Drug Category in US?

Amazingly, and something that not even I had realized until this article was being written, is that this class of antipsychotics has now surpassed cholesterol-lowering drugs as the top-selling category of drugs in the US!

This fact, in and of itself, should be a red flag that something has gone seriously awry, because no nation could possibly have that many psychotic residents.

And that’s just it... We don’t.

Using illegal marketing tactics to promote the use of Seroquel and other drugs like it has greatly expanded the sale of these types of drugs for far less serious, and at times completely unrelated, ailments.

Making matters even worse, they’ve also been heavily promoted for seniors and children – groups in which this drug can be far more dangerous.

Seroquel has been found to cause rapid weight gain and diabetes, for example. And seniors with dementia are at a higher risk of death when taking this drug. These are just a couple of reasons why Seroquel has been unable to gain FDA approval for certain uses. And yet, AstraZeneca, like so many other drug companies, chose to put profits before safety and health once again.

Puny Fines after Making Massive Illegal Profits Seem to Be the Norm

Just last month I discussed [the case of Pfizer](#), the world's largest pharmaceutical company, that was "punished" with a [fine that amounted to three month's worth of profit](#) for the illegal marketing of the painkiller Bextra.

In 2005, when Bextra was pulled from the market due to its [increased risks of heart attack and stroke](#), about half of its \$1.7 billion in profits that year were due to unapproved off-label uses.

There's no doubt that Seroquel's blockbuster status and massive sales are in large part due to dangerous off-label uses as well.

Seroquel was approved by the FDA in September 1997 for "the treatment of manifestations of psychotic disorders."

Three years, later, the FDA actually considered **NARROWING** its approval to the short term treatment of schizophrenia only. However, by January, 2004, the drug was approved for the short term treatment of acute manic episodes associated with bipolar disorder (bipolar mania), and two years later, they also approved it for bipolar depression.

Schizophrenia and bipolar disorder are serious mental disorders that in many cases may warrant drug treatment, at least short term. However, AstraZeneca also pushed Seroquel for things like anger management, ADHD, Alzheimer's disease, and even difficulty sleeping!

No federal criminal charges have been filed against the company, but I wonder if that wouldn't be justified. After all, they're promoting a potent drug for diseases that they were never formally studied or approved for. Without this important proof of safety and effectiveness, they have put countless human lives at risk for serious side effects, including premature death.

How is this NOT a crime?

But wait, of course no criminal charges will be filed because, just like Wall Street bankers, these [companies are "too big to fail"](#). What a load of horse manure, pardon my language. Nevertheless, that is what happens when your profits are so large you can afford to lobby and payoff the right people in government, to effectively insulate you from any prosecution.

Yes these companies are VERY clever.

Off-Label Use of Drugs Increase Your Risk of Harmful Side Effects

While doctors can legally prescribe FDA-approved medications off-label for any use, drugmakers are not allowed to market them for anything other than approved uses.

Many physicians, however, for all intents and purposes rely nearly exclusively on drug reps to educate them about the indications for drugs and what other leading physicians are using them for, and drug companies are not shy about suggesting off-label uses.

As demonstrated by this recent rash of lawsuits, drugmakers actually go several steps further, by fraudulently manipulating doctors into prescribing their drugs for ailments that they could not gain approval for in the first place.

Complicating matters further is the fact that it can be difficult for physicians to determine what certain medications are approved for, based on the Summary of Product Characteristics (SPC) -- the information given to physicians about drugs.

In fact, [according to a 2009 study](#), it was impossible for physicians to determine the licensing status for about 20 percent of drugs ... which means it's even more likely they'll rely on drug reps' opinions and suggestions.

Off-label drug use is actually *extremely common*, for drugs of all kinds.

According to [studies conducted in Britain](#), when a "suitable alternative" did not exist, doctors used unlicensed or "off label" medicine in:

- 90 percent of babies in neonatal intensive care units
- 70 percent of children in pediatric intensive care units
- Two-thirds of children on general medical and surgical pediatric wards in the UK
-

According to two of the studies, children taking these medicines face a higher risk of side effects, with one estimate suggesting they suffer up to **three times more side effects** as a result.

This is why it's so important that drug companies refrain from these illegal marketing tactics, because doctors misled by their pharmaceutical reps are literally putting their patients' lives at risk!

As [Michael L. Levy, U.S. Attorney for the Eastern District of Pennsylvania stated](#):

"People have a legal right to know that pharmaceutical companies are marketing their drugs only for uses approved by the FDA and that their doctors' judgment has not been affected by misinformation from a pharmaceutical company trying to boost revenues."

In the end that's all it is... Promoting drugs for off-label uses has nothing to do with trying to help more people. It's all about making more money off a drug that has a limited market.

The Dangerous Side Effects of Seroquel

It's hard to believe that anyone would agree to take such a potent antipsychotic unless they were suffering from a serious mental illness, but the numbers prove that plenty of people do.

This choice can be a devastating one. (And remember, it IS a choice. Your doctor cannot force you to take any drug, and in many cases, people see an ad on TV and voluntarily ask for the drug.)

The potential [side effects of taking Seroquel](#) are numerous, and some of them can be fatal.

For example, elderly patients who have lost touch with reality as a result of dementia are at an increased risk of death, which is why Seroquel is not approved for this use.

Seroquel can also increase your risk of suicidal thoughts and actions, especially in children, teens and young adults.

It's worth noting that the list of serious side effects is far longer – and these reactions are FAR MORE COMMON – than the list of the non-life threatening adverse reactions.

For example, some of the most [common side effects of Seroquel](#) include:

- High triglycerides in 23 percent of patients
- Weight gain in 23 percent of patients
- Agitation in 20 percent of patients
- High cholesterol in 17 percent of patients

Meanwhile, mild side effects like nausea, congestion and stomach pain are far less common, occurring in only two to ten percent of patients.

Be One Less Victim

Fortunately, you can avoid becoming the next victim by taking control of your health. This means educating yourself about your condition, any symptoms you may have, the drugs your doctor recommends, and other alternatives.

I can't stress this enough: You are **NOT REQUIRED** to take a drug recommended by your doctor.

You **ARE** allowed to demand detailed answers to any questions you have about the drug prescribed to you, and if you decide that the risks are greater than the potential benefit, you can "just say no," and seek out alternatives.

Remember, this is your life, and your health, so take an active role in it!. If your doctor pressures you to take it, remember that there are other doctors out there and it is probably best to find someone else who will actually **LISTEN** to you.

[Leading a healthy lifestyle](#) and staying educated about drug-free and non-invasive treatment options are the keys to your long-term well-being.

It's unfortunate, but many are still completely unaware of the pervasive corruption that exists within the field of pharmaceuticals. You need to understand that any corporation's primary and essential responsibility is to their shareholders -- **NOT** to you.

Drug companies have accumulated so much wealth, power and political influence that they're able to escape any serious consequences linking them to profiting from permanently disabling, crippling or even killing consumers. This is why it's so imperative you make your own informed decisions rather than blindly trusting the system.

Physicians must also, en masse, come to the realization that drug reps cannot be trusted. This may be one of the most difficult areas to change, as the pharmaceutical industry has devised a highly effective system of [indoctrination and very specific psychological techniques to manipulate physicians](#).

Doctors usually believe they are immune to persuasion tactics, and drug reps know just how important it is to maintain that illusion -- which is why it works so well. However, the idea that reps provide a valuable, informative service to physicians is total fiction, created and perpetuated by the drug industry, to keep this [deadly, but profitable, scheme going](#).

Until real change takes place, I urge you to not risk your money or your life on a paradigm designed to profit from your ill health.

Instead, take control by adopting [natural lifestyle strategies](#) that will promote your body's natural healing abilities without the need for the drug companies' latest creations.