

## Reliable Answers - News and Commentary

### Psychiatric Drugs:

#### An Assault on the Human Condition

##### *Street Spirit* Interview with Robert Whitaker

**SS: Weren't the early drug tests of Prozac so unpromising that they had to manipulate test results to get FDA approval at all?**

**RW:** What happened with Prozac is a fascinating story. Right from the beginning, they noticed only very marginal efficacy over placebo; and they noticed that they had some problems with suicide. There were increased suicidal responses compared to placebo. In other words, the drugs was agitating people and making people suicidal who hadn't been suicidal before. They were getting manic responses in people who hadn't been manic before. They were getting psychotic episodes in people who hadn't been psychotic before. So you were seeing these very problematic side effects even at the same time that you were seeing very modest efficacy, if any, over placebo in ameliorating depression.

Basically, what Eli Lilly (Prozac's manufacturer) had to do was cover up the psychosis, cover up the mania; and, in that manner, it was able to get these drugs approved. One FDA reviewer even warned that Prozac appeared to be a dangerous drug, but it was approved anyway.

We're seemingly finding all this out only now: "Oh, Prozac can cause suicidal impulses and all these SSRIs may increase the risk of suicide." The point is that wasn't anything new. That data was there from the very first trial. You had people in Germany saying, "I think this is a dangerous drug."

**SS: Even back in the late 1980s, they already knew?**

**RW:** Before the late 1980s -- in the early '80s, before Prozac gets approved. Basically what Eli Lilly had to do was cover up that risk of mania and psychosis, cover up that some people were becoming suicidal because they were getting this nervous agitation from Prozac. That's the only way it got approved.

There were various ways they did the cover-up. One was just to simply remove reports of psychosis from some of the data. They also went back and recoded some of the trial results. Let's say someone had a manic episode or a psychotic episode; instead of putting that down, they would just put down a return of depression, and that sort of thing. So there was a basic need to hide these risks right from the beginning, and that's what was done.

So Prozac gets approved in 1987, and it's launched in this amazing PR campaign. The pill itself is featured on the cover of several magazines! It's like the Pill of the Year [laughs]. And it's said to be so much safer: a wonder drug. We have doctors saying, "Oh, the real problem with this drug is that we can now create whatever personality we want. We're just so skilled with these drugs that if you want to be happy all the time, take your pill!"

That was complete nonsense. The drugs were barely better than placebo at alleviating depressive symptoms over the short term. You had all these problems; yet we were touting these drugs, saying, "Oh, the powers of psychiatry are such that we can give you the mind you want -- a designer personality!" It was absolutely obscene. Meanwhile, which drug, after being launched, quickly became the most complained about drug in America? Prozac!

### SS: What were the levels of complaints when Prozac hit the market?

**RW:** In this county, we have Medwatch, a reporting system in which we report adverse events about psychiatric drugs to the FDA. By the way, the FDA tries to keep these adverse reports from the public. So, instead of the FDA making these easily available to the public, so you can know about the dangers of the drugs, it's very hard to get these reports.



Within one decade, there were 39,000 adverse reports about Prozac that were sent to Medwatch. The number of adverse events sent to Medwatch is thought to represent only one percent of the actual number of such events. So, if we get 39,000 adverse event reports about Prozac, the number of people who have actually suffered such problems is estimated to be 100 times as many, or roughly four million people. This makes Prozac the most complained about drug in America, by far. There were more adverse event reports received about Prozac in its first two years on the market than had been reported on the leading tricyclic antidepressant in 20 years.

Remember, Prozac is pitched to the American public as this wonderfully safe drug, and yet what are people complaining about? Mania, psychotic depression, nervousness, anxiety, agitation, hostility, hallucinations, memory loss, tremors, impotence, convulsions, insomnia, nausea, suicidal impulses. It's a wide range of serious symptoms.

And here's the kicker. It wasn't just Prozac. Once we got the other SSRIs on the market, like Zoloft and Paxil, by 1994, four SSRI antidepressants were among the top 20 most complained about drugs on the FDA's Medwatch list. In other words, every one of these drugs brought to market started triggering this range of adverse events. And these were not minor things. When you talk about mania, hallucinations, psychotic depression, these are serious adverse events.

Prozac was pitched to the American public as a wonder drug. It was featured on the covers of magazines as so safe, and as a sign of our wonderful ability to effect the brain just as we want it. In truth, the reports were showing it could trigger a lot of dangerous events, including suicide and psychosis.

The FDA was being warned about this. They were getting a flood of adverse event reports, and the public was never told about this for the longest period of time. It took a decade for the FDA to begin to acknowledge the increased suicides and the violence it can trigger in some people. It just shows how the FDA betrayed the American people. This is a classic example. They betrayed their responsibility to act as a watchdog for the American people. Instead they acted as an agency that covered up harm and risk with these drugs.

### SS: In light of the FDA's failure to warn us about Prozac, what about their recent negligence on the issue of the risk of suicide in children given antidepressants like Paxil? Weren't England's mental health officials far better than their American counterparts in the FDA in warning about the dangers of suicidal attempts when antidepressants are given to youth?

**RW:** Yes. The children's story is unbelievably tragic. It's also a really sordid story. Let's go back a little to see what happened to children and antidepressants. Prozac comes to market in 1987. By the early 1990s, the pharmaceutical companies making these drugs are saying, "How do we expand the market for antidepressants?" Because that's what drug companies do -- they want to get to an ever-larger number of people. They saw they had an untapped market in kids. So let's start peddling the drugs to kids. And they were successful. Since 1990, the use of antidepressants in kids went up something like seven-fold. They began prescribing them willy-nilly.

Now, whenever they did pediatric trials of antidepressants, they found that the drugs were no more effective on the target symptom of depression than placebo. This happened again and again in the pediatric drug trials of antidepressants. So, what that tells you is there is no real therapeutic rationale for the drugs because in this population of kids, the drugs don't even curb the target symptoms over the short term any better than placebo; and yet they were causing all sorts of adverse events.

For example, in one trial, 75 percent of youth treated with antidepressants suffered an adverse event of some kind. In one study by the University of Pittsburgh, 23 percent of children treated with an SSRI developed mania or manic-like symptoms; an additional 19 percent developed drug-induced hostility. The clinical results were telling you that you didn't get any benefit on depression; and you could cause all sorts of real problems in kids -- mania, hostility, psychosis, and you may even stir suicide. In other words, don't use these drugs, right? It was absolutely covered up.

### SS: How was it covered up?

**RW:** We had psychiatrists -- some of those obviously getting money from the drug companies -- saying the kids are under-treated and they're at risk of suicide and how could we possibly treat kids without these pills and what a tragedy it would be if we couldn't use these antidepressants.

Finally, a prominent researcher in England, David Healy, started doing his own research on the ability of these drugs to stir suicide. He also managed to get access to some of the trial results and he blew the whistle. He first blew the whistle in England and he presented this data to the review authorities there. And they saw that it looks like these drugs are increasing the risk of suicide and there are really no signs of benefits on the target symptoms of depression. So they began to move there to warn doctors not to prescribe these drugs to youth.

What happens in the United States? Well, it's only after there's a lot of pressure put on the FDA that they even hold a hearing. The FDA sort of downplays the risk of these drugs. They're slow to even put black box warnings on them. Why? Aren't kids lives worth protecting? If we know that we have a scientifically shown risk that these drugs increase suicide, shouldn't you at least warn about it? But the FDA was even digging in its heels about putting that black box warning on the drugs.



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