

## FDA Warns that Paxil Makes Depressed Adults Suicidal

By Peter R. Breggin, M.D.

Getting the FDA to move forward by presenting it with scientific data is like using a peacock feather to tickle a sleeping giant tortoise on its shell. Many people die before the agency opens its eyes and then it barely reacts at all.

Bloated with conflicts of interest, under the best of conditions the FDA is barely able to drag itself along the ground. Slowly, oh, so slowly, it inches its way toward the obvious conclusion it can never quite reach: Antidepressants cause suicide; therefore, they aren't antidepressants at all. These drugs don't cure depression—and they frequently cause or worsen it. Regarding the most dreadful risk of depression, **suicide**, so-called antidepressants put depressed people of all ages at much greater risk of killing themselves.

### The FDA Confirms Antidepressant-Induced Suicidality in Adults

So, after years of prodding by me and more lately by a handful of other professionals, what new point in its journey has the FDA tortoise reached? In a May 2006 release in collaboration with the manufacturer GlaxoSmithKline (GSK), the FDA has acknowledged the antidepressant Paxil causes a statistically significant increased rate of suicidality in depressed adults as measured in controlled clinical trials. [1] The results are based on a re-analysis of all adult controlled clinical trials that compared Paxil with placebo.

Buried in the FDA/GSK release is an astounding fact: **Depressed people are 6.4 times more likely to become suicidal while taking an antidepressant than while taking a sugar pill.** [2]

No other antidepressants were mentioned in the FDA's warning but all SSRI antidepressants share a common profile of adverse mental and behavioral effects, including Paxil, Prozac, Zoloft, Celexa, Luvox, and Lexapro. Several other relatively new antidepressants have also been implicated in producing similar psychiatric abnormalities, including Wellbutrin, Effexor, Serzone, and Cymbalta. All of the newer antidepressants can produce stimulation or activation with the potential for increased agitation, anxiety, mood instability, disinhibition, irritability, aggression, hostility, mania, and crashing into depression and suicide. They can also cause a flattening of emotional responses, including a loss of caring, that can unleash dangerous actions. [3]

It is hard to cheer the FDA when in books and scientific reports, I've been warning about the risk of antidepressant-induced suicide (and violence) for fifteen years, starting in 1991 with Toxic Psychiatry. My most comprehensive scientific review of the subject was published in 2003. [4] In more recent years, other professionals have also joined the fray, especially Harvard psychiatrist Joseph Glenmullen. Scientific reviews confirmed that antidepressants cause suicidality in children and adults, [5] but the FDA delayed acting on mounting evidence. To this day, the agency waffles about the

importance of the antidepressant suicide risk. Thus far it has focused only on Paxil in regard to adult suicide and it has hinted that the risk may be slight when it is catastrophic. It also continues to avoid facing evidence that the drugs cause violence.

A few weeks before the FDA and GSK published their recent admission that Paxil can make adults more suicidal, I published a special report in Ethical Human Psychology and Psychiatry in which I released previously suppressed data indicating that GSK had manipulated its research results to hide the risk of Paxil-induced suicidality [6] (available on <http://www.breggin.com/>). I based my observations on suppressed company data that I had discovered during a three-day investigation inside the drug company's secret files, working as a medical expert in a murder-suicide product liability case against the company. Simultaneously, I published on my website the original product liability report with all the scientific data that I had unearthed during those three days. More than a year earlier, I had informed the FDA at two of its public hearings that I possessed this sealed smoking gun. They never responded to me directly. Perhaps they are responding to me now.

### The Struggle to Enlighten the Public, the Profession and the FDA

Beginning with the widespread use of Prozac in the early 1990s, the struggle to gain public and professional recognition of antidepressant-induced suicide and violence has a long and stormy history. Drug advocates accused critics of Prozac of taking away a "lifesaving" treatment from depressed patients. Ironically, these same drug advocates would never be able to prove that Prozac or any other antidepressant can reduce the suicide rate; but the evidence has mounted, ultimately proving that these drugs can increase suicide and violence.

The struggle peaked in 1994 when I testified against Eli Lilly in a case of Prozac-induced suicide and mass murder. My testimony, in effect, was that the perpetrator, Joseph Wesbecker, hadn't gone "postal," he'd gone "Prozacal." After the drug company won a split jury decision, the judge realized that the trial had been fixed. The plaintiffs had been paid off by the drug company to conduct a fake trial that was rigged to end in favor of the drug company. The outraged judge voided the verdict. I have documented these events, including the judge's conclusions, in numerous sources including Brain-Disabling Treatments in Psychiatry (1997).

The Prozac-soaked media simply ignored this bombshell. There were no headlines, "Drug Company Fakes Trial; Data Reveals that Prozac Causes Suicide and Violence." If either the media or the FDA had examined the data I generated for that legal case, followed by the fixing of the trial, it might not have taken twelve more years for the government and GSK to acknowledge that Paxil causes suicidality in children and adults. Meanwhile, the FDA and the antidepressant manufacturers continue to deny that the drugs also cause violence. Because of this delay, many lives continue to come to tragic ends because of this delay.

### Continued Obfuscation

The FDA and GSK continue to obfuscate the true risk in their May 2006

announcement concerning Paxil-induced suicidality in depressed adults. They emphasize the supposedly slight increase in suicidality among young adults (through age thirty) who take Paxil for a variety of conditions, including for depression, panic attacks, anxiety and obsessive-compulsive disorder. Far more important is the statistically significant increase in suicidality in all ages of depressed adults. It's worth restating that depressed people getting Paxil were 6.4 times more likely to display suicidal thoughts and behavior than depressed people taking a sugar pill. In regard to suicide—the most devastating risk associated with antidepressants—it is safer for depressed persons to stay off the drug!

The FDA allowed the Paxil manufacturer to soft pedal the results by claiming, for example, that the results could be compounded by the fact that suicide is an aspect of “psychiatric illnesses.” This is nonsense—and every scientist knows it. Since both groups were depressed, and since they differed only in the substances they were given to take, Paxil and not depression was the cause of this astronomical increase in suicidality.

If depression had caused the increased suicidality, then the placebo patients—who lacked the supposed benefit of an antidepressant effect—would have suffered a much higher rate of suicidality than the Paxil patients. Instead, they had a much lower rate. In other words, because the antidepressants were supposed to be helping the depressed patients, the relative ineffectiveness of the sugar pill should lead to more suicidality than the drug, not less. The FDA, the drug company, and the media ignored this important fact. Conventional assumptions would have predicted increased suicidality on placebo instead of increased suicidality on Paxil. It's a complete reversal of the expected outcome, underscoring the seriousness of finding increased suicidality on the drug.

### The Real-Life Risk Is Much Greater than Described

It's nothing short of a miracle that GSK-sponsored clinical trials have demonstrated the increased risk of suicidality from antidepressants. If not a miracle, it's a confirmation that the risk is enormous—far more so than indicated by the studies. Keep in mind that controlled clinical trials are planned by the drug companies, supervised by the drug companies, and carried out by paid lackeys of the drug companies. Keep in mind that all the data analysis is done at drug company headquarters by drug company execs. Keep in mind that the trials are constructed in order to prove the usefulness of the drug and to minimize its adverse effects such as suicidality. Keep in mind that the controlled clinical trials are very short, usually 4-6 weeks long, and that prescreening excludes suicidal and psychotic patients from participating in the studies.

In real-life medical practice, the rate of drug-induced suicidality will be much higher than in the research-oriented controlled clinical trials. In actual practice, many patients are already suicidal when they are started on the drug, increasingly the likelihood that the drug will push them over into self-injurious behavior. In actual practice, compared to controlled clinical trials used for research, busy doctors provide much less supervision or monitoring, the patients are almost never tested or evaluated for suicidality, multiple drugs are often given at once, and the doctors know little about looking for adverse effects on the mind.

If Paxil increased the rate of suicidality by more than six times in the drug company's controlled clinical trials, it may be doing so by sixty times in actual practice.

We can't determine exactly how much greater the risk will be in clinical practice but it will be astronomically greater.

### And the Antidepressants Don't Even Work

Meanwhile, a comprehensive review of all studies of antidepressant drugs submitted for approval to the FDA showed that when the studies are taken as a whole, antidepressants don't work. [7] A drug company may perform twenty studies in an attempt to show efficacy Exemplified by the case of Prozac, as I described in Talking Back to Prozac (1994), as long as two studies show a positive effective, the FDA will approve the drug. If a drug company cannot massage their self-generated data sufficiently to obtain a positive result in two out of twenty clinical trials, the company's paid consultants and employees don't deserve to stay employed. And of course, they won't stay employed if they fail to meet the company's needs to promote new products.

Of course, many people feel helped by antidepressants, as well as by many other psychiatric and even psychoactive drugs. The placebo effect is enormous. In addition, the artificial euphoria or emotional flattening produced at times by antidepressants may provide temporary relief at the cost of rationality or effective dealing with life.

It's time to say again what I've been saying for too many years on end. The antidepressants aren't antidepressants. They are more likely to make a person worse than better. More tragically, these toxic agents push many people over the brink into suicide and violence.

It's astonishing as I approach my 70<sup>th</sup> birthday that the FDA is beginning to catch up with what I've been saying for decades in regard to the limits of drugging children and adults to control their emotions and behavior. It's gratifying but also a little frustrating. No, I don't have a biochemical imbalance, I am outraged that my profession has consistently tried to foist off self-serving mythology as science and that so many people have been damaged or killed by the effects of the false biochemical diagnoses and toxic medications.

Meanwhile, the antidepressants are very difficult to stop taking. Withdrawal from antidepressants can lead to "crashing," with agitation, violence and suicide. Withdrawal from these noxious drugs should be done slowly with experienced clinical supervision. **These drugs are not only unsafe to start—they are dangerous to stop.**

The best approach to antidepressants: Don't start taking them.

---

#### Endnotes:

<sup>1[1]</sup> Dear Healthcare Professional: Important Prescribing Information [for Paxil]. By John E. Kraus, M.D., GlaxoSmithKline, Philadelphia, Pennsylvania, May 2006. Available on [www.fda.gov](http://www.fda.gov).

<sup>1[2]</sup> Among depressed adults taking Paxil, 0.32% displayed suicidal thoughts or behaviors compared to 0.05% among depressed adults taking placebo.

[3] Breggin, P. (2006). Recent regulatory changes in antidepressant labels: Implications for activation (stimulation) in clinical practice. Primary Psychiatry, 13, 57-60. Available on [www.breggin.com](http://www.breggin.com).

[4] Breggin, P. (2003). Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis." Ethical Human Sciences and Services 5:225-246. Simultaneously published in the International Journal of Risk and Safety in Medicine, 16, 31-49, 2003/2004. Available on [www.breggin.com](http://www.breggin.com).

<sup>1[5]</sup> For a review of increased suicidality in adults taking Paxil, see: Aursnes, I., Tvette, I., Gassemyr, J., and Natvig, B. (2005). Suicide attempts in clinical trials with paroxetine randomised against placebo. BMC Medicine, 3:14. For suicidality in children, see: Jick, S., Dean, A., and Jick, H. (1995). Antidepressants and suicide. British Medical Journal, 310, 215-218.

<sup>1[6]</sup> Breggin, P. (2006). Court filing makes public my previously suppressed analysis of Paxil's effects. Ethical Human Psychology and Psychiatry, 8, 77-84. Available on [www.breggin.com](http://www.breggin.com).

[7] For the review demonstrating lack of efficacy in antidepressant studies conducted for FDA approval, see: Antonuccio, D., Burns, D., and Danton, W. (2002). Antidepressants: A triumph of marketing over science? Prevention & Treatment, 5, Article 25, 1-17. For a study of the lack of efficacy demonstrated by Prozac studies submitted to the FDA, see Breggin, P. and Breggin, G., Talking Back to Prozac, New York: St. Martin's Press, 1994.