Whole Body Health!

Prozac Was Approved Even as Experts Warned it Could Turn Kids Into Killers

Warning: Link between flu shots and onset of major health problems found

By John Tiffany

Recently a "really good student" named Steve Kazmierczak, it seems, took several guns into a geology lecture on Valentine's Day at Northern Illinois University and shot up the class. One hundred to 120 students were in the class at the time. (Time: about 3 in the afternoon on February 14, 2008; weapons: a 12-gauge shotgun, a .22 pistol, a 9 mm pistol and a .45 Glock semiautomatic handgun.)

Why did he do it? Authorities are not quite sure. But whatever triggered the deadly rampage of this "nice boy," one key factor—as in other, similar events—seems to have been the drug Prozac (fluoxetine). According to some experts, it is reasonable to say that Prozac should never have been approved in the first place by the Food and Drug Administration (FDA).

Prozac was allowed on the U.S. market on December 29, 1987. But even before the drug was approved for the market, a British medical journal said recently, it had given American regulators confidential drug company documents suggesting a link between the popular "antidepressant" and a heightened risk of suicide attempts and violent acts.

Documents it received from an anonymous source indicated that Prozac's manufacturer, Eli Lilly & Co., was aware in the 1980s that the drug could have troubling side effects, *The British Medical Journal* reported (Jan. 1). The *BMJ* said a record dated November 1988 indicated that Prozac had caused "behavioral disturbances" in clinical trials.

(Eli Lilly is said to be linked to the George Bush family.)

BMJ said the documents, missing for 10 years, were part of a 1994 lawsuit against Eli Lilly on behalf of victims of a workplace attack in Louisville, Ky. Joseph Wesbecker, the gunman who killed eight people and himself in 1989, had been prescribed Prozac a month before the shootings. (Eli Lilly won that case but later disclosed it

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Good Doctors Refusing Gifts from Drug Lobbyists

By James P. Tucker Jr.

More and more physicians are refusing bad drugs and the accompanying favors. R. Jonathan Mohrer, MD, is among them, according to a lengthy article in *Newsweek* magazine.

He would receive up to 10 visits a day from drug salesmen, bringing free pens, lunches and drug samples.

"I'd been getting pitches for Vioxx almost every week, even while questions were being raised about it in medical journals," Mohrer told *Newsweek*. He kicked the salesmen out and made it clear he would not accept their calls. "It's been a real relief," he said. "I don't know how I juggled it all." (Vioxx, a heavily promoted painkiller, was withdrawn after clear evidence that it increased the risk of heart attacks was exposed.)

Mohrer is one of a growing number of physicians who are saying no to drug company promotions. Some belong to No Free Lunch, an organization that asks doctors to take a pledge not to receive drug company salesmen. Founded in 1999, No Free Lunch has 800 members out of 800,000 practicing physicians in the United States.

The American Medical Student Association has collected a similar number of pledges from the nation's 68,000 medical students—twice as many pledges as it had a year ago.

Increasing numbers of hospitals, health care systems, medical schools and states are starting to impose restrictive policies. Minnesota has already set limits on gifts, and three other states are considering similar legislation.

"There's growing evidence that these relationships color doctors' prescribing practices, even if doctors think they don't," Dr. Karen Antman, dean of Boston University's medical school, told *Newsweek*. BU imposed a ban on all gifts and lunches from drug salesmen and they can visit only if invited.

Big Pharma spends big bucks marketing to physicians. In 2004, the total reached $23 billion, including $15.9 billion in free drug samples, according to the Pharmaceutical Research and Manufacturers of America. ♥

Prozac

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had settled with the plaintiffs during trial.)

The history of Prozac was tainted from the start. It began in 1982, when David Dunner of the University of Washington began receiving money that would eventually total over $1.4 million from Lilly for his research and seminars.

Dunner was a member of the FDA's Psychopharmacologic Drugs Advisory Committee that is responsible for reviewing new drug applications brought before the FDA. These members are routinely asked if they might have any conflict of interest with each manufacturer presenting new drugs. Dunner responded to this question by stating "no pending commitments at the present time." The FDA assumed his answer was truthful, but in fact Dunner had already been paid by Lilly for conducting a clinical trial of Prozac on 100 people. Thus he apparently had a serious conflict of interest that he covered up.

Dunner had also given five seminars regarding "depressive disorders" sponsored by Lilly, which he failed to mention to the committee. Furthermore, Dunner also had two more paid seminars booked by Lilly that would take place after the approval of Prozac—another fact he failed to mention.

To make matters worse, Dunner received another Lilly grant to conduct a new study on the effects of Prozac on sleep patterns. This was five days after Prozac was approved.

In 1985, Lilly conducted tests on Prozac and found the drug not to be significantly more effective than the placebo. But an FDA statistician suggested to Lilly that the test results could be evaluated differently, causing the results to come out more favorably for Prozac. Guidelines constructed by Lilly for the clinical trials excluded the reporting of "adverse experiences caused by depression," thus skewing the results.

In 1986, Richard Kapit, MD, of the FDA stated that Prozac "may exacerbate certain depressive symptoms and signs."

Clinical risks of mild to moderate severity appeared to be associated with the use of Prozac, as determined by review of the safety data in the New Drug Application submission. The FDA safety review discovered that Lilly failed to report information about psychotic episodes during Prozac's testing, but the FDA failed to reprimand Lilly for omitting this important data.

By 1987, in fact, two months before Prozac was approved for the market there had already been 39 deaths from controlled clinical trials: 15 were listed as suicides, another six were by overdose, four more were by gunshot and another two were by drowning. These 27 fatal cases were confirmed to be directly related to taking Prozac. (An additional 12 deaths were reported but could not be directly related to the drug.)