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Health

Why are atypical drug users angry?

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August 19, 2005—We now know that atypical antipsychotics are responsible for a high incidence of diabetes, stroke, endocrine, cardiac problems and movement disorders.

In recent years, drugmakers have been forced to admit to misleading the FDA, physicians, and consumers about the deadly side effects of these drugs. But they are still routinely prescribed to patients of all ages, including children and the elderly.

On April 12, The New York Times reported that the FDA will now require black box warnings about the increased risk of death on the labels of some of the most aggressively marketed, hence widely prescribed drugs such as Zyprexa (Eli Lilly) Risperdal (Johnson & Johnson) Abilify (Bristol-Myers Squibb), Clozril (Novartis), Geodon (Pfizer).

On July 24, 2004, the Miami Herald reported that the maker of Risperdal "has acknowledged misleading doctors and other healthcare providers about the safety of the product, minimizing potentially deadly side effects."

"Risperdal is the leading drug used to combat schizophrenia and other types of psychotic disorders, earning Janssen about $2.1 billion in annual sales," the Herald wrote. "The drug was first marketed about eight years ago, and is prescribed to more than 10 million people worldwide."

The worst part of this tragedy is that atypicals are not even effective. One review of 52 studies involving 12,649 patients published in the December 2000 British Journal of Psychiatry reported: "There is no clear evidence that the atypical antipsychotics are more effective or better tolerated than conventional antipsychotics."

While the health and drug control agencies of Japan and Great Britain issued warnings against the drug Zyprexa in 2002, the FDA continued to allow its sale and distribution until September 2003, before it finally required a warning label on the drug.

The FDA made all atypicals carry the same warning label even though the risk of diabetes with Zyprexa was 37 percent higher than with the other atypicals.

In February 2004, the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity published a joint statement confirming the association between Zyprexa and diabetes.

An independent researcher, Dr David Healy, studied FDA raw data on Zyprexa and concluded that it was among “the deadliest drugs ever to gain FDA approval.”

Yet, despite all the warnings of adverse affects and lack of effectiveness, atypicals are being prescribed for patients in record numbers, including children. On April 25, the Ohio Columbus Dispatch reported an

investigation of state Medicaid records that found 18 newborn to 3 year-old babies in Ohio had been prescribed antipsychotic drugs in July 2004.

According to CBS.marketwatch.com on February 7, atypical Zyprexa, earned Eli Lilly $4.4 billion in 2004. A considerable amount when compared to Lilly's $13 billion total net sales in 2004. The global giant also produces other psychiatric drugs such as Prozac, Strattera, and Symbyax.

In 2003, Zyprexa became Lilly's top seller with worldwide sales of over $4 billion. According to The New York Times, 70 percent of the Zyprexa purchased in the US in 2003 was paid for by government programs like Medicare and Medicaid.

The State of New York's $4-billion-a-year bill for drugs covered by Medicaid is the biggest in the nation. In the first 10 months of 2003, the state spent $205 million on Zyprexa alone, far more than for any other one drug.

The state of California spent over $500 million on the atypicals Risperdal, Zyprexa and Seroqual in 2003.

In a New York Times Article (Leading Drugs for Psychosis Come Under New Scrutiny), Erica Goode reported a study by the Department of Veterans Affairs which found that Zyprexa cost the VA $3,000 to $9,000 more per patient each year than conventional drugs, with no benefit to symptoms, side effects or overall quality of life.

Today, a month's supply of Zyprexa is 10–30 times more expensive than a month's supply of a conventional antipsychotic, according to Leonard Roy Frank, author of *Zyprexa: A Prescription for Diabetes, Disease and Early Death* in the August 2005 Edition of Street Spirit.

Its ironic, that in the same year that the FDA got around to forcing the company to warn of the drug's link to diabetes, Lilly’s second most profitable line of products was drugs used to treat diabetes, which grossed $2.51 billion in 2003.

The profits from the sale of these drugs are not being spent on research and development, they in large part go for marketing and salaries for top executives. A report by the non-profit group Families USA showed that in 2001, former CEO of Bristol-Myers Squibb, Charles Heimbold Jr, received $74,890,918, not counting his $76,095,611 worth of unexercised stock options, and the chairman of Wyeth raked in $40,521,011, plus $40,629,459 in stock options.

Eli Lilly is currently under fire from the FDA, state attorneys general, doctors, and consumers, with complaints about Zyprexa.

On August 3, Reuter's reported that Lilly had received a subpoena from the Florida attorney general's office seeking documents on Medicaid-related sales of Zyprexa and Lilly's marketing of the drug.

In a regulatory filing, the drugmaker said it had received the subpoena in June from the Medicaid Fraud Control Unit and said it was possible that other Lilly products could become subject to the investigation and that the investigation could lead to criminal charges, fines or penalties against the company.

The Florida investigation comes amid a continuing investigation by the US attorney for the Eastern District of Pennsylvania into the company's marketing and promotion of Zyprexa and Prozac in that state. That investigation was initiated in March 2004.

In another turn of events in June, Lilly agreed to pay $690 million to settle lawsuits filed by approximately 8,000 Zyprexa patients who alleged they had not been warned the drug might increase the risk of diabetes.

"More than 2,500 other claimants refused to participate in the settlement, presumably in the belief that the amount received by each claimant, $62,500 on average, was insufficient compensation for the pain and

suffering Zyprexa caused them," according to Leonard Roy Frank, author of *Zyprexa: A Prescription for Diabetes, Disease and Early Death*, August 2005 edition of Street Spirit.

One of the litigants, Ellen Liversridge, who's son died at age 39 allegedly due to the adverse affects of Zyprexa, states, "both the FDA and Lilly fought putting a warning on the label, but thorough articles on the front pages of the Baltimore Sun, Wall Street Journal, and new York Times so embarrassed the FDA that they finally gave in to warnings."

"Rob was a peaceful, funny, brilliant man who battled manic depression with grace and dignity," said his mother, "he deserved the best."

She tells how her son "gained almost 100 pounds on Zyprexa, back before there was a warning on the label."

"Rob felt "funny" one Sunday morning," Ellen relates, "but his symptoms weren't psychiatric and, to my sorrow, I didn't take him to the ER."

"By Tuesday," she said, "he had fallen into a coma from which he never came out." Rob remained in a coma for four days and "died Saturday, October 5, 2002, of profound hyperglycemia."

"Rob didn't deserve to be killed by a drug carrying a lethal bomb that we knew nothing about" Ellen said, "He didn't deserve to become another Eli Lilly statistic."

"And we, his family, don't deserve to carry the pain that never goes away," she added.

Ellen will be the August 24 Washington, DC, protest, "I have a strong sense of justice as well as retribution," she said, "I plan to use these things in whatever way I can, in his memory."

Deceptive Marketing & Promotion

Award winning journalist Robert Whitaker, author of *Mad in America*, investigated the industry's marketing strategy of the atypicals and found biased reviews and deceptive reporting to be prominent in the promotion of the drugs. Via the Freedom of Information Act he gained access to FDA raw data on the drug trials and learned that the FDA’s review of the trials did not support industry claims that the atypicals were safer or more effective than existing generic drugs.

Marcia Angell is a senior lecturer in Social Medicine at Harvard Medical School. She is also a physician, former editor in chief of The New England Journal of Medicine and the author of the book, *The Truth About the Drug Companies*.

According to Marcia the industry is "primarily a marketing machine" to sell drugs of dubious benefit and uses its wealth and power to co-opt every institution that might stand in its way, including Congress, the FDA, academic medical centers, and the medical profession itself. Most of its marketing efforts are focused on influencing doctors, since they must write the prescriptions. "

And its obviously working. A study released in August 2004, noted that 41 percent of prescriptions for 765,423 people over age 65 were for psychotropic medications. (L Curtis et al, Archives of Internal Medicine, Vol 164, pp 1621–1625, 2004). Even though a recent analysis by the FDA noted that elderly patients using Zyprexa had “a higher chance for death than patients who did not take the medicine," and older persons have suffered strokes when taking Risperdal.

A May 2004 report by The New York Times explained how drug companies were using new strategies to capture the Medicaid and Medicare markets that involved a "focus on a much smaller group of customers: state officials who oversee treatment for many people with serious mental illness. Those patients—in mental hospitals, at mental health clinics and on Medicaid—make states among the largest buyers of anti-psychotic drugs."

Prime examples of this trend, include Ohio Mental Health Director Michael Hogan and California Director Stephen Mayberg. Both control mental health services in their respective states, and both are members of a Janssen advisory board.

Hogan has proven to be so useful that Eli Lilly has given him a "Lifetime Achievement Award." In granting the award it was noted that Hogan had given over 75 presentations at conferences and according to ace records researcher Sue Weibert, every conference she tracked down that featured Hogan, was sponsored by drug companies, and the group that organized the conference solicited money from pharma to pay the keynote speaker.

The particular scheme has become so blatant, that it is finally being investigated. On June 10, Senators Chuck Grassley and Max Baucus issued a press release that said they have asked a number of large drugmakers to explain a marketing practice where the companies give money to state governments and other organizations in the form of grants.

A request was sent to the following drugmakers: Pfizer, GlaxoSmithKline, Johnson & Johnson, Merck & Co, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb, Novartis Pharmaceuticals, Amgen, Wyeth Pharmaceuticals, Eli Lilly, Sanofi Aventis, Eisai, Boehringer Ingelheim Pharmaceuticals, Schering-Plough Corporation, Hoffman-LaRoche, Forest Pharmaceuticals, Abbott Laboratories, Genentech, Biogen Idec, Genzyme Corporation, Chiron Corporation, Serono, and TAP Pharmaceutical Products.

The senators said their inquiry is based on reports that some companies have awarded these grants to health care providers as inducements to prescribe medications the companies produce. In other cases, such grants to state agencies may have prompted those agencies to develop programs leading to overmedication of patients at the expense of patient health or to unnecessary expense for taxpayers.

"We need to know how this behind-the-scenes funneling of money is influencing decision makers," Grassley said, "The decisions result in the government spending billions of dollars on drugs. The tactics look aggressive, and the response on behalf of the public needs to be just as vigorous."

In addition to influencing and corrupting state officials, drugmakers have infiltrated the nation's health care facilities and gained influence over prescribing physicians who engage in the practice of overmedicating patients.

For instance, they have set up schemes to funnel profits through senior citizens in nursing homes. Researcher have found that 75 percent of long-term care elderly residents receive psychotropic medications. (D Fisk et al) Archives of Internal Medicine, Vol 163, pp 2716–2724, 2003).

Child advocates say kids are being overmedicated in state run foster care systems. The children go into the system neurologically normal but leave neurologically damaged. Austin psychologist and author, John Breeding said, "Children are not just placed on one drug. Typically, they're placed on two or three or we've seen literally up to 17 different drugs for the same child in foster care."

In 2001, the Miami Herald published a series of stories about the common use of Risperdal among children in state care. Child-welfare advocates said the drug routinely was being used by foster care providers.

In April 2001, Broward lawyer and child advocate Andrea Moore told the Florida Department of Children & Families administrators that a large number of children in foster care were being given Risperdal—an antipsychotic drug a UCLA child psychiatrist describes as among the ``big guns'' of psychiatric medications.

At that time, Florida officials confirmed that thousands of children, including toddlers, were being prescribed psychiatric drugs, from Ritalin to powerful drugs like Risperdal and Haldol.

"I had clients who were displaying severe side effects, and I tried to alert the Department of Children & Families both as to the local problem and the growing national concern about a range of psychotropic medications, Risperdal and other antipsychotics in particular," said Coral Springs attorney and children's advocate Moore.

A prime example of bribing doctors in state institutions was unearthed in Massachusetts, where doctors were found to have changed the medication of four patients for non-medical reasons. A Boston Globe article published on November 10, 2003, reported that the patients were switched to the atypical Risperdal, without consent or medical necessity, to make them eligible for a drug trial sponsored by drug company Janssen, maker of Risperdal.

When other staff members complained, a state agency investigated the matter and the drug trial was stopped. All state hospital doctors were required to undergo recertification in the ethics of medical research and the facility's director, Dr Douglas Hughes, resigned after it was revealed that he had received $30,000 in speaker’s fees from Janssen in 2003.

The current prices for a month's supply of the top three antipsychotics are: Risperdal $342; Seroquel $414; and Zyprexa $572

Because these drugs are the most expensive on the market, and are so often paid for by the government, the rampant overprescribing of these medications is bankrupting state Medicaid programs all over the country. (for reports on Massachusetts, Florida, Texas, Illinois, and more information go to www.ahrp.org)

According to the May 8, issue of Lab Business Week, a new analysis by the US Substance Abuse and Mental Health Services Administration reveals that Medicaid is now the largest single payer of mental health services, exceeding private insurance, Medicare, or other state and local spending. The report notes that one out of every $5 spent on mental health care now goes for psychotropic drugs.

Pennsylvania Under Fire

In addition to an investigation by the US attorney for the Eastern District of Pennsylvania into Eil Lilly's marketing and promotion of Zyprexa and Prozac in that state, two former state investigators are diligently working to expose the industry's corruption of state institutions.

According to former investigator turned whistleblower, Allan Jones, Pennsylvania taxpayers are saddled with an expensive drug treatment model known as PennMap, for the treatment of mentally ill persons in state care.

"This model is part of a large pharmaceutical marketing scheme designed to infiltrate public institutions and influence treatment practices," he explained. "Pennsylvania is paying tens of millions of dollars for patented drugs that have no proven advantage over cheaper generic drugs."

As part of the overall scheme, on July 27, 2001, Tom Ridge appointed Gerald Radke, an Eli Lilly marketing director, to head the Pennsylvania Office of Mental Health and Substance Abuse. With Radke at the helm, Pennsylvania Medicaid-funded sales of Lilly’s Zyprexa rose from approximately $26.5 million in 2000 to $34.2 million in 2001, and reached $39.2 million in 2003. In state hospitals, hundreds of patients had their medications switched in the absence of medical need or indication, to comply with administrative decisions.

In 2003, there was a total of $139 million in public spending on just two classes of drugs, SSRI (selective serotonin reuptake inhibitor) antidepressants and atypical antipsychotics. "A large portion of these dollars were spent to maintain children on these drugs," Allen reports, "despite the fact that they have not been proven effective in children and the FDA has not approved them for use in children."

"My best effort at correlating dollars spent with deaths from drug side effects suggests that people may be dying from side effects from the schizophrenia drugs alone at the rate of at least one death for each one

million dollars spent on these drugs," Allen said. "The actual numbers may reflect a much higher death rate," he added.

On July 1, 2004, another former Pennsylvania investigator, Dr Stefan Kruszewski, a Harvard psychiatrist/screenwriter-turned-activist, from Harrisburg, Pennsylvania, filed suit against six major pharmaceutical companies after discovering that commonwealth's children and adults were being abused and defiled by excessive psychiatric drugs and hazardous psychiatric inpatient environments.

People are being drugged for profit in Pennsylvania state institutions. While PennMap was being implemented, Stefan was a psychiatric consultant for the Department of Health and Human Services, in charge of the mental health programs, and found that some patients were on as many as five neuroleptic psychiatric drugs at the same time.

Stefan also discovered corrupt financial relationships between Pennsylvania politicians and pharmaceutical representatives, fraudulent medication billings to the government, and that four children and one adult died while under the state's care, after they were prescribed lethal combinations of anti-psychotic drugs under the PennMap model.

According to Stefan, the new generation of antipsychotics substantially increase the risk of obesity, diabetes type II, hypertension, cardiovascular complications, heart attacks and stroke. The drugmakers had this information and "simply ignored the problem," he said.

"So, what we have now is a drug, Zyprexa, whose massive revenues and promotion are based upon faulty disclosures by the manufacturer, Eli Lilly," Stefan said. "The drug causes both a severe metabolic syndrome and cardiovascular problems at the same time that it continues to cause neurological side effects like its older ‘typical’ antipsychotics."

It does have a decided advantage for Lilly, Stefan contends, "It is far more expensive, dose per dose, than a comparable ‘generic’ antipsychotic." A dose of haloperidol might sell for 6 pennies while Zyprexa might sell for over $6 per pill, he said.

Stefan, is also board certified in adult, adolescent, geriatric and addiction psychiatry, and he and Allen Jones will both be attending the Washington protest.

Unreported Trials and Studies

Based on the results of a six-week clinical trial sponsored by Lilly, the FDA granted the company approval to manufacture and distribute Zyprexa in September of 1996 for the treatment of adult schizophrenics. The trial leading up to approval involved 2,500 people, and two-thirds of the participants didn't even complete the trial.

Among those who stuck it out, 22 percent of the Zyprexa subjects suffered a "serious" adverse effect, compared to 18 percent in the group taking Haldol, according to Leonard Roy Frank, author of *Zyprexa: A Prescription for Diabetes, Disease and Early Death*, August 2005 Edition of Street Spirit.

That same year, FDA data obtained by Robert Whitaker, under the Freedom of Information Act, revealed Zyprexa's adverse effects to include: cardiac abnormalities and hypotension, 10 percent to 15 percent; Parkinson-like motor impairment, 11.7 percent; unbearable restlessness (akathisia), 7.3 percent; and acute weight gain, 50 percent, increasing the risk of diabetes.

The data also disclosed a participant drop-out rate during six-week clinical trials of 65 percent. In a one year trial, the drop out rate rose to 83 percent.

FDA reviewers found an average weight gain of almost one pound a week for subjects during the six-week trial, and a 26-pound increase for Zyprexa patients who remained in the trial for a year. Other side effects included shaking, spasms, sedation, diabetic complications, rapid heartbeat, restlessness,

constipation, seizures, liver problems, white blood cell disorders, decreased blood pressure; and neuroleptic malignant syndrome, which is potentially fatal.

There were also 20 deaths, including 12 suicides, in the Zyprexa group. "Shockingly, these deaths went unreported in the scientific literature," Leonard Frank said. "The death cover-ups also took place in reporting trial results of several other atypicals during the 1990s."

In his book, *Mad In America*, Robert Whitaker, reported that one in every 145 subjects who entered the trials for Zyprexa, Risperdal, Seroquel, and Serdolect had died.

Despite these severe known side effects, children between the ages of 6 to 11 were recruited for a clinical trial conducted at the University of California Los Angeles soon after Zyprexa was approved for adults. The children were not schizophrenic, but were diagnosed with other disorders. According to the published report on the research, all of the children experienced adverse effects and none were helped. The study was terminated less than six weeks after it began. Yet to this day, doctors continue to regularly prescribe atypicals to children, even though they have never been FDA approved for treatment of any illness in children.

In 2002, P Murali Doraiswamy, the chief of biological psychiatry at Duke University, conducted a review of adverse events reported to the FDA by Zyprexa patients and found:

Of the 289 cases of diabetes linked to Zyprexa, 225 were newly diagnosed cases. One hundred patients developed ketosis (a serious complication of diabetes), and 22 people developed pancreatitis, or inflammation of the pancreas, which is a life-threatening condition. There were 23 deaths, including that of a 15-year-old adolescent who died of necrotizing pancreatitis (Pharmacotherapy, July 2002).

Persons on atypicals have been found to commit suicide at rates two to five times more frequently than schizophrenics in general. According to Bob Whitaker, "researchers in Ireland reported in 2003 that since the introduction of the atypical antipsychotics, the death rate among people with schizophrenia has doubled."

In an interview this month with Street Spirit, he said, "They have done death rates of people treated with standard neuroleptics and then they compare that with death rates of people treated with atypical antipsychotics, and it doubles. It doubles! It didn't reduce harm. In fact, in their seven-year study, 25 of the 72 patients died."

The industry routinely hides negative results of studies. "We do not know the results of the clinical trials they sponsor—only those they choose to make public, which tend to be the most favorable findings," Marcia Angell advises.

The problem with the FDA is the fact that it is practically owned by the industry that it is supposed to regulate. In recent years, nearly half of the agency's $400 million annual budget has been paid for by drug companies. This arrangement stems from a 1992 agreement, made partly at the urging of AIDS activists, that the FDA would speed up approvals in exchange for "user fees" from industry, according to the May-June 2005 issue of Mother Jones Magazine.

According to the September 9, 2004, Washington Post, because of the industry's pattern of hiding research that shows adverse affects, medical journals are taking matters into their own hands. The Post reported that a dozen editors of prestigious medical journals jointly announced they will refuse to publish drug research sponsored by pharmaceutical companies unless the studies are registered in a public database from the outset—a step designed to ferret out unpublished studies that find medications to be ineffective or dangerous.

The initiative creates a potent incentive for companies to register their drug trials and is expected to give physicians and the public a window on unfavorable studies that companies routinely suppress, the Post

wrote. The new requirement calls on companies to register their trials well before anyone knows whether a study will turn out positive.

The Journal of the American Medical Association, the Annals of Internal Medicine, the Lancet, the New England Journal of Medicine and several other international publications have signed on to the initiative, and their editors hope that more will join in, the Wall Street Journal reported.

Activists who will be attending a three-day protest in Washington this month, beginning August 24, have one thing in common. They want to raise awareness of the fact that the pharmaceutical industry has allegedly injured Americans with dangerous products to increase profits and the nation's regulatory agencies have aided and abetted them.

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