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# Activists Take on Eli Lilly Over Sale of Zyprexa

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Opinion: Evelyn Pringle

## Activists Take on Eli Lilly Over Off-Label Sale of Zyprexa

By [Evelyn Pringle](#)

On February 23, 2007, a new grass roots advocacy group issued a press release to rally support for attorney, Jim Gottstein, in his legal battle with Eli Lilly over his role in providing secret company documents obtained in litigation to the media to alert the public about the health risks associated with Zyprexa that were kept hidden since the mid-90s.

In turning the document over to the press, Mr Gottstein's goal was also to alert the public about Lilly's illegal off-label marketing schemes aimed at getting doctors to prescribe Zyprexa, a drug FDA approved only for adult patients with schizophrenia or bipolar disorder, to patients of all ages for uses that were not approved as safe and effective.

Although a doctor may prescribe a drug for an unapproved use, it is illegal for Lilly to promote Zyprexa for an off-label use. The illegal marketing in this case includes influencing doctors to prescribe the drug to millions of consumers for conditions not listed on the label, prescribing Zyprexa in combination with other drugs or for a longer duration than recommended, and prescribing a drug for children that was only approved for adults.

Activists say most consumers are not even aware that it is legal for a doctor to prescribe a drug for an off-label use and take for granted that a prescribed drug picked up at a pharmacy is approved to treat their condition and their children.

The recent overdose death of 4-year-old, Rebecca Riley, in Massachusetts, demonstrates the dire need to educate the public about the practice of prescribing drugs for unapproved uses and the dangers of prescribing drugs like Zyprexa to children.

At 2-and-a-half-years-old, Rebecca was diagnosed with attention deficit disorder and bipolar disorder and was prescribed Zyprexa's atypical cousin, Seroquel, along with Clonidine, an adult high blood pressure drug, and Depakote, a drug approved to treat adults with epilepsy. None of these drugs were approved for children and they were prescribed in a combination that has never been tested even with adults.

From age 2 on, Rebecca remained on this daily drug off-label concoction until she was found dead on the floor in her parent's home on December 13, 2006. The autopsy report stated that she died of the "combined effects" of the drugs and that her lungs and heart were damaged by "prolonged abuse of these prescription drugs, rather than one incident."

Experts say, this case reinforces the assertion that judges have got to quit allowing drug makers to seal documents with court orders that show the side effects of drugs and the illegal conduct of promoting the sale of drugs for unapproved uses.

With the Zyprexa documents, as soon as the New York Times began running articles about Lilly's off-label marketing scheme and the side effects of Zyprexa, Lilly went to court and got the judge in the underlying litigation to issue a permanent injunction against Mr Gottstein, and other persons who obtained the documents from Mr Gottstein, ordering them to return the documents to the court.

However, after a couple months of legal wrangling, the court recognized that it could not restrain the world because the documents were all over the internet and lifted the part of the injunction that enjoined certain web sites from revealing the documents.

One of the documents that Lilly fought to keep secret, is a November 12, 1999, letter from a psychiatrist at the Ventura County Behavioral Health Department, Dr Albert Marrero, to Lilly's medical director, and describes the blood sugar problems occurring specifically with Zyprexa patients stating: "We have had eight patients out of possibly thirty-five patients on Zyprexa show up with high blood sugars."

Dr Marrero further informed Lilly that, "Two patients had to be hospitalized due to out of control diabetes....We have certainly never seen this with Haldol, Navane, Risperdal and others to this extent."

And yet, despite this clearly stated notification of these serious adverse events in 1999, Lilly did not revise the labeling on Zyprexa to include a warning about high blood sugar and diabetes until the fall of 2003, and then it was only because the FDA said do it.

With the health risks of Zyprexa concealed for all that time, doctors were led to believe Lilly sales representatives who said they could safely prescribe Zyprexa and Lilly gained millions of new customers.

With this in mind, the new advocacy group has launched, "The Just Say "Know" to Prescription Drugs Campaign," with a goal of getting one million people to stop and reevaluate the medications they are taking. It is also supporting Mr Gottstein in his battle with Eli Lilly over the release of the Zyprexa documents.

"If there is a case that dramatically highlights the need to stop blindly taking prescriptions drugs, this is it," says Dr Greg Tefft, co-founder of the Just Say "Know" Campaign. "We're talking 20 million people potentially at risk and more being added daily," he says.

But instead of focusing on Lilly or the judge who suppressed the documents, the Campaign says, it will educate the public about off-label prescribing and what consumers can do to protect themselves against unwittingly taking Zyprexa, or other drugs, without knowledge of the side effects or that the drugs are not approved for their condition.

"We are convinced that the way to solve this problem is to work the demand side of the market," Dr Tefft said. "We are going directly to consumers and encouraging them to know what they are taking."

To that end, a Zyprexa radio series, hosted by Dr Dominick Riccio, Chairman of the Campaign, and Dr Laurence Simon, provides information to consumers about the drug. The official web site for the Campaign is <http://justsayknow.kpncradio.com>

This group has a lofty goal because the off-label sale of Zyprexa has literally been unstoppable so far. Throughout years of litigation, while settling out of court with an estimated 26,000 Zyprexa victims, Lilly has been successful in keeping the company's off-label marketing schemes sealed under the ruse that they contain trade secrets and confidential information.

Mr Gottstein obtained the documents from Dr David Egilman, who had discovered that Lilly had failed to disclose Zyprexa's link to rapid weight gain, high blood sugar levels, and diabetes, while he was serving as an expert witness in the underlying litigation.

It's likely that Dr Egilman also knew that by settling the second batch of Zyprexa lawsuits out of court, that Lilly planned to go right on concealing the information.

The men had every reason to believe that the off-label prescribing would continue because even after paying over \$1 billion in settlements, Zyprexa was still Lilly's top-selling product with sales of more than \$4 billion in 2006.

The story behind Rebecca Riley's death, gives a clear picture of how blatant the off-label marketing scams have become. After she died, investigators discovered that her 2 siblings, ages 6 and 11, were also fed the same 3 drug cocktail every day and that the parents were on psychiatric medications as well.

Which means, if not for the disruption by Rebecca's untimely death, this family represented five steady customers for the "mental health industry," with 100% of the costs for doctor's visits and prescriptions paid for by public health care programs.

Psychotropic drug expert, Dr Ann Blake Tracy, Director, International Coalition for Drug Awareness, and author of "Prozac: Panacea or Pandora?," says, "this is what is referred to as the "Family Discount," when everyone in the family is drugged."

And this is the type of tragedy she worries about, Dr Tracy says. "The parents unable to function, the children acting up and unable to function - all due to the effects of the drugs."

She states that she would not be surprised to learn that the mother was on psychiatric drugs while she carried Rebecca which also may have caused problems for the child.

One of the world's leading experts pharmacology experts, former Secretary of the British Association for Psychopharmacology, Dr David Healy, also maintains that there is no justification for giving these drugs a 2-year-old and "certainly not for the combinations mentioned here," he states.

Testing a 2-year-old for these mental disorders, he says, can not be done.

Rebecca's parents have been charged with first-degree murder for the overdose death of a child, but many legal experts and advocacy groups say the main perpetrator is still on the loose. That being the psychiatrist with the prescription pad, Dr Kayoko Kifuji of Tufts-New England Medical Center, who diagnosed these kids with bipolar disorder and ADHD, and prescribed the drugs for all 3 children.

Attorney, Ted Chabasinski, who works on cases involving psychiatric drugs, says he is shocked that the parents are charged with the death, "while the psychiatrist who prescribed the drugs that killed her will probably never be held accountable."

"The prosecutor makes much of the fact that the parents gave drugs to their daughter that were not

approved for use in children,” he points out, “but it is the doctor, not the parents, who is responsible for that.”

Mr Chabasinski says the drug company executives, and the psychiatrists who collude with them, are criminally responsible for Rebecca's death. “This is an example,” he states, “of how the drug industry and the psychiatric profession are out of control.”

Houston Attorney, Andy Vickery, has been representing persons harmed by psychiatric drugs for many years and he also finds this story “appalling.”

He states that the father seems to be a bad actor and he may have purposely overdosed the child, but says, “he isn’t the one that started her on the psychoactive medications and someone needs to do something to hold the prescribing physician accountable.”

David Oaks, director of MindFreedom, an international human rights organization, also believes the psychiatrist should be charged with criminal negligence. “It's revealing,” he notes, “that the criminal justice system has so far targeted the parents and not the psychiatrist.”

MindFreedom is calling for criminal penalties against physicians for this level of abuse, Mr Oaks says, because it may be the only way to change their behavior.

Vera Sharav, the Director of the Alliance for Human Research Protections, also believes that the only way to stop the prescribing assault on children is to put the professionals who prescribe the toxic drug cocktails on trial in open court. “Let the public bear witness,” she states, “to the proceedings that will demonstrate the absence of scientific-medical evidence to support the widespread misprescribing of harmful drugs for children.”

Kelly Patricia O'Meara, author of, “Psyched Out: How Psychiatry Sells Mental Illness and Pushes Pills That Kill,” says the most important issue raised in the media is the response by the psychiatrist who prescribed the drugs. “Given the known adverse reactions to many of these drugs, and that they are not approved for children,” she also says, “the psychiatrist needs to be held responsible.”

As for the behaviors of family members described in the media, Ms O'Meara says, the prescription drugs they were taking could have caused many of the same. “Hostile, violent behavior,” she says, “is a possible side effect of many of the mind-altering drugs.”

Dr Healy also notes that it is at least possible that some of the alleged behaviors of the parents could be caused by the drugs they were on. As far as drugging the whole Riley family, he says, there is no mental illness that effects an entire families.

The off-label drugging of the Riley children is not an isolated incident. None of the atypicals drugs are approved for children, yet on May 11, 2006, the Associated Press reported that the number of prescriptions written for children had increased 73% over a four year period, according to Medco Health Solutions, a pharmacy benefits manager.

In addition to Zyprexa, the other atypicals in the same class include Seroquel (AstraZeneca) the drug given to the Riley children, Abilify (Bristol-Myers Squibb); Risperdal (Johnson & Johnson); Geodon (Pfizer); and Clozril (Novartis).

Dr Timothy Scott, author of, “America Fooled: The Truth about Antidepressants, Antipsychotics and

How We've Been Deceived, reports a 2005 study that found there are approximately 30,000 children under 5 on these drugs.

Overall, child neurologist, Dr Fred Baughman, author of "The ADHD Fraud: How Psychiatry Makes "Patients" of Normal Children," reports that 10 million of the 50 million school children in the nation are on one or more psychiatric drugs and states: "This is death by psychiatry."

Along with Lilly, many of the above drug makers are currently under investigation by Federal and state law enforcement agencies for promoting the atypicals for off-label use. Lawsuits have also been filed to recover the money paid by public health care programs for the actual purchase of the drugs, as well as the cost of medical treatment for patients who developed diabetes and other health problems as a result of taking them.

While Mr Gottstein and Dr Egilman may have set themselves up for big trouble by releasing the Zyprexa documents to the press; in light of the harm to the public from off-label prescribing, evidenced well by the Riley case, drastic measures were called for and they obviously believed the risks were worth taking.

According to Dr Lawrence Diller, a behavioral-developmental pediatrician, and author of "The Last Normal Child," and A Prescription for Disaster: "The extensive prescription of these medications for children, without adequate testing for safety and effectiveness in children constitutes a hidden time bomb that could explode with still more casualties."

"Catastrophic side effects," he says, "may be rare, but they become predictable when we treat so many children with so many drugs."

As for Lilly, the company has billions of reasons to keep the documents buried because they prove beyond any doubt that the company knew about the health problems caused by Zyprexa and intentionally kept the information hidden while it influenced doctors to write off-label prescriptions for million of consumers in the name of the almighty dollar.

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