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Craig Newmark Graduate School of Journalism

Fall 12-3-2019

Off-Label, On Brand: How Psychiatric Drugs Reached Unsuspecting Youths

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[Timothy Stange](#) was 12 years old, growing up in Wisconsin, when his parents took him to a doctor to treat his Tourette's syndrome, an illness marked by sudden involuntary tics and sounds.

His doctor, a neurologist who specialized in treating children, prescribed Risperdal. The drug is an antipsychotic medication that has never been approved by the U.S. Food and Drug Administration for treating Tourette's.

Instead, the prescription for Stange is deemed an off-label use, where a doctor believes a drug may still be useful, even though the FDA has not found evidence that the medication is safe or effective for treating that illness.

For Stange, the drug did not work as planned.

A year later he began Risperdal, Stange's mother took him to a pediatrician for stabbing pains around his left chest. Two years after that, Timothy had grown female-like breasts.

Classmates noticed. Timothy recounted being bullied. Six years after he first took Risperdal, the teenager needed a plastic surgeon to give him a double mastectomy to remove the breasts, leaving him with scars on his chest.

He is far from alone.

Roughly [16](#) to [20](#) percent of children and adolescents in the United States suffer from mental health illness, ranging from anxiety to depression to attention-deficit disorders and other behavioral issues, according to federal government statistics.

To treat these illnesses, psychiatrists and other mental health professionals deploy a range of therapies like counseling, classroom support, accommodations -- and drugs.

About 6 percent of all youths age 12 to 19-years-old take some kind of drug for treating a mental health issue, according to one of [the most recent studies by the US Centers for Disease Control and Prevention](#), echoing work by other researchers.

Among the more common drugs are antipsychotic medications. They are designed to help those with illnesses like schizophrenia, bipolar disorder and aggressive behaviors stemming from autism. But an expansive [study several years ago](#) estimates that two-thirds of all

antipsychotic medications prescribed for children and adolescents in the United States is off-label.

That translates into [one in every 100 adolescents](#) in America is on an antipsychotic medication like Risperdal.

Even more youths are on different medications for treating mental illness -- like antidepressants and, for attention-deficit disorders, stimulants like Adderall.

When prescriptions to those youths are for antipsychotic and antidepressant medications, there is a good chance it is off-label, with no FDA approvals. This pattern has raised concerns in the medical profession and among patients and their families.

Stange is [among](#) more than 13,600 who have sued Janssen Pharmaceuticals, a subsidiary of the drug giant Johnson & Johnson, for the physical damage he suffered, alleging the company had hidden and downplayed evidence of ill side effects. Stange's doctor said that while he was aware that Risperdal could cause a boy to grow breasts, he was under the impression this was rare.

After winning before a jury and later appeals altering the judgement, Stange settled out of court for an undisclosed sum. Others have recently won amounts from \$2.5 million to \$70 million.

Johnson & Johnson, and its subsidiary Janssen, faced an investigation by the U.S. Justice Department for [promoting](#) off-label uses of Risperdal and allegedly paying kickbacks to physicians. The companies settled the probe for \$2.2 billion. The probe included allegations regarding Risperdal and two other drugs, the antipsychotic Invega and the vascular medicine Natrecor.

Other parents and patients have sued different drug makers for promoting off-label treatments for mental health illnesses, like depression and anxiety, alleged they suffered mental damage and physical harm. Some surviving family members allege these prescriptions spurred youths to kill themselves.

HOW OFF-LABEL WORKS

To understand how off-label prescriptions work, consider the case of Clinton Harper.

Clinton was four years old when he was diagnosed with autism in 1994. His mother recalled that he was a handful.

"My son would not sleep," his mother Teresa Harper said. "He would stay up and he was like the Energizer rabbit. He'd never stop. He was just going and going and going and going. We had to slow him down."

By age six he was prescribed Risperdal, which at the time was not approved by the FDA for any use in children.

A doctor, Jan Mathisen, prescribed Risperdal to manage his symptoms.

Mathisen later testified that he had no record of telling his mother that this was off-label -- that there is no FDA-approved use of this drug for this treatment.

The FDA approves drugs and also oversees the language put on the labels of pharmaceuticals. These labels tell doctors and patients uses and risks of a drug. The approved uses mean there is a body of academic work and studies about the effectiveness and safety of the medication.

But there are times when doctors may choose to go beyond the FDA-designated uses.

Congress has long permitted wide leeway for doctors to decide when is best for prescribing drugs for off-label uses.

[Doctors are not required to tell](#) patients or -- in the case of youths, their parents -- that the medications are off-label.

For psychiatrists treating youths, this may be because standard medications are not working. A drug that helps adults -- even though it has not been tested on children for safety, side effects and effectiveness -- may be an alternative.

"There are times where it is not a totally unreasonable thing to do," said Dr. Ryan S. Sultan, a Columbia University professor and psychiatrist who has examined the use of antipsychotic medications for children.

Sultan said among the times when off-label uses might make sense is for children "getting kicked out of school regularly. They're getting suspended. You've tried behavioral treatment. You've tried individual psychotherapy. You've tried parent management and you've tried the medications that are more likely to be helpful."

While Clinton Harper was not on the verge of getting kicked out of school, the drug **worked -- at least for treating the manifestations of his autism.**

But along with the drug came side effects -- something the doctor has no record of ever warning the mother or son about, though they are listed on packaging that comes with the prescription.

In just one year, according to his mother, Clinton went from being a normal-sized kid to being “obsessed with food.” When he became too big for Teresa so manage, she felt she needed to put him in a group home.

“My child went from a baby to a grown man in one year,” Teresa Harper said. “How do you prepare for that? You don’t. You can’t. You talk about some pain.”

“If I had to do it all over again, I would not have put him on Risperdal? No,” she said. “Because it changed my son’s whole life.”

In 2016 doctors diagnosed Clinton with gynecomastia, the condition that causes the enlargement of male breasts.

Cases like Harper’s are not unusual.

Sultan [published a study](#) in 2019 examining prescriptions for treating attention deficit disorder. Medical manuals outline that the standard medications are stimulants. Sultan found 2.6 percent of those with attention deficit diagnoses were instead on antipsychotic medications, and for about half of them, stimulants were never tried.

“One of the arguments is this should never ever ever be used. And anyone who is a decent practicing clinician would say that’s ridiculous,” said Sultan. “**It should be used as a sort-of last resort.**”

WIDE RANGE OF DRUGS PRESCRIBED FOR MENTAL HEALTH

Antipsychotic medications are not the only type of medication prescribed off-label to children suffering from mental illness, and are just one category of the array of drugs that are used for mental health treatment.

The two most [common kinds of medications](#) are antidepressants -- like Lexapro and Zoloft -- and attention disorder drugs -- like Adderall and Ritalin. A little more than 3 percent of youths are on each category of these pharmaceuticals.

Antipsychotics -- such as Risperdal and Zyprexa are the third most commonly prescribed type of medication. About 1 percent of youths are on these.

[Less commonly used](#) categories of drugs are anti-anxiety medications; sedatives; hypnotics like Ambien; and drugs designed to prevent mania, like Lithium.

The use of these medications is prevalent not just for teenagers but for younger children.

When it comes to using these drugs off-label for children and adolescents, the practice is prevalent not only prevalent in the U.S, but also in other Western countries. Exact numbers are hard to come by, but by analyzing a range of data troves, researchers have documented widespread off-label use, and it is more prevalent in some categories of drugs.

A [2016 study](#) in the European Child & Adolescent Psychiatry journal found that the rates of off-label prescribing worldwide are as high as 65 percent in pediatric hospitals.

The same journal, in a separate study, found drugs for mental health illnesses were prescribed off-label at a rate of 96.4 percent at Danish outpatient clinics treating children and adolescents. It examined healthcare insurance claims that showed an off-label prescription rate for youths of 70 percent in the United States.

A [study](#) comparing Germany, the Netherlands and the United States showed that antidepressant, stimulant and antipsychotic medication use were 1.5 to 3 times higher in the United States compared to the other two nations.

The authors wrote that this indicates American families are more likely to favor medications to address mental health problems than families in Germany and the Netherlands.

Off-label prescribing of antipsychotic medication

Antipsychotic medications began entering the marketplace in the [1950s](#) are mainly for treating conditions such as bipolar disorder and schizophrenia.

A new wave of antipsychotics began entering the market in the 1990s and early 2000s that [reduced side effects like tremors, tics and Parkinsons-like tremors.](#)

Today, bipolar disorder and schizophrenia among older youths and adults are commonly treated with drugs like Risperdal and Zyprexa, which are FDA-approved on-label uses.

Throughout the last two decades, antipsychotics have undergone various label changes to better inform patients about the potential risks of both on and off-label use.

As these newer antipsychotics began [receiving](#) FDA approvals for bipolar, schizophrenia and irritability associated with autism, new age groups were also approved.

As such, the market for these drugs has exploded. In 2011, antipsychotic sales [totaled](#) \$18.2 billion, up \$2.1 billion from the prior year. [From 2013 to 2014](#), sales of Abilify, a newer antipsychotic, increased from \$6.5 billion to \$7.8 billion.

Many of the children and teenagers taking these medications are not suffering from FDA-approved conditions like schizophrenia. Instead they are taking these for off-label needs.

Between 1993 and 2010, one study found more than [two-thirds](#) of outpatient visits for those ages 4 to 18, where the result was an antipsychotic prescription, received the medication for an off-label use.

As many as 31 percent of children treated with antipsychotic medication have been diagnosed with attention disorders, while 34.5 percent of young adults treated with antipsychotics have been diagnosed with depression, [according](#) to another study.

Antipsychotics work by blocking dopamine, one of the body's naturally produced chemicals to signal pleasure.

The medications "destroy your capacity to detect the pleasurable signal in the world," said William Wirshing, a psychiatrist at the University of California in Los Angeles.

No antipsychotics have been approved for treating depression or attention disorders by the FDA for children.

The newer generation of antipsychotics have reduced some adverse events, such as involuntary movements, associated with the earlier versions of the drugs.

But the new pharmaceuticals have other side effects that the older drugs do not have -- like rapid weight gain and diabetes.

[A study in Europe](#) in 2019 found elevated adverse events for youths prescribed antipsychotic medications. While many patients benefited from the medications, 12 percent experienced an adverse event. The researchers urged doctors to closely monitor side effects.

Thousands of adolescent boys like Timothy Stange and Clinton Harper who have been prescribed Risperdal, one of the newer drugs, have suffered from growing breasts, a disorder known as gynecomastia.

In 2003, Nicholas Murray was 9 years old when he was prescribed Risperdal off-label to treat sleeping troubles attributed to his autism. He stayed on the medication until 2008, and was later diagnosed with gynecomastia.

Murray sued Janssen Pharmaceuticals, a subsidiary of the drug manufacturer Johnson & Johnson, and a jury awarded him a \$1.7 million in 2015, which was later reduced to \$680,000.

Last October, a Philadelphia jury ruled that both Janssen and its parent company would pay Murray \$8 billion in punitive damages.

Murray is far from alone. Johnson & Johnson's most recent SEC [filings](#) from October show that at least 13,600 others have sued the company over its antipsychotic drug Risperdal.

Pharma response to off-label uses, cases

Pharmaceutical companies make clear that there are countless patients who have benefited from medications to treat the mentally ill, including when doctors prescribe drugs off label.

But drug giants such as Johnson & Johnson, AstraZeneca and Eli Lilly have denied wrongdoing when faced with allegations regarding life-changing consequences from their antipsychotics.

In court they have argued that there is little evidence the drugs have caused these ill effects, and instead have blamed a patient's unhealthy diet, lifestyle or other medications.

In Murray's case, Janssen [denied](#) "any significant risk of gynecomastia from the use of Risperdal."

Under FDA regulations, drug companies are limited from promoting off-label uses. They cannot promote off-label drugs directly to patients, but they can distribute studies to doctors that show an off-label use that may be helpful.

Yet, several pharmaceutical companies have been accused of off-label marketing in recent years, and even [published brochures and professional journal ads](#).

In one of the largest health care fraud settlements in U.S. history, Johnson & Johnson reached a massive [settlement](#) with the Department of Justice in 2013.

The company paid more than \$2.2 billion "to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal, Invega and Natrecor." Both Risperdal and Invega are antipsychotic drugs.

"J&J's promotion of Risperdal for unapproved uses threatened the most vulnerable populations of our society – children, the elderly and those with developmental disabilities," [said](#) U.S. Attorney for the Eastern District of Pennsylvania Zane Memeger. "This historic settlement sends the message that drug manufacturers who place profits over patient care will face severe criminal and civil penalties."

In 2009, Zyprexa drug manufacturer Eli Lilly and Company also [entered](#) a global resolution with the Justice Department and pled guilty "to resolve criminal and civil allegations that it promoted its antipsychotic drug Zyprexa for uses not approved by the FDA."

Eli Lilly paid fines of a little more than \$1.4 billion.

Astrazeneca was forced to pay \$520 million in fines in 2010 for illegally marketing its antipsychotic drug Seroquel, including to youths, [according](#) to the Justice Department.

Combined, the manufacturers of three of the most commonly prescribed antipsychotics - AstraZeneca, Eli Lilly and Johnson and Johnson - have paid more than \$4 billion in fines in the last decade to settle off-label marketing claims. That price tag is nearly the equivalent of the net worth of the New York Yankees, the second most valuable sports franchise in the country.

Not Just Antipsychotics: Anti Depressants And Off Label Incidents

Antipsychotics are not the only drugs prescribed off-label for mental illness in youths that have been the subject of litigation.

In Massachusetts, [Delana Kiossovski was looking to treat her daughter's depression](#). Dr. Stephen Barnett put the 12-year-old on Celexa in July 2001.

Her daughter then attempted suicide twice. Her family, in court, asserted the drug was to blame.

Kiossovski joined with another patient in 2014 to sue the pharmaceutical manufacturer Forest Labs, charging that Celexa and Lexapro, another antidepressant, were promoted for off-label use in children.

The evidence in cases like the one for Kiossovski “strongly suggests that Forest engaged in a comprehensive off-label marketing scheme from 1998 through 2009 aimed at fraudulently inducing doctors to write pediatric prescriptions of Celexa and Lexapro,” US Appeals Court Judge [William J. Kayatta Jr., wrote in January 2019](#). This happened, he wrote, even though “Forest had insufficient reason to think that these drugs were effective for the treatment of depression in children and adolescents.”

Celexa was also the subject of [another lawsuit](#) against Forest Labs in 2014.

Woody Wilcox was 12 when he was prescribed Celexa off-label by an adolescent psychiatrist, David Ritvo. Ritvo stated that Wilcox exhibited signs of obsessive-compulsive disorder , attention deficit disorder, depression and anxiety. To treat these, he prescribed Celexa.

Wilcox the suffered from violent nightmares, maniacal behavior and symptoms of bipolar disorder.

Another psychiatrist, Peter Breggin, said this could have been a result of Celexa.

[Wilcox's father, Scott, sued Forest Labs](#) on the grounds that they made “fraudulent, false, unlawful and misleading representations that [Celexa] was safe and effective for minor children.”

Forest Labs countered that TK

The case was dismissed by a judge.

Eleven-year-old Trevor Blain, a Kansas resident, suffered from fear and anxiety about attending school. His parents had also divorced and his mom, Pamela Blain, became increasingly concerned about Trevor's mental stability.

She took him to a pediatrician, who would end up determining that Trevor had separation anxiety and suggested Pamela take him to a psychiatrist.

Blain followed the doctor's advice and went to see the psychiatrist, who would diagnose Trevor with depression in addition to the separation anxiety. As a result, in October 2000, Trevor began taking between 10mg and 20mg of Paxil, a popular antidepressant, daily.

Shortly thereafter, Trevor would begin exhibiting explosive outbursts, restlessness, insomnia and emotional detachment. He would end up committing suicide.

Blain [sued](#) Paxil's manufacturer, SmithKline Beecham, in 2007. She claimed in the lawsuit that "despite its specific knowledge of Paxil's association with the increased risk of suicidality in pediatric patients, the defendant GlaxoSmithKline ("GSK") failed to warn doctors, the medical community and the public of this danger."

The case continued until [2008](#), when United States District Judge Monti L. Belot denied Blain's motion for reconsideration of her case.

Self worth

The dangers of off-label prescriptions on children and adolescents isn't limited to physical side effects.

There is the bullying, as experienced by Timothy Stange, the boy who grew breasts after being prescribed Risperdal for Tourette's syndrome at age 12.

But prescribing medications for mental health can affect children's sense of self, said Tony Stanton, a child psychiatrist in Bainbridge Island near Seattle.

"Long-term, this has some really unfortunate results," he said, "For one thing, it tells the child that there's something organically wrong with them, that their brain isn't right. And they kind of have that as a legacy."

"One of the things that it does is it takes away their agency -- their ability to actually make changes in their own lives," he said.

Ali Aird, growing up Massachusetts, experienced this firsthand.

When Aird was 14 she began self-harming for attention. It was not serious, she said, but when her parents discovered the marks and read her diary, where she documented her desire to self harm, they immediately sent her to an acute hospital facility.

Aird spent ten weeks there where she was prescribed a cocktail of drugs including Seroquel.

She said her medical records indicate that she was prescribed the antipsychotic to target anger and impulsivity — both off-label uses for Seroquel — but that the anger she exhibited stemmed from being institutionalized, and arose in response to the situation she was in.

Following her hospital stay, Aird went to a group home, a therapeutic high school and wilderness therapy. She likens the experience of being “stuck in the underworld.”

At 22 — eight years after her initial hospital stay — Aird stopped taking Seroquel. She immediately felt less tired and depressed.

Aird believes that being on the medication altered her sense of who she is.

“I thought I was just lethargic, and it didn’t take me long after coming off of it [Seroquel] to realize I have a lot more clarity and energy than I thought,” she said. I was on it for so many years when I was getting to know myself. I’m a capable person; I’m not sick.”

— THE END —