

Atypical Antipsychotics for a Case of the Terrible Two's

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Until the 1950s, patients who experienced psychotic episodes were typically committed to long-term hospitalization as the only way to treat mental illness.¹ Although the welcomed 'first generation' antipsychotic medications hit the market in the 1950s, these drugs were accompanied by numerous severe side effects.² It is important to note that antipsychotic drugs do not cure mental illness but have been found to be helpful in reducing some symptoms of the illness.³ Traditionally, antipsychotic drugs have been used to treat schizophrenia and bipolar disorder, both currently incurable illnesses.⁴ Atypical antipsychotic drugs are a relatively new class of antipsychotics used to treat psychosis and other mental and emotional conditions.⁵ This new class of antipsychotics was developed in part as a response to the severe side effects of traditional first generation antipsychotics. However atypical antipsychotics are far from side-effect free. In fact, antipsychotic medication has become the dominant form of treatment for mental illness in children,⁶ Atypical antipsychotics have been approved for adults by the Food and Drug Administration ("FDA"), but there has been a recent trend escalating the prescriptions of these drugs for children by general practitioners not only for bipolar and schizophrenia, but also for mood disorders such as attention deficit hyperactivity disorder (ADHD), obsessive compulsive disorder (OCD), and sometimes even undiagnosed behavioral problems.

What Can General Practitioners Prescribe?

When a medical professional prescribes a drug for a use or manner not authorized by the FDA, it is called off-label prescribing.⁷ Off-label prescribing is a fairly common practice.⁸ Once a drug has been approved by the FDA for a specific purpose, general practitioners are given free reign to prescribe the approved drug for off-label uses.⁹ Both the American Medical Association and the FDA have recognized that physicians are in the best position to determine the treatment method for their patients, and are therefore

¹Michael D. Jibson and Rajiv Tandon, *New atypical antipsychotic medications*, 32:3-4 J. OF PSYCH. RESEARCH 215 (May 1, 1998), available at <http://www.sciencedirect.com/science/article/B6T8T-3VVVTN92-F/2/46cf1a09f5c948ddf80a206822cce492> (last visited Dec. 2, 2010).

² *Id.*

³ *Id.*

⁴ Rachel Freeland, *Traditional Versus Atypical Antipsychotics*, <http://serendip.brynmawr.edu/bb/neuro/neuro06/web2/rfreeland.html> (last visited Oct. 4, 2010).

⁵ Jibson, *supra* note 1.

⁶ H. Pincus, T. Tanielian, *et al.*, *Prescribing trends in psychotropic medication: primary care, psychiatry, and other medical specialties*, 279 JAMA 526 (1998).

⁷ Veronica Henry, *Off-Label Prescribing Legal Implications*, 20 J. LEGAL MED. 365 (1999).

⁸ Jae W. Joo, *Limit Physicians' Off Label Prescribing Practices?*, Health Reform Watch.com (Aug. 12, 2010), <http://www.healthreformwatch.com/2010/08/12/limit-physicians-off-label-prescribing-practices/>.

⁹ *Id.*

given wide discretion and autonomy in prescribing drugs for off-label uses.¹⁰ Since atypical antipsychotics have only been approved for adults, prescribing them to children is an off-label use. Unfortunately, researchers are not sure how exactly these medications affect a child's growing body. Still, physicians are free to prescribe the antipsychotic drug in a child as off-label use, even though the medicine is not approved for the specific mental disorder or age.¹¹

Who is Prescribing Atypical Antipsychotics

General practitioners typically receive only a four- to eight-week clerkship in psychiatry during medical school.¹² Non-psychiatric physicians prescribe more than 70 percent of all psychotropic medications, with nurse practitioners as the second largest group of prescribing medical professionals. This may be due in part to the well-established acute shortage of psychiatrists, as detailed by both the Surgeon General's Report on Mental Health¹³ and George W. Bush's New Freedom Commission on Mental Health.¹⁴ This critical shortage of doctors specializing in child psychiatry lead parents to rely on either adult psychiatrists for their children or, more frequently, general practitioners, obviously lacking training in the field of child psychiatry.¹⁵

What are General Physicians Prescribing Antipsychotics

Traditionally, antipsychotics were only used to treat schizophrenia and bipolar disorder but, now off-label uses include treating aggression, attention deficit disorder, and autism, as well as behavioral problems, OCD, eating disorders, refractory anxiety disorders, agitation, and anxiety.¹⁶ According to a Journal of Ambulatory Pediatrics study, a skyrocketing number of prescriptions are being written for children with attention deficit disorder and other behavioral problems even though FDA-approved package inserts state that safety and effectiveness of atypical antipsychotics has not been established for use in children.¹⁷ A nationwide study showed that the number of children prescribed atypical antipsychotic drugs has increased five-fold from 1995 to 2002, to an estimated 6 million prescriptions.¹⁸ Of those, over half of the prescriptions were written for non-psychotic

¹⁰ Jae W. Joo, *supra* note 8.

¹¹ Nat'l Inst. of Mental Health (NIMH), *Mental Health Medications*, <http://www.nimh.nih.gov/health/publications/mental-health-medications/complete-index.shtml#pub2>

¹² *Id.*

¹³ U.S. Dep't of Health and Human Servs., *MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL*, (Rockville, Md. 1999).

¹⁴ U.S. Dep't of Health and Human Servs., *The President's New Freedom Commission on Mental Health, Achieving the Promise: Transforming Mental Health Care in America* (2003).

¹⁵ Jennifer Egan, *The Bipolar Puzzle*, N.Y. TIMES, Sept. 14, 2008, <http://www.nytimes.com/2008/09/14/magazine/14bipolar-t.html>.

¹⁶ U.S. Dep't of Health and Human Servs., *Clinician Guide: Off-Label Use of Atypical Antipsychotic Drugs*, July 12, 2007, <http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=8>.

¹⁷ Eveyln Pringle, *Kids Dying From Off-Label Use Of Antipsychotics*, Lawyers and Settlements.com, May 5, 2006, <http://www.lawyersandsettlements.com/articles/00183/antipsychotics.html>.

¹⁸ *Id.*

conditions.¹⁹ Experts note that any child under the age of five receiving a prescription for antipsychotic drugs intended for adults is alarming.²⁰ Equally troubling is a report published in the *Columbus Dispatch* detailing an investigation of Ohio Medicaid records that revealed 18 children, ranging from newborn to 3 years-old had been prescribed antipsychotic drugs in July 2004 alone.²¹ Another study found that among new users, 41.4 percent had no diagnosis for which treatment was supported by a published study, the highest level of non-evidence based use was with aripiprazole at 77.1 percent.²²

Unknown Effects of Anti-Psychotics in Children

Because atypical antipsychotics work by attacking the central nervous system, the most common side effects are neurological and can include involuntary muscle spasms of the tongue, face, jaw, neck, back, larynx or eyes.²³ This is a condition commonly referred to as dystonia.²⁴ These reactions can be painful and even life-threatening if they affect the patient's airway.²⁵ Patients on antipsychotic drugs can also experience pseudo-parkinsonism, a condition that mimics the symptoms of Parkinson's disease.²⁶ The patient may develop a shuffling gait, tremors, rigid muscles or a decrease in spontaneous movement.²⁷ Many patients experience weight gain on antipsychotic drugs, with the average patient gaining between 3 and 9 pounds. Other less common side effects include seizures, sensitivity to light, jaundice (a liver condition), and increased secretion of prolactin, which can cause enlarged breasts in both boys and girls.²⁸ Prolactin can cause impotence and boys and an absence of menstrual bleeding in girls.²⁹ A few studies performed in the 1990s suggest that traditional antipsychotic agents might even contribute to such the long-term symptoms as emotional withdrawal and a blunting of the patient's ability to express emotion.³⁰

Children are especially sensitive to the effects of antipsychotic drugs. This sensitivity may increase the chance of side effects, especially muscle spasms and involuntary movements.³¹ In one study, neuroleptic malignant syndrome showed up in 41 children, and was the most troubling side effect, according to child psychiatrist Joseph Penn, of Bradley Hospital and Brown University School of Medicine, because it can kill within 24 hours.³² There are also severe long-term side effects of antipsychotic medications—some of which may be permanent. Tardive Dyskinesia is one of the most disturbing permanent

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² Pam Harrison, *Unsupported Antipsychotic Use in Children Widespread*, Medscape Medical News, <http://www.medscape.com/viewarticle/7117544>.

²³ Jibson, *supra* note 1.

²⁴ Pringle, *supra* note 17.

²⁵ Jibson, *supra* note 1.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ Pringle, *supra* note 17.

³² *Id.*

side effects, leading to facial grimaces, tics, writhing of tongue, abnormal movements of lips, neck, trunks, and limbs.³³ There is no treatment for TD and it is irreversible. Also especially troubling among children is excessive weight gain, and the inevitable diabetes diagnosis that follows.³⁴ Recently, *USA Today* sponsored an in-depth review of the FDA database from 2000 to 2004 and found at least 45 deaths of children under 18 with atypical antipsychotics listed as the "primary suspect," and 1,328 reports of other serious side effects, some life-threatening.³⁵ While these numbers are disturbing, the FDA's adverse event reporting system is voluntary and therefore is estimated to only capture between 1 percent and 10 percent of the side effects and deaths, meaning the true numbers may be significantly higher.³⁶ Of the 45 deaths, at least six were diabetes related, and other causes ranged from heart problems to choking, liver failure and suicide.³⁷

Costing Us More Than Side Effects

Three billion prescriptions for medications were written in 2001, at a cost of \$132 billion according to the Agency for Healthcare Research and Quality.³⁸ It has been estimated that costs for the treatment of medication-related injuries are in the area of \$72 to \$172 billion per year,³⁹ meaning that the annual cost of increased harm from medication approaches equal or may exceed the cost of the medications themselves. More disturbingly, antipsychotic medications have not been proven to result in improved patient functionality lowering costs of care.⁴⁰ According to some experts, "overreliance on drug therapies alone can increase the rate of treatment failure and increase the cost of mental health care."⁴¹ Although antipsychotic drugs are noticeably cheaper than long-term hospitalization and therapy, "they are still the single biggest drug expenditure for Medicaid, costing the program 7.9 billion in 2006, the most recent year for which data is available."⁴²

With All the Side Effects and Costs Why Prescribe Them at All

³³ *Id.*

³⁴ Pringle, *supra* note 17.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ U.S. Dep't of Health and Human Servs., Agency for Healthcare Research and Quality, *Reducing and preventing adverse drug events to decrease hospital costs*, Research in Action, Issue 1, no 01-0020, Mar. 2001.

³⁹ D. Classen, S. Pestonik, *et al.*, *Adverse events in hospitalized patients: excess length of stay, extra costs, and attributable mortality*, 277 JAMA 301 (1997).

⁴⁰ W.T. O'DONOHUE, K.E. FERGUSON, *ET AL.*, REFLECTIONS ON THE MEDICAL-COST OFFSET EFFECT, IN THE IMPACT OF MEDICAL COST OFFSET ON PRACTICE AND RESEARCH: MAKING IT WORK FOR YOU (Context Press, 2002).

⁴¹ J. McCombs, M. Nichol, *et al.*, *The cost of antidepressant drug therapy failure: a study of antidepressant use patterns in a Medicaid population*, 51 J. CLINICAL PSY. 60 (1990); H. Henk, D. Katzelnick, *et al.*, *Medical costs attributed to depression among patients with a history of high medical expenses in a health maintenance organization*, 33 ARCHIVES OF GEN. PSY. 899 (1996).

⁴² Duff Wilson, *Poor Children Likelier to Get Antipsychotics*, N.Y. TIMES, Dec. 12, 2009.

Psychiatrists do agree antipsychotic drugs can be helpful for children with serious mental illnesses and have been known to save young lives. In fact, it is well documented that the lives of schizophrenic and severely manic children may be saved by antipsychotics.⁴³ John March, chief of child and adolescent psychiatry at Duke University School of Medicine, prescribes antipsychotic drugs to children in some cases of serious illness when he believes the benefits outweigh the risks.⁴⁴ "I use them myself for patients," says March, "I have a 9-year-old who threatened to jump out of a second-story window if her mom didn't give her the car keys to drive down to the 7-Eleven to get a Coke. If I took her off antipsychotics, she'd disintegrate."⁴⁵ Even though antipsychotic drugs cannot cure mental illness, they manage illnesses enough for the patient to undergo counseling and lead a more normal life.⁴⁶ In a child with severe mental illness, antipsychotic drugs may minimize or even eliminate the effects of psychosis.⁴⁷ There are also dangers of misdiagnosing a child who does in fact suffer from a severe mental illness with a behavioral disorder. For example, if the doctor diagnosis a child with ADHD, instead of the proper bipolar disorder, the doctor is likely to prescribe a stimulant such as Ritalin and can make the child's symptoms worse.⁴⁸

Conclusion

Antipsychotics are too powerful and come with too many costs to be given freely, especially to children. According to the National Institute of Mental Health, schizophrenia is rare in children under 18, affecting about 1 in 40,000, as opposed to 1 in 100 adults.⁴⁹ Nobody knows exactly how many kids have bipolar disorder; psychiatrists cannot even agree on criteria to diagnose the disease in children. This is troubling since the number of 2-5 year-olds prescribed antipsychotic drugs has doubled between the years of 2000 and 2007, according to a recent study by Columbia University.⁵⁰ Paul Vincent, of the Child Welfare Policy and Practice Group, says children as young as four are getting prescriptions for antipsychotics, oftentimes from unqualified counselors. "They aren't psychiatrists or even psychologists. I have considerable worry about the accuracy of these diagnoses."⁵¹ These medications work differently for different people. Some patients get great results, some end up persisting in a somewhat drowsy vegetative state, some need them only a short time, and others for life.⁵² Patients with schizophrenia or bipolar disorder may need to take medication for a much longer time.⁵³ Doses can be small or large, depending on the medication and the person, as well as factors which affect how medications affect those who taken them, including:

⁴³ Marilyn Elias, *New Antipsychotic Drugs Carry Risks For Children*, USA TODAY, May 2, 2006, http://www.usatoday.com/news/health/2006-05-01-atypical-drugs_x.htm.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Jibson, *supra* note 1.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Elias, *supra* note 43.

⁵⁰ USA Today, *For foster kids, oversight of prescriptions is scarce*, May 2, 2006, http://www.usatoday.com/news/health/2006-05-01-antipsychotics-foster-kids_x.htm.

⁵¹ *Id.*

⁵² NIMH, *supra* note 11.

⁵³ *Id.*

“...type of mental disorder, such as depression, anxiety, bipolar disorder, and schizophrenia, age, sex, and body size, physical illnesses, habits like smoking and drinking, liver and kidney function, genetics, other medications and herbal/vitamin supplements, diet, whether medications are taken as prescribed.”⁵⁴

For example, NIMH produced an article in the Journal of American Academy of Child and Adolescent Psychiatry warning that, “the validity or diagnosing bipolar disorder in preschool children has not been established...until the validity of diagnosis is established in preschoolers, caution should be taken before making the diagnosis in anyone younger than six.”⁵⁵ Due to the large discrepancy in diagnosing severe mental illness, general practitioners are just not equipped with the specialized knowledge necessary to make a proper diagnosis and subsequently prescribe antipsychotic medication for children. Dr. Teri Carlson notes, “if you have a child who’s got this behavior but you’re not sure how it’s going to evolve, to say to somebody, ‘You’ve got to be on this medication for the rest of your life’ is sentencing someone to something that is premature. And in the case of some of these medications, when we’re not sure of some of the metabolic side effects, you may be exposing them to a risk they don’t need to have.”⁵⁶ Dr. Phyllis Hyman blames the recent over-prescription of antipsychotics in children on, “the diagnosis being spread too broadly, so that powerful drugs are being prescribed too widely” and warns, “we are going to have hell to pay in terms of side effects.”⁵⁷

Even if a general practitioner could accurately diagnose a mental illness in a child, antipsychotic drugs should not be prescribed without a full psychiatric care plan. The National Mental Health Association points out that although atypical antipsychotic medicines offer hope to many patients, the medicines themselves must be used in a supportive environment to be effective.⁵⁸ This type of full psychiatric medical screening and supportive plan is simply not within the purview of a general practitioner’s job description.

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⁵⁴ *Id.*

⁵⁵ Jerome Groopman, *What’s Normal?*, THE NEW YORKER, Apr. 9, 2007, at 28.

⁵⁶ Alix Spiegel, *Children Labeled ‘Bipolar’ May Get a New Diagnosis*, NPR (Feb. 10, 2010), <http://www.npr.org/templates/story/story.php?storyId=123544191>.

⁵⁷ Groopman, *supra* note 55.

⁵⁸ Jibson, *supra* note 1.

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