# Drugging Our Children

## Introduction

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The field of children's mental health has recently undergone a disturbing change. Market forces rather than medical research drive the practice of child psychiatry.[i] The profit motive has undermined even the most basic elements of safe and effective care. While giving children multiple psychiatric diagnoses and placing them on questionable polypharmacy regimens has been an accepted practice for some time[ii], the past decade has witnessed an alarming increase in the use of antipsychotics.

A landmark study conducted by Columbia University Professor Mark Olfson and his colleagues cataloged prescription rates of over a million children covered by private insurance, and revealed that since 2001 the number of antipsychotic prescriptions written for toddlers and preschoolers has doubled.[iii] They also discovered that in a majority of cases, prescriptions were written to treat conditions for which the use of antipsychotic medication is neither FDA approved nor justified by research and mental health assessments were rarely conducted. While antipsychotic drug use among middle class children has doubled, prescribing rates to low-income children covered by Medicaid have quadrupled.[iv] Poor children are also more likely to receive an antipsychotic prescription from a pediatrician with no expertise in psychiatry and to have no recourse to psychotherapy. It is not only unethical but illegal for doctors billing under Medicaid to write "off label" drug prescriptions for children and youth. This common practice has been largely ignored by the mental health community, an issue which attorney and childhood advocate Jim Gottstein addresses in chapter 6[v]

It is commonly believed that Medicaid favors drug therapies because they are more cost and time effective than psychotherapies, but neither claim is accurate. At 8 billion a year (and climbing) Medicaid now pays more for antipsychotic medication than for any other category of drug, and once on an antipsychotic, withdrawal symptoms make it not only difficult, but often dangerous to stop. Also, antipsychotics don't cure illness, they mask symptoms and if the cause of the symptoms aren't addressed the child will not improve and drug use will likely continue. Consequently, antipsychotics prescribed in childhood often become a lifelong habit.[vi] Clearly, these "cradle to grave" prescribing practices are a financial bonanza for the pharmaceutical industry.

**Dangerous Drugs**

The antipsychotic drugs that are currently in use are referred to as "atypical" to distinguish them from the original antipsychotic drugs developed in the 1950s for the treatment of adult Schizophrenia. Atypical antipsychotics came on on to the market in the 1990s because the older antipsychotics were no longer under patent and generic versions were undercutting profits. The "new and improved" antipsychotics were introduced to the public through a well orchestrated series of stories in the media about the poor efficacy of the first generation of antipsychotic medications which were "exposed" as carrying a high risk of dangerous side effects (although this was in fact known for decades). The atypical antipsychotics were widely touted as highly "precise" drugs for the treatment of schizophrenia, with very few side effects.[vii]

But these claims were not borne out in the research. A review of clinical trials involving more than 12,000 patients, which was published in the *British Medical Journal* in 2000, found "no clear evidence that atypical antipsychotics are more effective or better tolerated than conventional antiypsychotics."[viii] In fact, in the letter of approval to Janssen – the manufacturer of the atypical antipsychotic Risperdal – the FDA stated that:

> "We would consider any advertisement or promotional labeling for Risperdal false, misleading, or lacking fair balance under 502 (a) and 502 (n) of the ACT if there is presentation of data that

conveys the impression that risperidone[1] is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness."[ix]

Furthermore, once Risperdal came on to the market, researchers without ties to drug companies were free to test it, and study after study has raised significant doubts about it's safety and efficacy. Studies from McMaster University in Canada, the NIMH and the University of Pittsburgh demonstrated that even a low dose of risperidone could cause Parkinsonism, akathisia, and extrapyramidal symptoms; the very same side effects associated with the first generation of antipsychotics. The prestigious medical journal *Lancet* wrote a scathing review of the research practices that Janssen's researchers used to gain approval from the FDA, and concluded that risperidone was a "marketing success, if nothing else."[x] But, lacking Janssen's PR budget, Lancet's findings were not aired in the media.

Similarly, though Eli Lilly's atypical antipsychotic drug olanzapine – which goes by the trade name Zyprexa – received FDA approval, twenty of the 2,500 patients who received olanzapine in clinical trials died. Twelve killed themselves, and two of the remaining eight deaths, from "aspiration pneumonia" were seen by FDA reviewers as possibly causally related to olanzapine. Twenty-two percent of the olanzapine patients suffered a "serious" adverse event. Two-thirds of the olanzapine patients didn't successfully complete the trials. More than one-fourth of the patients complained that the drug made them sleepy. Weight gain was a frequent problem, and other problems documented included Parkinson's akathisia, dystonia, hypotension, constipation, tachycardia, diabetic complications, seizures, increases in serum prolactin, liver abnormalities, and white blood cell disorders.[xi] Paul Leber, the former director of the FDA's Division of Neuropharmacological Drugs concluded that "*no one should be surprised if, upon marketing, events of all kinds and severity not previously identified are reported in association with olanzapine's use*."[xii]

These very same atypical antipsychotics, initially marketed to adult schizophrenics are now prescribed to hundreds of thousands of children across the U.S. But, as award winning journalist Robert Whitaker demonstrates in chapter 2, these drugs are even more injurious to children's developing brains and bodies.[xiii] Risperdal and its generic cousin risperidone account for three quarters of the antipsychotics prescribed to children. Risperidone has proven to be such a dangerous drug that it is the subject of multiple lawsuits.[xiv] One side effect, which has prompted several of the law suits, is that it dramatically increases children's prolactin levels which has resulted in numerous boys experiencing full breast development, necessitating mastectomies.[xv]

**Off-Label Prescriptions**

Once a drug receives FDA approval, it can also be prescribed "off label" for *any* condition by *any* MD billing under private insurance, regardless of whether he or she is a mental health specialist. As award winning journalist Robert Whitaker demonstrates in chapter 2 when a drug is used "off label", its efficacy in treating the condition for which it was prescribed has not been proven. Atypical antipsychotics have been approved by the FDA for use with children to treat Bipolar Disorder, Schizophrenia and irritability associated with Autism, but in a majority of cases antipsychotics are prescribed to children to treat other conditions such as ADHD and Depression, or to control aggression and insomnia, though that no sound research exists to support these applications.[xvi] Even where FDA approval for the use of antipsychotics with children has been granted, the research is scant, short-term and as we will see, of questionable validity.

**Marketing Versus Evidence-Based Research**

The pharmaceutical industry has insinuated itself into every aspect of medical education, research and practice. It provides the lion's share of funding for medical schools and hospitals, designs and implements drug research, supports medical journals through its advertising, and "ghost writes"

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[1] Risperdal is the trade name for risperidone.

many lead articles. It heavily underwrites medical conferences and continuing education and bankrolls MDs, researchers and even FDA employees. And it relentlessly markets its psychiatric drugs to mental health practitioners and the public at large. Even children are directly targeted by its marketing schemes through promotional materials such as coloring and picture books. As a consequence, psychiatric drug research and prevailing prescribing practices have become deeply enmeshed with the interests of pharmaceutical corporations, and they are thoroughly compromised as Gwen Olsen, a former pharmaceutical industry insider reveals in Chapter 1.[xvii]

The collusive relationship between psychiatry and the pharmaceutical industry compels us to scrutinize research that supports the use of psychotropic medication. We need to ask whether the researchers were in the employ of or received grants from any drug companies, whether the lead author actually conducted the research and wrote the article or whether his or her reputation was purchased, and what drug companies support the journals in which the research appears. A recent inquiry headed by Senator Charles Grassley, the ranking member of the Senate Finance Committee, revealed that Harvard professor Joseph Biederman – who almost single handedly popularized the Pediatric Bipolar diagnosis, received 1.6 million dollars in undisclosed consulting fees from assorted drug companies. Even more damning, email communications and slide presentations to Johnson and Johnson revealed that Biederman promised that his future research would "support the safety and effectiveness of their antipsychotic risperidone" in preschoolers.[xviii] It is impossible to overstate the cynicism entailed in creating a market among young children for a drug that is so perilous to their physical and neurological integrity.

**Generic Effects**

In a perfect world, after the cause and course of an illness is understood, a medication is then designed to combat it with great specificity. This has virtually never been the case with psychiatric drugs, most of which were discovered by accident or through trial and error to mitigate some of the symptoms of a given psychiatric syndrome. Thorazine (chlorpromazine), the first drug to be marketed as an antipsychotic in the 1950s – was originally used as a surgical anesthetic. Its ability to calm the delusions and hallucinations of schizophrenic patients was stumbled upon by a surgeon who was using it to tranquilize a patient prior to surgery who just happened to be schizophrenic.[xix] Antipsychotics were not *designed* to correct the alleged neurochemical imbalances that cause the psychotic and manic states associated with Schizophrenia and Bipolar Disorder in the way that insulin treats diabetes. And marketing claims notwithstanding, the newer, "atypical" antipsychotics are no more precise than their older cousins that have fallen into such disrepute. Antipsychotics used to be referred to as Major Tranquilizers. They will, at least initially, "calm" an aggressive or agitated child. *Anyone* who takes an antipsychotic will be tranquilized.[xx] But at the same time, they constitute such an assault to a child's body and brain that it is hard to fathom why they are being prescribed so widely and casually, when safer and more effective and humane treatment modalities already exist.

**Sidelining Professional Practice**

As antipsychotics become more widely prescribed by non mental health specialists, there has been a precipitous drop in thorough, thoughtful diagnostic assessments and access to psychotherapy.[xxi] It is unethical to prescribe an antipsychotic, or any psychiatric drug, without a comprehensive assessment. Prescribing a potent antipsychotic to a child without an assessment when other, more reliable methods of treatment are available is not only unethical, it is profoundly dehumanizing. When children act out or experience overwhelming fear, anger or sadness, their behaviors and emotions are meaningful communications that need to be understood and addressed. Treating their actions and feelings as symptoms to be medicated away desensitizes us to the cause and depth of their suffering and denies them access to effective care.

In the 1980s, the children's mental health field witnessed the unprecedented rise in the use of stimulant medication. SSRI antidepressants became the "drug of choice" in the 1990s. Both classes of drugs are associated with a host of risk factors. In fact, SSRI antidepressant prescriptions to children

now come with a “black box” warning issued by the FDA that taking these drugs place children at a higher risk for suicide.[xxii] With each passing decade the field of child psychiatry is careening wildly towards increasingly dangerous treatment regimens that now include drug “cocktails” and antipsychotics for preschoolers. Drugging our children offers a “quick fix” that relieves us of the challenging work of addressing complex and multifaceted cultural and environmental factors that are often the source of children's suffering.[xxiii]

**A Culture that has Lost It's Compass**

When children’s cries for help are silenced by thoughtless and inappropriate prescriptions that could tranquilize an elephant, we conveniently ignore a host of social issues that undermine the integrity of families and children's mental health. The U.S. has the weakest public policies among wealthy nations in support of family life. It is the only economically advantaged country that does not guarantee maternity leave to all women, and one of a handful of countries that does not subsidize and regulate its daycares. As a consequence, women who cannot afford to forgo a paycheck after giving birth are forced to rush back to work before they or their newborns are physically or emotionally ready, while placing their infants in settings that offer substandard care. It does not take a degree in psychology to appreciate that this arrangement undermines the health of the mother who is still recovering from childbirth and robs parents and their children of a critically important opportunity to form secure and loving attachments. Other significant challenges to children's mental health include weak environmental protection policies that expose children to scores of neurotoxic chemicals, a public school system that privileges standardized testing over developmentally appropriate curricula, limited opportunities for young children to play creatively in natural settings, and pervasive media that immerse children in sexualized and violent worlds while reducing their worth to a market share. Each of these issues, which I discuss at length in chapter 4, are complex and require time and energy to address. But we can't eradicate their impact on children's health by giving them psychiatric drugs that numb their feelings and damage their brains.

**Fixing the Problem**

The psychiatric community is evidencing some awareness of its own culpability. The American Psychiatric Association recently revealed that it does not plan to include pediatric Bipolar Disorder (BD) in its newest revision of the Diagnostic and Statistical Manual (DSM) due out in 2012[xxiv], a tacit acknowledgement that this diagnosis has been far too casually applied to children. The alleged symptom picture of pediatric BD has no continuity with the symptoms of adult BD, and research has shown that children assigned the pediatric Bipolar label are not developing into adults with BD. However, plans are afoot to replace the pediatric BD diagnosis with a new diagnostic category called Temper Disregulation Disorder (TDD) an alleged brain disorder which has no research support, and will likely generate as many drug sales as Pediatric BD. And so the impact of this change is cosmetic at best.

While it is necessary to hold child psychiatrists and pediatricians accountable for their prescribing practices, those of us who work in the mental health arena but do not have the mandate to prescribe drugs, including psychologists, social workers and counselors, must examine our own responsibility to protect our young clients from harm. With increasing frequency, mental health professionals who may diagnose and treat but not medicate are referred children who have already begun a course of psychiatric medication or are scheduled to see a psychiatrist. If we feel that a child has been misdiagnosed and in consequence inappropriately prescribed an antipsychotic, or if we agree with the diagnosis but are aware of the harmful side effects of the medication, what legal and ethical considerations should guide our actions? These issues are addressed by psychologists Jacqueline Sparks and Barry Duncan in chapter 5 and attorney Jim Gottstein in chapter 6.

**Drugging Our Children**

*Drugging Our Children* is divided into three parts. The first section articulates the problem in all of its complexity:

- the role of the pharmaceutical industry in creating a child market for antipsychotics
- the impact of antipsychotics on a child's developing, brain and body
- the factors that have led the field of child psychiatry to make a devil's bargain with the pharmaceutical industry in its relentless promotion of antipsychotic medication as first line treatment
- the ways in which American culture undermines children's healthy psychological development and foments the belief that the lion's share of children's behavioral and emotional issues are biochemical processes that can be fixed with a pill.

The next section explores the legal and ethical ramifications of drugging our children. For example, what recourse do parents have if they believe that their child has been harmed by medication? What are the risks involved if they refuse to medicate their child? What ethical and legal rights and responsibilities do non prescribing mental health practitioners have if they believe that a child in their care is being wrongfully medicated and harmed in the process?

The final section offers solutions that address the power of family and community to foster and protect children's psychological development before problems arise or become entrenched, and provides examples of effective interventions without recourse to antipsychotics. Child psychiatrist Tony Stanton shares more than a quarter of a century of experience in a residential setting, working with children who had cycled through multiple failed placements and were heavily medicated with drug cocktails that usually included antipsychotics when they first arrived. Social worker George Stone describes his decades of experience as a family therapist working with violent and "Bipolar" children, who had already been prescribed or were candidates for antipsychotic medication. Psychologist Adena Meyers and her colleague Laura Berk, a leading expert in child development remind us of the central role that parents can play in supporting their children's development and inoculating them against some of the psychological risk factors that we all inevitably face. And Stuart Shanker, an internationally known childhood expert introduces a model of community intervention to proactively protect children's health and avoid the behavioral and emotional issues that lead to drugging.

When I began my research for this book, I believed that antipsychotics were dangerous drugs that were being recklessly prescribed to children but imagined that in rare instances, they were warranted. After immersing myself more deeply in the literature and the work of my fellow authors, I now share my co-editor Brent Robbins' position that antipsychotic drug use with children is not warranted by the research. The risks that it poses to children's minds and bodies far outweigh any conceivable benefits, and as such there should be a moratorium on antipsychotic prescriptions to all children. Many, but not all of the authors who have contributed to *Drugging Our Children* share this position, We are however, united in our belief that the cause and cure of children's psychological challenges are as complex and multifaceted as human nature itself, and tranquilizing children with antipsychotics who have no recourse to a thorough assessment and psychotherapy represents nothing less than malpractice It is in my opinion a form of legally sanctioned child abuse. The authors who contributed to *Drugging Our Children* include some of America's leading childhood experts and advocates, and are committed to putting an end to the rampant and irresponsible use of antipsycotic medication with children while promoting effective and humane mental health practice.

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