

The Overmedication of Vulnerable Youth with Psychiatric Medication

A Call for New Regulations

Introduction

In the past ten years much concern has been raised about the increasing, excessive and inappropriate use of off-label psychiatric medications for children. In addition, the use of medication cocktails (polypharmacy) has become increasingly common in child psychiatry. These medications have significant potential for harm. Many have serious, long-term side effects such as weight gain, obesity, diabetes, high cholesterol, movement disorders, seizures, cardiac arrhythmias, neurological disorders, violence and suicide. Several medication-related deaths have been reported in the past ten years. In 2006, the Food and Drug Administration (FDA) received reports of at least 29 children dying and at least 165 more suffering serious side effects in which an antipsychotic was listed as the “primary suspect.” That was a substantial jump from 2000, when there were at least 10 deaths and 85 serious side effects among children linked to the drugs¹. Since reporting of bad drug effects is mostly voluntary, these numbers likely represent a fraction of the toll. Poor children who are covered by Medicaid insurance² and children in State Care (foster care)³, also covered by Medicaid insurance are more likely to be prescribed psychiatric medication. In addition, the use of antipsychotics in children with Medicaid coverage is five times that of children in the private sector⁴. The unholy alliance between the Pharmaceutical industry, Media Industry, Insurance industry, Medical profession, Academic/

University centers and school systems across the county combined with the lack of government oversight (FDA, Medicaid, State medical boards) has led to a confluence of influence to create the current situation.

The Pharmaceutical Industry

The pharmaceutical industry has been wildly profitable in their quest to create and market psychiatric medications to doctors and consumers. In 2012 the top 11 global drug companies made \$85 billion in net profits.⁵ In the past decade these companies have spent large amounts of money providing gifts, expensive dinners etc for doctors in hopes of influencing their prescribing patterns. Psychiatric medications are among the most widely prescribed and biggest selling class of drugs in the U.S. So why are so many children being prescribed off label psychiatric medication? **Off-label use** is defined as the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, unapproved dosage, or unapproved form of administration. The Federal Drug Administration (FDA) does not have the legal authority to regulate the practice of the medicine, and the physician may prescribe a drug off-label.

Under the Federal Food and Drug Cosmetic act it is illegal for pharmaceutical companies to promote their products for uses not approved by the FDA, and corporations that market drugs for off-label indications may be subject to civil liability under the False Claims Act as well as criminal penalties. Despite this law, many pharmaceutical companies heavily marketed off-label psychiatric medications for use in children to psychiatrists and primary care physicians such as pediatricians and family practitioners. Several successful lawsuits have been brought against

companies such as Bristol Myers Squibb, Eli Lilly, Astra Zeneca, Forrest and Pfizer since 2007 for off-label marketing of psychiatric medications for children.

The pharmaceutical industry spends more than any other industry group each year to influence lawmakers. They spent 2.6 billion dollars on lobbying activities from 1998 to 2012 according to Opensecrets.org. This amount is significantly larger than the 1.6 billion spent by the Oil and gas industry during the same time frame. ⁶ One may wonder why Medicaid would pay for children to be prescribed off-label psychiatric medications or worse, dangerous medication cocktails that are not supported by any valid practice guideline. There is little doubt that the lobbyists have influenced decision makers regarding which medications are available on Medicaid Formularies.

Academic Research Programs

Pharmaceutical companies have also invaded academic research centers providing large monetary payments to research physicians. The most egregious example of this occurred in 2008 when three child psychiatrists at Harvard Medical School were disciplined for not disclosing their acceptance of millions of dollars in consulting fees from pharmaceutical companies. One of these doctors, Dr. Joseph Biederman, one of the world's most influential child psychiatrists was disciplined for accepting these consulting fees while conducting research on drugs manufactured by these companies. The National Institute of Health (NIH) relies upon research institutions themselves to monitor the interests of researchers. Universities do this by requesting academics to voluntarily declare conflicts. The three Harvard scientists, who failed to report the full extent

of their industrial payments, said that their collective misconduct was an honest mistake and that they had always believed that they were “complying in good faith with institutional policies”.⁷

Media

The Media is considered by many to be the watchdog that highlights the interconnections between doctors, researchers and the drug companies. In recent years, concerns have been raised about the financial ties between medical journalists and pharmaceutical companies.⁸ 90% of school shootings have been linked to the use of psychiatric medications⁹. It is quite curious that the U. S. mainstream media provided minimal to no reporting on this connection.

Insurance Industry Influences Child Psychiatry Training and Practice

With the advent of Managed Care in the 1970’s, insurance plans with a focus on cost cutting began to decrease reimbursement rates for psychotherapy, while readily covering the prescription of psychiatric medications by physicians. When psychiatric patients were hospitalized (very expensive), the insurance reviewers typically pushed the doctor to increase the patient’s medications or add more medications and then discharge the patient as soon as possible.

Needless to say, the role of psychiatrists in the U.S. mental health system has significantly changed. These specialist physicians have essentially been forced into a singular role as medication prescriber, since psychotherapy is now the preveue of Psychologists and therapists.

One could argue that psychiatrists should be willing to take less money and offer therapy to their patients as well. It must be kept in mind that many Psychiatrists are saddled with educational

debt after completing a very long training program (four years post medical school for general psychiatrists and five years post medical school for child psychiatrists). The median starting salary for general and child psychiatrists is among the lowest of the medical specialties¹⁰. It is also important to note that over the past ten years, Academic training programs for child psychiatrists have increasingly focused on medication interventions as opposed to psychotherapy. Most newly trained child psychiatrists are not competent to perform psychotherapy even if they could afford to do so. Finally, the shortage of fully trained child psychiatrists in the U.S. has been well documented for over twenty years¹¹. By 2015, the American Psychiatric Association predicts a shortage of about 22,000 child psychiatrists according to data on the American Academy of Child and Adolescent Psychiatry website. Many children with severe mental health issues are and will receive medications from primary care physicians who are not adequately trained and therefore unqualified to be prescribing psychiatric medications.

Medical Profession and role of Professional Organizations

As previously noted, the FDA does not have the legal authority to regulate the practice of medicine. So, what agency does? Under the 10th Amendment of the U.S. Constitution, states have the authority to regulate activities that affect health, safety and welfare of their citizens. To protect the public from the unprofessional, improper, unlawful, fraudulent and/or incompetent practice of medicine, states provide laws and regulations that outline the practice of medicine and the responsibility of the medical board to regulate that practice in the state's "Medical Practice Act". Prescribing off-label is not malpractice. Case law supports clinicians' authority to

do it. In the case of *United States v Evers*,¹² the court held that a physician could prescribe a drug for a different dose than recommended in the prescribing guides if it was not contraindicated. In one court case, the opinion read, "In some circumstances, the off-label use of a particular drug or device may even define the standard of care".

Off-label prescribing is an especially important issue for pediatric patients. Approximately 75% of all drugs prescribed for children have not been tested in children, so the labeling approved by the FDA regarding dosing, indications, and precautions in the drug references are, for the most part, applicable to adults, not children. One may wonder what role Professional organizations play in supporting safe and evidence-based medication practices. The American Academy of Child and Adolescent Psychiatry (AACAP) has published several guidelines called *Practice Parameters* that clearly address safe medication practices for child psychiatrists. However, there is no law or requirement that physicians must follow the guidelines. Despite growing criticism by the public about the inappropriate use of psychiatric medications in the pediatric population, AACAP has been relatively silent. Since they are dependent upon member dues payments, it is likely that they would not want to offend their membership. It is also important to note that AACAP and its members have come under fire in recent years for accepting Pharmaceutical payouts for providing promotional lectures as Key Opinion Leaders (KOL's). AACAP had developed new Ethics rules in recent years in response to these criticisms. Finally, it is important to realize that physician autonomy- having the freedom to treat patients according to their best judgment- has been a huge part of how doctors have traditionally defined themselves as professionals. The American Medical Association (AMA) has a long history of

fighting for the rights of doctors to remain autonomous. The AMA has filed many legal briefs over the years addressing issues impacting physician autonomy.

U.S. Education System

Overwhelmed and under funded public school systems across the country often view psychiatric medication as a way to “control” disruptive children. Inner city school districts that are responsible for educating children who are poor and/or disabled are often saddled with the burden of large classrooms and inadequate resources. It is not surprising that teachers in such schools suggest medication to parents out of a sense of desperation. Most parents are unaware that schools cannot require a child to take a psychiatric drug as a condition of attending school. Any coercion or pressure put on the parent violates federal law¹³. In addition, for disabled children to obtain special education services as mandated by Federal law through the Individuals with Disabilities Act (IDEA), parents are typically required to jump through numerous administrative hoops. When these children are frequently getting suspended due to disruptive behavior, parents feel increased pressure to medicate.

Government

The rates of social security disability applications for children due to mental illness have significantly increased. Mental illness is now the leading cause of disability in children. Between 1987 and 2007, the number of disabled mentally ill children rose by thirty-five fold. ¹⁴ Many have posited that this is a direct result or unintended consequence of Welfare Reform. Families living in poverty may see this as a way to replace lost welfare benefits. The current system may

be contributing to the inappropriate use of psychiatric medications in poor children since the more medication a child is prescribed, the more “ill” (disabled) the child looks on paper.

As already covered, the FDA has no legal authority to regulate physician practice. The federal government in partnership with State governments does have the authority to determine how Medicaid dollars are spent. Psychiatric medications are among the most costly and commonly prescribed drugs in Medicaid¹⁵. Many drug manufacturers provide rebates to the federal government each time their drug is dispensed to a Medicaid patient through the Medicaid Drug Rebate Program. Even with the rebates, the Medicaid program is a clear profit maker for the pharmaceutical industry.

Children have few rights and legal protections in the U.S. They are generally medicated with psychiatric drugs because their legal guardian has provided consent. Psychiatrists who prescribe these medications to children are expected to complete a robust informed consent process such that the risks and benefits are clearly outlined. There is currently no law that requires a physician to inform a patient or guardian that a medication is being prescribed off-label or outside practice guidelines.

Hope For Change

In the past few years, The Media has begun to pay closer attention to this issue. Several articles have been published in the *New York Times* and *Time* magazine. ABC news aired an informative, compelling *20/20* special in 2012 about the overmedication of children in State care. Congress held public hearings in 2008 and 2012 that focused on the use of psychotropic drugs for children in foster care. The outcome of these hearings was a new requirement (regulation)

that States develop a policy for oversight/monitoring of psychiatric medication use for children in State care. A few States such as Florida and Massachusetts have shown leadership in this area by requiring a second opinion review by a State employed, board certified Child Psychiatrist.

There has been increasing activism around this issue by influential authors, physicians and lawyers in the past decade. Robert Whitaker, a successful journalist has written numerous award-winning articles on the mentally ill and the pharmaceutical industry such as *Mad in America* and *Anatomy of an Epidemic*. He is a sought after speaker all over the country and has many followers through social media. Doctor Peter Breggin, a well respected, Harvard trained psychiatrist has written numerous books detailing the dangers of psychiatric medication. Though, Dr. Breggin is not a child psychiatrist he has been an outspoken critic of recent trends in the U. S. of overmedicating children with psychiatric drugs.

Alaska attorney, Jim Gottstein has made it his life's work to "change the mental health system". A Harvard law school graduate and psychiatric survivor himself, Mr. Gottstein has successfully brought numerous lawsuits promoting the rights of the mentally ill. He founded the non-profit organization PsychRights –Law project for psychiatric rights. This organization has aggressively focused on the issue of overmedication of poor children through their *Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth*. Mr. Gottstein's organization has encouraged others to bring Qui Tam Complaints based on the False Claims Act. Mr. Gottstein notes that in 42 USC 1396R-8(k)(3), as relevant here, Congress prohibited reimbursement under Medicaid for any outpatient drugs "used for a medical indication which is not a medically accepted indication." Therefore any doctor or pharmacist who processes off-label psychiatric prescriptions is committing Medicaid Fraud. On August 28, 2013, in *United*

States and State of Wisconsin ex rel. Dr. Toby Watson v. Jennifer King-Vassel, the United States Court of Appeals for the Seventh Circuit issued an opinion validating the approach.¹⁶

In September, 2013 the American Psychiatric Association (APA) through the ABIM foundation initiative, *Choosing Wisely*[®] published a set of guidelines entitled “Five Things Physicians and Patients Should Question” which included five “Don’ts” regarding the prescribing of psychiatric medications. The fifth “Don’t” specifically addresses the dangers associated with prescribing antipsychotic medications to children. It is important to note that the APA is not AACAP (professional organization for child and adolescent psychiatrists).

Recommendations

1. Physicians should be required by law to disclose and document said disclosure to legal guardians when prescribing off-label medications to pediatric patients.
2. State Medical boards should pro-actively monitor the prescribing practices of its physicians rather than waiting for a complaint or bad outcome.
3. Tax payer funded Medicaid formularies should only allow the prescription of unapproved psychiatric medications or multiple medications for children after the physician has provided a written request/explanation for such medications and the request has been approved by a board certified child psychiatrist (funded by the government).
4. Ex-pharmaceutical executives should be banned for ten years from serving on government Medicaid Committees where formulary decisions are made.

5. School officials who attempt to force/pressure parents into using psychiatric medications for their children should be prosecuted for violation of federal law.
6. An easily accessible web site should be developed that reports all pharmaceutical lobbying activities and the politicians who are benefiting from such activities.
7. A new law should be passed that requires all pharmaceutical drug trials, both negative and positives be published for doctors and patients to review.

"Any society, any nation, is judged on the basis of how it treats its weakest members; the last, the least, the littlest."

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