

Medicating America's Children

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There is growing concern about the increased prescribing of psychotropic medication in the child and adolescent population. A very recent study new study from Rutgers University and Columbia University shows that prescriptions for antipsychotic medications to children aged 2 to 5 years doubled between the years 1999-2001 and 2007. The top-selling medicines in 2008 were anti-psychotics for schizophrenia and bipolar disorder with \$14.6 billion in sales.¹⁹⁸ The studied group was a population of privately insured children. Moreover, the age of children being medicated with psychotropic drugs is getting younger and the number of children being medicated increasing every year. These same researchers produced a previous study in a population of children enrolled in a government Medicaid program.¹⁹⁹ They concluded that children seen by physicians insured under Medicaid are about four times as likely to be prescribed an anti-psychotic medication.

What is more problematic about this growing practice is there appears to be little evidence, if any, that these drugs are effective in this population of patients. Physicians, on the other hand, seem unconcerned about the lack of evidence or effectiveness of these drugs. They are aware, however, that children are not part of the population included in clinical trials, so why the rush to prescribe wholesale these potentially dangerous medications to such a vulnerable population? This is an important question. What we do know is that these drugs are dangerous in adult and aged populations. Given the lack of data, can we rationally infer there is a great likelihood that danger extends to children? We believe we can.

The Role Of The Federal Drug Administration (FDA)

The manifest role of the FDA is to approve the use of medications, medical devices and other drugs for their use in medical treatment. It is supposed to be both a licensing agency and a watchdog to protect the public from dangerous drugs and devices. Few would argue that the FDA has accomplished or achieved its stated mission. The FDA is essentially controlled by the drug industry. Its overview of medications and the research supporting manufacturer's claims to market these drugs simply are appalling. Drug manufacturers have been charged with hiding, obscuring and falsifying the results of clinical trials. The efficacy of Prozac could not be distinguished from placebo in 6 out of 10 clinical trials.²⁰⁰ The FDA, however, was quick to authorize its use. When introduced, Prozac was almost

immediately prescribed to children. Even though many researchers pointed out to the FDA that many antidepressant trials have serious methodological weaknesses, the FDA still approves these drugs. Moreover, the FDA was well aware there is an industry practice in which negative results are less likely to be published than those with positive results.²⁰¹

This practice makes it difficult to ascertain the effectiveness or meaningfulness of studies actually showing differences or improvements to existing drugs. It is because of these issues that NAPPP questions the specific efficacy of antidepressants relative to pill placebo, particularly when these drugs are prescribed to a vulnerable population of children. The FDA needs to perform its job more effectively. Physicians, on the other hand, need to be less "pad happy" when prescribing these drugs. Patients will be better served by a physician who looks at the underlying research before using his patients as guinea pigs for the drug companies. Better yet, refer these patients to a psychologist, who is more qualified to make an appropriate diagnosis and who will recommend a treatment plan based on the latest outcome research.

Does ADD/ADHD Qualify As A Real Diagnosis?

Before even considering ADD/ADHD as a medical problem, it seems to us that the current use of psychostimulants also should be scrutinized as a treatment option. Many of the patients are treated after being referred for ADD/ADHD had long-standing but undiscovered sleep disorders.²⁰¹⁻²⁰³ Not surprisingly, psychostimulants do produce gains in performance with these patients. One would expect these results if a sleep disorder is present. For too long, many have accepted that ADD/ADHD are established conditions that need medical as opposed to behavioral treatment.

To date, not a solitary cause has yet been identified for ADHD. ADHD will likely prove to be an umbrella term for a number of behavioral and/or neurologically based disorders. Furthermore, there hasn't been any identified cause specific to ADD, leaving open the likelihood that ADD may be a catch-all condition. The National Institutes of Health Consensus Development Conference and the American Academy of Pediatrics²⁰⁴ agree that there is no known biological basis for ADHD. The more one reviews the literature on hyperactivity or ADD, the less certain we are about what it is, or whether it really exists as a stand-alone disorder. So, at issue is not only the question of drugs for the treatment for attention-deficit problems, but also the question of why physicians prescribe these medications for children when other factors may be the cause of the problems. In May 2010, The American Medical

Association issued a news release on this specific issue, detailing the numerous co-morbidity conditions found along side ADD/ADHD. In that release, several researchers made the following statement: "Among children and adolescents with attention-deficit/ hyperactivity disorder, more than 80 percent had a diagnosis of at least one other psychiatric disorder, most commonly oppositional defiant disorder and conduct disorder, according to new research presented at the American Psychiatric Association's Annual Meeting. (AMA News lease, May 26, 2010)"

It is important to note that the conditions specified in the news release are behavioral disorders. Moreover, the issue is whether the condition labeled ADD/ADHD is a primary diagnosis or a symptom related to other, established behavioral disorders. It appears that the latter is the case, and raises to the question of why these children are being treated with drugs when they more than likely are experiencing a behavioral disorder amenable to non-drug treatment.

Children Diagnosed With Attention Deficit Problems

In 2007, the FDA issued an administrative order that requires that all makers of ADHD medications to develop and provide patients with Medication Guides. The guides must contain and warn patients, in clearly readable language, to possible heart and psychiatric problems related to ADHD medicine. The FDA took this action because of complaints and the increasing data that concluded ADHD patients with heart conditions had a higher risk of strokes, heart attacks, and sudden death when using these medications. The psychological symptoms associated with these drugs include hearing voices, having hallucinations, becoming suspicious for no reason, or becoming manic. The FDA found that these symptoms occurred in patients who had no history of behavioral disorders. Ritalin is a psychostimulant medication prescribed primarily to children.

In addition to Ritalin, the non-amphetamine based medication prescribed to children with ADHD is Strattera. The FDA warns that children and teenagers who use Strattera are more likely to have suicidal thoughts than children and teenagers with ADHD who do not use this medication. Child who use Strattera must be supervised and their behavior carefully monitored. Symptoms may develop symptoms suddenly, and they are a serious threat to the child.

These medications have become ubiquitous in schoolyards across America. In 2001, the average total annual expected cost per patient was \$1,631 for Concerta, and \$2,080 for Ritalin. Adderall, another

widely used psychostimulant cost \$2,232 per patient.²⁰⁵ In 2003, psychostimulants had sales of \$2.4 billion. By 2008, sales of Adderall reached \$1.1 billion while sales of Starttera were \$479 million.²⁰⁶ Clearly, these medications are big profit-producers for the drug companies, but are dangerous when prescribed to children. The FDA has been derelict in its duties and too industry-friendly. The FDA appears unwilling to challenge the drug companies, no matter how demonstrable the research on the dangers and ineffectiveness of these medications.

The FDA, as well as every pediatric physician group, are aware of the effectiveness of non-drug treatment for attention-deficit problems.²⁰⁷⁻²⁰⁹ They also are aware of the problems with the long term use of psychostimulants.^{210, 211} These medications can change brain structure and inhibit growth in children. Moreover, these drugs are sold on school grounds as a "drug of choice" because they are so easy to get.^{212,214} It seems that these drugs are viewed by so many professionals as potentially dangerous to children that some in the psychiatric community prefer that marijuana be prescribed instead of psychostimulants.

An important study by Cummings and Wiggins published in 2001,^{214a} looking at children and adolescents diagnosed with ADD/ADHD and prescribed psychotropic medications when entering treatment, showed a dramatic reduction in the use and amount of medications at the conclusion of treatment when these patients were provided with behavioral interventions. Cummings and Wiggins advocated for a collaborative model between primary care physicians and psychologists to bring about a rapid stabilization of the patient's condition while at the same time reducing or eliminating medications. This was not a small study. The records of 168,113 episodes of children and adolescents over a four-year period, who received behavioral intervention while on medication, was reviewed for the study. At the conclusion of treatment, only 13% of the children remained on medications contrasted with about 67% of children and adolescents who were on medication when they first entered behavioral treatment. More importantly, 95% of the 5 to 6 year olds and 92% of the 1 to 17 year olds did not need any medication at the end of treatment. This success was achieved with an average of only six sessions of behavioral intervention. The implications for cost control are obvious. However, the rapid stabilization of symptoms without medication and over such a short time is impressive and important.

Contrast these results with the meager clinical trials reported by the drug manufacturers of psychostimulants. Although this data comprises a large number of data points, both the number of prescriptions for psychostimulants continues to increase along with the costs for these medications. In

the same time period, behavioral intervention has significantly been diminished. But even as the use of psychostimulants is questionable, some psychiatrists have called for adding marijuana to be used in treating attention deficit symptoms.

Recently, an article appeared in the New York Times ²¹⁵ reporting on the use of marijuana for treating children with ADD/ADHD. The Times article is just one of several that have been popping up since medical marijuana initiatives have been passed a handful of states. Initially, the use of marijuana to treat pain and suffering related to the side effects of chemotherapy and to increase appetite in HIV patients were used as the rationale for the medical marijuana initiatives. Right now, however, a patient can get a prescription for almost any type of complaint. Anxiety, depression and other behavioral disorders are now at the top of the complaint list. Thus, it is not surprising that more disorders are being added to the list.²¹⁶ How safe can a drug be when psychiatrists are advocating that these patients would be better off with marijuana?²¹⁷

Childhood Bipolar Disorder

Psychostimulants are not the only drugs to which children and adolescents have been subjected. Increasingly, children as young as 5 years old are being diagnosed with bipolar disorder by physicians without even a thorough evaluation by a psychologist. Every psychologist has had a patient who was diagnosed by a psychiatrist or physician as having "Bipolar Disorder." In the case of children, adolescents and young adults, this label appears more frequently than any objective analysis shows it should. A 2005 study by Jennifer Harris, a clinical instructor at Harvard Medical School, published an article in the Journal of the American Psychiatric Assn. that clearly shows that much of the evidence that juvenile bipolar disorder is as widespread as currently diagnosed is highly suspect. A major finding of this research is: "Diagnoses for children are generally far less precise and meaningful than they are for adults. These uncertainties should be discussed with patients and their families, particularly when bipolar disorder is being considered as a "diagnosis."²¹⁸ Dr. Harris' alarm is not a singular call that questions the overdiagnosing of bipolar disorder. ^{218,219,220.}

Frequently parents have no place to turn to get appropriate information when their child's behavior appears different. Many articles on bipolar disorder available on the Internet imply that a simple pill prescribed by a psychiatrist will make everything better. What these articles do not tell parents, or anyone else for that matter, is that the physician most likely has received many "incentives" for prescribing medications as opposed to ordering an evaluation to find out if the child really does have

bipolar disorder. Thus, getting labeled with a bipolar disorder diagnosis has increasingly been part and parcel of medical practice.

Typically, by the time psychologists are recommended, patients are resistant to make appointments because, as the truism goes, "psychologists do not prescribe medications." In those infrequent cases in which a psychologist is consulted, we become the referral source for psychiatrists and we lose the patient. I am not suggesting we lose the patient because psychologists cannot prescribe medications. We lose the patient because psychologists typically are not part of the treatment process. The ability to prescribe not only gives one control over the treatment process but also the ability NOT to prescribe. Many physicians and parents simply do not understand this, as they want relief for their children and are not provided with the information that physicians often withhold. As a consequence, patients are reluctant to listen about alternative diagnoses or alternatives to medications. Physicians gain, patients lose. It is not uncommon for patients and parents to hear that, "You must take this pill for the rest of your life. Bipolar is a lifetime diagnosis." Imagine, some people take solace in finally getting a diagnosis before realizing how desperate they were that getting a lifetime diagnosis of mental illness made them happy.

Then reality sets in. Most psychiatrists these days prescribe Abilify for bipolar disorder. Yet, Abilify, as is true of most or all psychotropic medications, has not been tested in children or teenagers. These are serious drugs, and a 15-minute session or shorter that leads to a lifetime prescription is patently absurd and unwarranted. Psychologists can provide a proper and appropriate diagnosis that can spare parents and their children a lifetime of misery. We are specialists at looking at differential diagnoses. We can do better because we are not standing in line at the drug company counter waiting for a handout. As to cost-effectiveness, having an appropriate diagnosis is key to controlling healthcare costs. Bipolar disorder is now replacing the pediatric diagnosis du jour of Attention Deficit Hyperactivity Disorder. NAPPP does not think that there is any absence of a connection between the increase in these diagnoses and the push by drug companies in the psychiatric and medical communities.

NAPPP believes that ceding ground to physicians at the expense of our patients is unacceptable. Psychologist specialists need to be part of the treatment process. To get this, we need to have the ability to question medications as being the first and only consideration in a treatment plan. There are just too many psychotropic medications being prescribed for our children and for the wrong reasons. Medicine will never admit to this, because it is part of a drug distribution system that maintains its status and

provides physicians with too many perks and incentives to prescribe medications. We need to change this process. Medicating without thorough, professional diagnosis and research into alternative treatments is not only wrong, but abusive to the patient. Medications may be necessary for some patients, but their irresponsible overuse is a serious problem.

Some solutions, which NAPPP endorses, is to regulate when and how some of these medications are used. We advocate eliminating ads for prescription drugs from television and magazines. We did this for alcohol because, as a society, we recognize that advertising is directly related to substance abuse. Also, physicians should be empowered and mandated to better inform parents of the possible harms many drugs can cause their children, and that no medications will be prescribed unless there is a thorough evaluation by a qualified, doctoral-level psychologist. Physicians need to be trained and directed to shift more of their concentration on the underlying causes of behavioral disorders in children. Today's society can be very difficult for many people. Stress can produce many symptoms that can lead to many problems. Learning to manage stress is a long-term solution. Medications are short-term, at best. Medicating a child without a substantial evaluation should never be equated with good medical treatment, counseling and professional guidance.

Even Fetuses Are Not Safe From The Misuse of Antidepressants

The use of antidepressant medication is commonly prescribed for pregnant women. The use of these drugs during pregnancy is based upon the false assumption that they are safe to the fetus and the mother. A recent study, however, challenges this assumption.²²¹ Women who are pregnant and who are prescribed Selective Serotonin Reuptake Inhibitors (SSRIs) may increase their risk of having a miscarriage by 68 percent. Clearly, physicians strive to relieve a patient's symptoms. They typically justify the use of antidepressants in pregnancy invoking the idea that, while taking antidepressants during pregnancy may pose health risks for the fetus, stopping may pose risks for the mother.²²² Overall, drug manufacturers' studies conclude that the risk of birth defects and other problems for the fetus is low, but these studies may be suspect because manufacturers are notorious for downplaying and even hiding studies that show harm. Few medications have been proved safe without question during pregnancy, and some types of antidepressants have been associated with health problems in newborns.

Although SSRIs comprise similar compounds and act similarly, they seem to produce a different set of problems to newborns. Lung problems, septal heart defects; brain and skull abnormalities, and abnormalities of the abdominal organs have been reported with SSRIs.²²³⁻²²⁵ Tricyclic antidepressants and Monoamine Oxidase Inhibitors, two other classes of drugs used to treat depression, also present significant risks to newborns.²²⁶

If medications were the only alternative to treat women who are pregnant and severely depressed to the point where they were a danger to themselves or their fetus, then perhaps some of these risks would be acceptable. However, there are available behavioral treatments that work well and pose no risks to mothers, the fetus, or the newborn. Moreover, since primary care physicians have such a dismal record diagnosing depression, there is no reason to believe that OBGYNs are any better at evaluating and diagnosing behavioral disorders.

What appears to be the case is that physicians, with some exceptions, no matter their motivation to relieve symptoms, simply are not up to the task, and are putting their patients and newborns at risk when they prescribe antidepressant medications in and out of pregnancy. Consequently, every population is at risk when behavioral healthcare is seen as a "medical" disorder and treated by physicians who are not trained in behavioral health or are not inclined to refer to a psychologist, who are trained to evaluate, diagnose and provide treatment to these vulnerable populations.