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Pediatric Antipsychotics: A Call for Ethical Care

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> Having heard all of this, you may choose to look the other way . . . but you can never say again that you did not know.
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> —William Wilberforce, Address to the English Parliament Regarding the Slave Trade

A mother has a moment of panic, spying her daughter's arms criss-crossed with red cuts. Heartsick, she recalls a recent *Newsweek* article about bipolar illness and children. Could her child's boundless energy be mania and now this, depression? Where to turn? She picks up a phone book, scanning the yellow pages under *p* for *psychologist.*

A harried teacher does a double take when the behavior of a typically disruptive middle schooler takes a bizarre turn. One minute he has his head on his desk, and the next, she spies him out the window shimmied halfway up the flagpole. All she can think as she rushes to the office is "this kid needs help!"

Young parents are at a loss to explain the uncontrollable rages of their five year old. As the mother barricades herself in the bedroom until his tantrum wears out, she remembers a family story of her great-uncle not being right. The preschool teacher's report about behavior problems suddenly takes on new meaning.

In each case, the specter of mental illness hovers. In each case, the family, a mental health professional, and others—teachers, social workers, and helpers—are drawn together in a reactive network. Decisions

need to be made and a path charted, and time is critical. The decision faced by the clinician at this point represents a unique ethical dilemma. How the first professionals respond—what assessments are conducted, treatment plans developed, and recommendations made—has immediate and far-reaching consequences. The aftermath of these early decisions means no less than how the child comes to view his or her identity and whether relationships, school, and eventual career and civic work will be domains of competence or failure. They may mean the difference between a lifetime of health or chronic disability.

In the scenarios described, the likelihood that the child will be diagnosed with a mental disorder leading to a prescription of an antipsychotic is high. Would this possibility harm or help? Is this solution the best of available options? Is it ethical? Client welfare is the core of ethical practice in all mental health professions. Embedded in this is the centuries-old Hippocratic maxim to first do no harm. Additionally, all mental health practitioners are bound to give the best available information to clients to help them decide among various treatment options. Do no harm and informed consent form the centerpieces of ethical mental health practice. We believe that psychologists and other mental health practitioners hold these principles inviolable and work diligently to adhere to them. Our question, and one addressed in this chapter, is whether efforts to act ethically in challenging circumstances such as those described above achieve their intended purpose. What guidelines do clinicians have to chart a course that does the least harm and maximizes the chance that the young person can live a full and rewarding life? Finally, who decides what passes for do no harm and informed consent?

SCIENCE AND ETHICS

Antipsychotics are increasingly prescribed for teenagers, school-age children, and even preschoolers[1] to treat a growing array of problems including irritability, tantrums, aggression, mood dysregulation, and hyperactivity, in spite of the fact that there is no compelling research to support their use for these indications.[2] In many instances antipsychotics are being prescribed off label and for symptoms and diagnoses that don't involve psychosis. Moreover, multidrug cocktails consisting of various combinations of stimulants, antidepressants, and anticonvulsants in addition to antipsychotics are common.[3] Children often leave psychiatrists' or primary physicians' offices with a prescription that was not based on a mental health assessment and without a referral for psychotherapy.[4] Help, more and more, means a psychiatric drug and, all too often, several in combination.

Disturbingly, there is evidence that poor children are more likely to receive an antipsychotic prescription than their more fortunate counterparts.[5] According to a recent study, children covered by Medicaid are prescribed antipsychotics at a rate four times higher than those with private insurance and for less serious conditions.[6] In addition, there is disconcerting evidence about the extent of antipsychotic use with youth incarcerated in American juvenile detention centers. A groundbreaking, yearlong investigation published by *Youth Today* found that many incarcerated youths are getting these potent drugs, even without a diagnosis of schizophrenia or bipolar disorder.[7] Most often, the drugs are prescribed for diagnoses of intermittent explosive, oppositional defiant, and attention-deficit/hyperactivity disorders. According to the survey, more than a quarter of the prescriptions were written for youths who had no diagnosis. In other words, antipsychotics appear to serve as behavior management tools in these facilities—chemical restraints substituting for now banned physical restraints. Given that only 16 states responded to the *Youth Today* survey, including many with the largest state-held juvenile populations, the real extent of this practice is unknown.

How have antipsychotics become a first-line option for so many vulnerable children and adolescents, especially since these drugs have long been reserved for adult psychoses? Many clinicians and the public—parents, caregivers, teachers, and others grappling with how to address troubling child and adolescent behaviors—would likely say that the drugs are safe and effective and that scientific studies prove this. The scientist-practitioner and practitioner-scholar models and evidence-based practice require that intervention be supported by sound empirical research, ensuring that treatments are not likely to cause harm and are expected to help.[8] Presumably, when clinicians follow evidence-based guidelines, ethics is not a concern. Based on this common wisdom, burgeoning pediatric antipsychotic prescription is scientifically grounded and therefore ethical.

Let's examine this assumption—that science provides a solid foundation for the practice of pediatric psychotropic prescription. How well does the science hold up under scrutiny? Put another way, does current science provide an empirically and ethically valid case for placing so many children on powerful drugs? Several years ago, the American Psychological Association (APA) Working Group on Psychoactive Medications for Children and Adolescents looked at this very question.[9] Specifically, they examined whether the benefits of antipsychotics outweigh the risks for the under-18 age group. After a comprehensive investigation of the scientific literature, they found that studies supporting the use of antipsychotics to treat children were plagued with

methodological limitations, including small sample sizes, open trials, and lower tier evidence (e.g., retrospective chart reviews and case reports). Moreover, they found an alarming picture of side effects. Many children participating in antipsychotic trials experienced some combination of somnolence, involuntary movement, cognitive impairment, elevated prolactin, intracardiac conduction, neuroleptic malignant syndrome, polycystic ovarian syndrome, weight gain, and general metabolic disorders, including type 2 diabetes mellitus, and transaminase elevation.[10]

Young people appear particularly susceptible to weight gain and associated cardiometabolic effects. One study found that 257 children and adolescents aged 4–19 added 8 to 15 percent of their weight in less than 12 weeks on either aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), or risperidone (Risperdal).[11] Wayne Goodman, head of a Food and Drug Administration (FDA) advisory panel on the pediatric antipsychotics, described the degree of weight gain in this trial as "alarming . . . the magnitude is stunning."[12] In an editorial accompanying the study,[13] Christopher Varley (Seattle Children's Hospital) and Jon McClellan (University of Washington School of Medicine) wrote that weight gain and changes in blood fat levels early in life have "ominous long-term health implications".

> These data confirm prior findings that children and adolescents are highly vulnerable to antipsychotic medication–induced weight gain and metabolic adverse effects. The magnitude of weight gain is particularly concerning, as is the implication that metabolic adverse events may be underestimated in studies in which participants have had prior atypical antipsychotic medication exposure. Furthermore, the development of clinically significant hyperlipidemias and insulin resistance after only 12 weeks of treatment portends severe long-term metabolic and cardiovascular sequelae.

They concluded that the results of the study "challenge the widespread use of atypical antipsychotic medications in youth".

Adding to this grim picture, second-generation (atypical) antipsychotics do not appear to have a clear advantage over older ones when it comes to movement disorders, despite popular belief. In a recent, well-designed study with adults diagnosed with mood disorders or schizophrenia, rates of tardive dyskinesia (abnormal movements) for those taking second-generation antipsychotics (but naïve to conventional antipsychotics) were similar to those taking the older drugs.[14] Moreover, the incidence and prevalence of tardive dyskinesia in clinical practice, despite the widespread use of the newer drugs, remains unchanged from the 1980s. "It's definitely sad news for the patients," Scott Woods, lead author from Yale University Department

of Psychiatry commented.[15] Movement disorders consistently surface in clinical trials of pediatric antipsychotics and at rates significantly greater than placebo, though they are rarely highlighted in article discussion sections or subsequent press releases.[16] No one has studied the long-term impact of these drugs on a developing nervous system. But even in the short term, one can only imagine how a stigmatizing and debilitating movement condition might sabotage a youth trying to succeed in school and at home.

Two recent reports of the National Institute of Mental Health (NIMH)–funded Treatment of Early Onset Schizophrenia Spectrum Disorders study (TEOSS)[17] provide more evidence of an unfavorable risk/benefit profile for pediatric antipsychotic use. This trial compared the efficacy, tolerability, and safety of two second-generation antipsychotics (risperidone, or Risperdal, and olanzapine, or Zyprexa) to a first-generation antipsychotic (molindone, or Moban) for youths, ages 8–19, diagnosed with early onset schizophrenia spectrum disorder. At the end of 8 weeks, the liberally defined response rate was 50 percent for those treated with Moban, 46 percent for Risperdal, and 34 percent for Zyprexa.[18] Participants in the study were allowed concomitant use of antidepressants, anticonvulsants, and benzodiazepines, making it difficult to determine what actually accounted for even these disappointing findings. During the trial, a 17-year-old boy committed suicide, and an unspecified number of participants were hospitalized due to suicidality or worsening psychosis. These events are particularly disturbing in light of the fact that youths considered at risk for suicide were excluded from the study. Weight gain was deemed serious enough to warrant suspension of the Zyprexa arm. Adverse events were frequent in all three groups.

Youths who responded during the initial 8 weeks—47 of the 116—were entered into the 44-week maintenance study.[19] Seven other youths who did not meet responder criteria but had "sufficiently improved" according to the investigators, were allowed to continue, making a total of 54 participants in this phase of the trial. Forty of these dropped out during this period because of "adverse effects" or "inadequate response." Thus, only 14 of the 116 youths (12%) who entered the study responded to the medication and stayed on it for as long as one year. The optimistic wish that this well-heeled study would allay the fears of many, especially in light of rising rates of prescriptions, was dashed. Instead, TEOSS findings have fueled mounting concerns that the cost relative to benefit of these drugs for youth is too high.

It is hard, in fact, to locate any pediatric antipsychotic research to bolster a pro-antipsychotic case. An oft-cited series of studies examining the safety and efficacy of Risperdal for children diagnosed with autism

reveals a familiar pattern of flaws that raise serious questions regarding author claims of efficacy and safety.[20] For example, the Risperdal trials (as well as all pediatric antipsychotic studies) did not use active placebos (sugar pills that mimic the side effects of active drugs). Without a placebo that feels like the real thing, youth, caretakers, and clinical raters likely can tell who is taking the actual drug and who isn't, effectively compromising the double blind and giving an unfair advantage to the drug. This is particularly problematic for the Risperdal trials as many trial participants recruited were not naïve to antipsychotic treatment. In other words, they knew well how it felt to be on the drugs and could readily determine if they were on them or not. Second, follow-up studies employed an abrupt drug withdrawal design to create the placebo group. This meant that children who were stable on the drug were shifted abruptly to placebo. Withdrawal symptoms experienced by children taken quickly off the active drug were labeled relapse and proof that the antipsychotic was needed for the longer term. Sedated children generally are not acting out or bothersome and score lower on scales that rate these types of behaviors. When we look at patient-rated measures, a different story emerges. For example, in the 2008 study of aripiprazole (Abilify) for youth aged 13–17 diagnosed with schizophrenia,[21] no differences were found between placebo and both drug groups (10 mg and 30 mg aripiprazole) on the total score of the *patient-rated* measure (Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire). In other words, the measure that assessed how the teenagers felt they were doing in their lives, *from their perspectives,* failed to distinguish drug from placebo conditions.[22]

Finally, the duration of many pediatric antipsychotic studies is hardly adequate to determine the impact of these drugs on children over time. Aripiprazole (Abilify) was approved by the FDA for children between the ages of 10 and 17 for mania associated with bipolar I on the basis of one four-week trial. Approval for use of risperidone (Risperdal) for adolescents experiencing psychotic-type symptoms was based on two studies, only one of which was double-blinded and lasted six weeks. FDA approval of Risperdal for mania for children and adolescents aged 10–17 was granted based on one three-week double-blind trial. The high rates of dropout due to inefficacy and intolerability in the TEOSS follow-up study casts a large shadow of doubt on the clinical validity of these brief trials. Instead, disturbing facts are beginning to emerge over time as the realities of serious negative effects can no longer be spun and the real harm being wrought is uncovered in story after personal story.[23]

Considering the reality of meager improvements extracted from studies that utilize methodologies that favor finding treatment effects,

weighed against consistent findings of significant adverse effects and largely untested long-term safety, a favorable risk/benefit profile in support of antipsychotics as first-line treatment for children and adolescents, regardless of the diagnosed disorder, appears untenable. The APA Working Group concurred, finding enough "significant risks" in its review to advise psychosocial treatments rather than antipsychotics for pediatric bipolar disorder (PBD), citing that nonpharmacological interventions "confer benefit with no risk".[24]

MYTH AND SCIENCE

When the evidence is explored, no reasonable scientist or practitioner would come down on the side of a favorable risk/benefit profile for pediatric use of antipsychotics. How, then, can we explain the fact that prescription rates continue their upward march in numbers and downward march in the age for which they are prescribed? How has it become so commonplace for antipsychotics to be listed first on the treatment plan for so many youth, even without manic or psychotic symptoms? The taken-for-granted acceptability and widespread use of pediatric antipsychotic drugs must be considered in light of the interests of those who have the most to gain. It is tempting to dismiss this viewpoint as cynical. We believe that not to explore a direction likely to shed light on the glaring discrepancy between the evidence and current practice is an ethical error on several counts. First, skeptical curiosity lies at the heart of the scientific and ethical enterprise—there should be no "Do Not Trespass" signs blocking the road. Second, scientific inquiry is critical. This does not mean that it points the finger like a critical teacher or parent, but it refuses to succumb to pressures to look away. Instead, critical science views restrictions on full exploration of the facts as indications that there likely are vested interests in diverting attention elsewhere. This possibility fuels the imperative even more to explore what those interests might be and how they operate. Finally, when it comes to safeguarding the rights and health of children, every road should be taken, particularly when common sense points the way and so much is at stake.

As a start on this path, we ask how our field has come to accept uncritically the proposition that many child and adolescent problems are not by-products of poverty, interpersonal distress, or other context-dependent factors, but of chronic disease and unbalanced neurotransmitters. We believe this collective myopia is *not* a triumph of science, but a triumph of marketing *over* science. It is, in short, a myth! Myths are stories, but bigger than your average fairy tale. They have the power to operate at basic, cultural levels and in unexamined ways.

That is, people don't identify their thoughts and actions as shaped by these "grand narratives";[25] they just act. In short, people live by myths without knowing it. The fact is, no one has identified any biological marker for any of the diagnosed conditions assigned to so many young people today.[26] Nevertheless, the *myth* of a biological foundation for certain childhood behaviors creates a certainty in which the prescription of powerful drugs for even the youngest and most vulnerable becomes automatic. And this is the breeding ground for decisions made by medical and nonmedical mental health practitioners.

Myths do not spring fully articulated overnight into the common consciousness but evolve over time. We suggest that the myth that children are well served by taking antipsychotic drugs has been constructed intentionally through the co-opting of science and media. It is not hard to see who might benefit from increased prescriptions. Psychiatric drugs comprise a hefty portion of the swelling drug sales in the United States. In 2009, antipsychotics maintained their number one ranking from 2008 as the top-selling class of drugs sold in the United States with $14.6 billion in sales.[27] Undoubtedly, the pharmaceutical industry is invested in the continued success of these highly profitable products.

One way to increase prescribing (and profit) is to offer financial incentives to physicians and psychiatrists in return for product promotion. For example, psychiatrists topped a recent published list of physicians receiving drug company money.[28] Payments to psychiatrists go for things like speaking fees, travel, meals, and consultation. Speakers' bureaus essentially turn physicians into mouthpieces for the industry. Psychiatrists give presentations, usually at upscale restaurants, using slides and responses to audience questions prepared by the drug manufacturer. Some argue that the largesse showered on physicians is legal and does not skew oaths to do no harm. However, physicians are susceptible to financial incentive as evidenced by increased prescription following pharmaceutical "perks."[29]

Pharmaceutical visits to prescribers not only include financial incentives but education to help busy doctors know the latest findings. Fortunately for the drug companies, the data is not hard to come by. Clinical drug trials are almost solely the purview of pharmaceutical companies who spend significant dollars to create networks of highly visible scientists to research their products. Invariably, the findings tell an optimistic story of the investigated drug's benefits, cloaked in the language of statistical and methodological intricacies. Can these stories be believed?

Unfortunately, what is pawned off to prescribers, medical and nonmedical mental health trainees, and the public is largely fiction. The

notion that science is deliberately being manipulated to construct a particular tale cannot be simply chalked off as another conspiracy theory. The extent to which pharmaceutical companies have manipulated medical research for their own interests has been exposed by some of the most respected voices in the field. For example, Marcia Angell, former editor-in-chief of the *New England Journal of Medicine,* blew the whistle over a decade ago regarding the "ubiquitous and manifold . . . financial associations" authors of drug trials had to the companies whose drugs were being studied.[30] The editor-in-chief of the *Lancet* decried that "journals have devolved into information laundering operations for the pharmaceutical industry."[31] As yet another example, consider the recent exposé in the *New York Times* documenting drug company ghostwriting of an entire textbook for primary care physicians about recognition and treatment of psychiatric disorders.[32]

The result of industry influence is a direct correlation between who funds the study and its outcome. For example, in 2006 Heres looked at published comparative trials of five antipsychotic medications.[33] In 9 out of 10 studies, the drug made by the company that sponsored the trial was found to be superior. Davis, coauthor of the study, surmised that "90 percent of industry-sponsored studies that boast a prominent academic as the lead author are conducted by a company that later enlists a university researcher as the 'author' ".[34] Similarly, *JAMA*'s systematic review found that "financial relationships among industry, scientific investigators, and academic institutions are pervasive," and "by combining data from articles examining 1140 studies, we found that industry-sponsored studies were significantly more likely to reach conclusions that were favorable to the sponsor than were non-industry studies".[35] Meanwhile, studies with negative findings for investigated drugs rarely see the light of print.[36] Angell, with more than a touch of sadness, concludes,

> It is simply no longer possible to believe much of the clinical research that is' published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*.[37]

Regarding pharmaceutical influence over the science of pediatric antipsychotics, one need not look far to detect a smoking gun. One highly visible researcher, Joseph Biederman, Harvard Medical School professor and psychiatrist at Massachusetts General Hospital, has touted the efficacy and safety of the antipsychotic Risperdal for more than a decade. From its early days as the drug of choice for children diagnosed

with autism, Risperdal has migrated along with other potent antipsychotics to the popular pediatric bipolar diagnosis. This label has been so fervently championed by Biederman that reporter and historian Robert Whitaker has called him the "Pied Piper of pediatric bipolar disorder".[38] Thanks in large part to Biederman's efforts, PBD and antipsychotics are now a taken-for-granted pairing.

As additional evidence of conflict of interest, an investigative report in the *New York Times* claimed that Biederman, in violation of Harvard policies, failed to report at least $1.4 million in income from drug companies.[39] A second article asserted that Biederman repeatedly asked Johnson & Johnson, makers of Risperdal, to fund a research center at Massachusetts General to focus on PBD.[40] A prime mission of the center, according to Biederman, would be to "move forward the commercial goals of J. & J." Johnson & Johnson allegedly joined with Biederman to produce science that favored Risperdal when Johnson & Johnson drafted a scientific abstract and requested Biederman's signature. According to the report, the company also sought his advice on how to handle the fact that children given placebos in Risperdal trials also improved significantly. More recently, Senator Grassley of Iowa has broadened an investigation to learn if Biederman promised positive results for Johnson & Johnson for studies yet to be conducted.[41]

Another researcher leading pediatric antipsychotic drug trials has significant connections to pharmaceuticals. Robert L. Findling, professor of psychiatry and pediatrics at Case Western Reserve University and director of the Division of Child and Adolescent Psychiatry, University Hospitals of Cleveland, is particularly visible as a contributor to a widely circulated online medical forum, Medscape. Findling serves as an advisor or consultant for 22 pharmaceutical companies, has served as a speaker or member of a speakers' bureau for 3, and has received research funding from 14.[42] Findling led the 2008 trial for aripiprazole (Abilify), a second-generation antipsychotic, for 13 to 17 year olds diagnosed with schizophrenia.[43] Adolescents in the aripiprazole groups (10 mg and 30 mg) in this trial increased their body weight more than 5 percent, up to five times greater than youth in the placebo group. There were more than double as many youth experiencing extrapyramidal disorder in the 10 milligram group and more than four times as many in the 30 milligram group compared with those in placebo. Abilify takers were as much as three times more likely to report somnolence than those on placebo. In spite of these glaring red flags, Findling concluded that Abilify was "generally well tolerated".[44]

One would hope that the pharmaceutical industry is kept in check through university ethics and government oversight. However, government agencies and academic advisory panels, presumably the watchdogs over industry-sponsored research, are not the firewalls

many would assume. Willman, in a Pulitzer Prize–winning report, found widespread breaches in ties of National Institutes of Health (NIH, umbrella organization of the NIMH) researchers to pharmaceutical money.[45] Whitaker has systematically detailed the involvement of the NIMH with industry propaganda promoting psychiatric products.[46] In addition, financial conflicts of interest among U.S. FDA advisory members are common.[47] Moreover, Cosgrove noted "strong financial ties between the industry and those responsible for developing . . . the diagnostic criteria for mental illness", especially where drugs are the first-line of treatment for a specified disorder.[48] Experts who formulate practice parameters often serve as consultants and speakers for major drug companies.[49] For example, the Texas Children's Medication Algorithm Project (TCMAP), funded by the Texas Department of State Health Services, convened a panel of experts to derive consensus-based recommendations for stepwise pediatric medication regimens (interestingly, of the higher priced drugs). Disclosure statements for prominent academics and researchers involved in TCMAP span nearly half an entire printed page.[50] Industry infiltration into all aspects of government-sponsored research, oversight regulation, and consensus panels means that clinicians and consumers have no safety net to fall back on for unbiased information and protection against the potential harm these drugs can cause the youngest in our society.

The net effect of drug industry control over psychiatric research is the construction of a distorted picture of actual risks and benefits of the drugs in question. Thus, clinicians and consumers weighing treatment options lack honest information to determine the best and most ethical course to pursue. It no longer can be assumed that time-honored journalistic peer-review or impartial government regulation produce a sound body of science to support ethical mental health practice. Clients and clinicians are essentially flying blind if they uncritically consume the cliff notes version of clinical trials to guide practice. Very few obstacles can withstand the onslaught of an industry as politically and financially powerful as the pharmaceuticals. They have ruthlessly violated long-standing rules of conduct for ethical research to enrich shareholders and perpetuate their wealth into the foreseeable future. In sum, science has been bought for corporate profit, even when it compromises the health of children who depend on adults for protection and who *are* the future.

MYTH AND MEDIA

It takes more than tainted science and drug reps to create myth. Myths are born when repeated, intersecting narratives converge over

time into a unified superstory—in this case, one that permeates not only the halls of academia, the hospital, and public clinic, but also the classroom, the living room, and eventually the minds of whole populations within a culture. Like "Mom," "Apple Pie," and "Freedom for All," the superstory's unquestioned veracity does not permit the curtain to part on the multiple contradictions and darker sides that lie within it. In the case of our critical examination of antipsychotic medications for children, we can peer inside to see how this type of story comes about. What we find goes by the general term *media,* including print, television, and film as well as the various modes of electronic communication that occupy an immediate presence in the lives of so many. The long arm of the pharmaceutical industry is evident in all these, perhaps more than in the elite world of empirical research. Antonuccio, Danton, and McClanahan detail its reach beyond clinical trials—from Internet, direct-to consumer advertising, grassroots consumer advocacy, and professional guilds to medical schools and clinical training programs.[51] They conclude, "It is difficult to think of any arena involving information about medications that does not have significant industry financial or marketing influences".

Those involved in mental health practice, as members of the culture, take in all these forms of messaging, including professional press and the policies and procedures of work sites. For example, practice parameters for PBD approved by the American Academy of Child & Adolescent Psychiatry specifies pharmacotherapy as the minimal standard (applies 95% of the time or in almost all cases) for mania in bipolar I disorder for children.[52] Psychotherapy is considered to be adjunctive, relegated to teaching the child and caregivers about bipolar illness, including its heritability, and to ensure medication compliance. These so-called truths trickle down. The American Association of Marriage and Family Therapy (AAMFT) is a case in point. The AAMFT website describes "childhood-onset mental illness" (COMI) as "biologically based, meaning that chemicals or structures in the brain are not working as they are supposed to."[53] This means that "almost all children with bipolar disorders need to take medication to help stabilize their moods" and "many times, a combination of two or more medications works better, if one medication alone does not produce a satisfactory response."[54] This a striking testimony to the power of myth as the AAMFT represents a field founded on the belief that interpersonal dynamics more appropriately explain human distress than biology.

These types of unquestioned pronouncements are commonplace in many practice settings. For example, pharmaceutical intervention often is built in to mental health agency procedures via the psychiatrist

who provides supervision and has prescribing power for more challenging cases. Pressure to think medical is established well before the first paid position and persists through the span of a career. For example, it is widely considered desirable to include *DSM* and psychopharmacology training in clinical graduate coursework, even in those fields most known for their emphasis on environmental influence. Trainees and experienced clinicians alike are inundated with invitations to workshops and continuing education courses so they can be up-to-date on the biology of the brain and the neurochemistry of psychotropics. Pharmacology and psychotherapy are rapidly aligning as inseparable, yet unequal, interventions in daily practice.

Having created and disseminated the science, the pharmaceutical/psychiatric conglomerate is in a position to define "do no harm" and set the terms of informed consent. Clinicians choosing nonmedical options may fear the risk of a lawsuit and even censure from their own peers and professional guilds for ignoring science and practicing unethically. In so many ways, the psychiatric establishment enshrines psychopharmacology as best *and* ethical practice.[55]

How many stories are told, in one form or another, of the out-of-control, defiant child destined to fail at school and wind up behind bars, magically transformed into an obedient, studious youngster with the help of a pill. How many parents would want to deny their child the chance to star in this story? And how many clinicians would not want the same for their young clients? Bleeding through these trouble-to-triumph narratives are those that speak about irreversible tremors, life-shortening obesity, or a child's death at the hands of a potent psychiatric drug cocktail. In spite of counterstories, the view that antipsychotics *must* be given and are reasonably safe for children exhibiting certain forms of extreme behavior has become accepted and normal.

CRITICAL ETHICS

This is the world in which medical and nonmedical mental health professionals live and practice. It is a world where certain child behaviors are assumed to be heritable, organically based diseases and where subduing difficult and aggressive youths is ethically justified by a belief that such treatment wards off a future life as a social outcast or degenerate. The mandate of medical intervention imposed by a dominant medical paradigm hangs over the head of the nonmedical practitioner. With the presumption of science behind it, the most evident ethical choice is to defer to medical expertise. In the world of everyday practice, this means that psychologists, social workers, and other mental health clinicians refer their most troubled youngsters for psychiatric

evaluation. And, psychiatric evaluation almost always includes medication. Psychotherapists, then, are left to police the medical regimen and mitigate the fallout of the disorder in the child's world. Psychologists and mental health professionals cannot—*are not qualified to*—treat the underlying disorder.

In such a world, how can a practicing, nonmedical mental health clinician respond when faced with the immediate crisis of a child out of control, at risk of self-harm, or inexplicably exhibiting strange or frightening behaviors? Is the most ethical action one that follows the treatment guidelines constructed by the financial and political clout of a for-profit industry linked to the psychiatric establishment? Or, is the most ethical choice one that is based on a critical examination of the science, including knowledge of one's own ability to provide effective, nonpharmacological help and an awareness of context (e.g., cultural, socioeconomic, racial, gender, and sexual orientation disparities) that expands understanding of presented problems in terms other than discreet psychiatric disorders and biology? It is likely no surprise at this point that we believe that critical analysis lies at the heart of ethical practice. Without it, do no harm and informed consent are largely preset by entities whose ethics may serve the well-being of stockholders rather than children.

Critical ethics does not stop, however, with critical analysis but requires practitioners to advocate for greater transparency in research and the dissemination of critical commentary into the public sphere. It also urges practitioners to become advocates for change within their practice and professional circles. Further, consistent with standing mental health ethical mandates, critical ethics obligates clinicians, within the scope of their expertise, to act for the betterment of client welfare and to provide information regarding the risks of their treatment. It is our view that it is within the scope of nonmedical clinicians' expertise to provide counseling and psychological intervention for problems facing children frequently considered biological in origin. Moreover, this intervention is justifiable as primary and standalone, rather than merely adjunctive, based on the client's preference. In addition, nonmedical practitioners have a right and obligation to share reasonable and researched information about the risks and benefits of psychiatric medications with their clients when this is a relevant concern for the client. This information falls within the range of expected knowledge for any practitioner today and requires that he or she be informed beyond drug company propaganda. To threaten clinicians under the guise of ethics violation when they provide information regarding known drug risks undermines their right to assist clients making critical decisions about treatment. Furthermore, it begs

the question of why nonmedical clinicians are asked to become fluent in psychopharmacology so that pharmacological intervention can be suggested for an ever-expanding range of child difficulties but are forbidden to seek and use knowledge to offer a more research-based picture. Our concept of critical ethics, therefore, requires that mental health clinicians, consistent with their code of ethics, take the following steps[56]:

1. *Become educated in how to evaluate research for methodological flaws, bias, and conflicts of interest, and discern noteworthy, underreported findings.* Research needs to be studied in its originally published form with a careful exploration of flaws and conflicts of interest.[57]
2. *Become educated about the evidence base for nonpharmacological interventions.* Clinicians should have a solid knowledge of nonmedical options for the variety of problem behaviors they might encounter in their client population. Moreover, they should have confidence that these approaches have proven records of efficacy and are powerful, no-risk forces for positive change.[58]
3. *Hold a questioning attitude regarding media portrayals of psychotropic medications for children.* Practitioners need to be wary of slick websites and know how to find out who produces or sanctions their content and provides funding. If it sounds too rosy or too cozy to be true, it probably is.
4. *Provide true informed consent to clients, including informing clients of the risks and benefits of antipsychotic medications for children and adolescents.* In providing real informed consent, children, even those of school age or younger, and their parents and/or caregivers need to know the meaning of off-label prescription, the lack of evidence for acute and long-term antipsychotic pediatric use, and the real risks these drugs entail. The fact that children are not legally able to give consent, but rely on parents or caretakers to act in their best interest, should not deter clinicians from gaining youth assent. It is ethically justified, and empirically supported, to elicit and address children's questions and concerns, especially when it involves psychiatric medications that are likely to profoundly influence a child's day-to-day life as well as future. Given a young person's dependent status on adults underscores the ethical imperative that clinicians give balanced information to caretakers who ultimately will make the final call regarding their child's treatment.[59]
5. *Support clients to be at the helm of their treatment, regardless of the choice to take or not take psychotropic medications.* At each step, children and caregivers' preferences are honored. If antipsychotic medications are chosen, clinicians can help the youth and parents/ caregivers be in the driver's seat, to monitor side effects or to decide when to discontinue the drugs. All too often, the prestige of prescribing physicians or psychiatrists intimidates consumers and stifles their questions and preferences. Systematically obtaining regular feedback from all involved, including the young person and caregivers, helps ensure that their preferences are privileged throughout treatment.[60]
6. *Help children, adolescents, and their caregivers become critical consumers.* For clients who want to know more, clinicians can inform them that much of what can be

found on the Internet is biased and urge them to seek information from a variety of reputable and unbiased sources, including psychiatrists or physicians, before committing to a particular treatment.

7. *Work for change in mental health agencies, organizations, and institutions to combat the appropriation of mental health counseling and psychotherapy by medical, for-profit enterprises.* Working ethically, one client at a time is essential, but not enough. Without taking a stand for transparency and change beyond the immediate level of therapeutic practice, we are part of the problem. The larger structures in place at every level of mental health—funding, policies, procedures, and training, for example—ensure that the business of mental health operates in specific ways. In child and adolescent mental health, these structures, for the most part, promote medical intervention. Change at these levels does not occur solely within the therapeutic encounter, but in the professional and public sphere through direct challenge and proposal of alternative discourses. This additional step means that we advocate for a transformation of our professions for the welfare of our clients and as reclamation of our identity as helpers.[61]

ETHICS IN ACTION

Science, in the case of childhood psychiatric drugs, is not the objective, pure, and noble enterprise that holds such sway in the popular imagination. The dark cloud of corruption hangs over it in the form of multiple and enduring financial ties to industry whose primary purpose is to increase profit. Tainted science is not an ethical foundation upon which to base any practice designed to serve the welfare of the public, much less the youngest in our society who count on us for protection. The ethics we propose is critical in that it looks beneath the veneer of myth to discern meaningful scientific evidence. It is critical also in the sense that it provides an important safeguard for maintaining the independence and integrity of the work most of us chose because of our desire to be of help to others.[62]

Critical ethics requires time and energy. It is much easier to take the common wisdom at face value and go on with one's practice and life. Our belief is that this constitutes a violation of the ethical imperative that we do no harm to our clients and that we provide them with genuine informed consent. Even more than time and energy, critical ethics requires courage. This means courage to do no harm after you know what you know, despite possible repercussions. It means the courage to act locally in one's workplace or professional group to challenge unquestioned assumptions. For example, it is an act of great courage to simply question, in the midst of the staff meeting with the psychiatrist, the validity and usefulness of a child's diagnosis of bipolar disorder or the prescription of more than one drug.

Finally, critical ethics means reclaiming one's identity as a helper, not just for those worrisome, expected problems, but for young people and their families in dire distress. If we cannot be of help to those who come to us, is it ethical for us to practice at all? For example, several meetings with the mother and her daughter, Alison, who had cut her arms, meant that many aspects of their lives became relevant to the presenting problem, not just the more visible act of cutting. In the first session, the mother listened with astonishment as her daughter mentioned that she had read about cutting in a teen magazine and thought it might help her feel better after the breakup with her boyfriend. To everyone's relief, she proclaimed that it only made things worse and vowed not to try it again. What had started out as a possible trip to the emergency room turned into a routine (if these discussions are ever routine) heart-to-heart talk between mother and daughter, with the clinician as referee, about the daughter's privacy and her desire for a later curfew. In the context of no other identifiable risk factors in her life, including normative scores on the intake psychological assessment and the obvious presence of a watchful and caring mother, this family avoided the march toward medication and resolved a crisis of adolescent development over the course of a few meetings. The strong relationship the clinician established with Alison and her mother reassured the clinician, that, if there were additional signs of danger, the family would seek his help.

Similarly, the young boy, Nathan, who sought safety at the top of the school flagpole, after being coaxed down, found the open arms and ears of teachers, his social worker, and a home-based counselor where he talked mostly about the recent passing of his father and the trouble he was having in his new foster home. When asked what he needed, he listed two things—his bicycle (stored at a relative's home in another city) and a chance to be reunited with his two sisters, even if for a day. These wishes clearly did not require medications, nor could they be found in any standard book of psychological techniques. However, retrieving the bike as first order of business showed this young boy that people took him seriously and gave him a sense of normalcy and an important vehicle, literally, to make friends in his new neighborhood. A trip to spend the day at the ocean allowed the siblings to be together, to see that each was okay, and to share their memories about that fateful Christmas Eve when their father, the rock of their struggling, single-parent family, died suddenly. Over the course of the next six months, a plan was created for a permanent home for Nathan, one that included regular contact with his siblings. Nathan settled into his schoolwork and graduated on time with his class.

Finally, for Kyle, the tantrum-prone five-year old, the solution was standard parenting management strategies combined with a reevaluation of how the father's job and the family's finances meant that Kyle's mother shouldered the burden of parenting for Kyle as well as his little sister. When the family established more shared parenting and more fun time together, Kyle's behavior improved dramatically.

Nathan's case was time intensive and involved a whole team of helpers, whereas only one therapist and several meetings were needed to help Alison get her life back on track. Work with Kyle and his family involved eight family meetings and collaboration with his preschool teacher. All three cases required empirically informed skills. This is the everyday work of mental health professionals that is far from ordinary and far from second rate. It challenges the view of the necessity of powerful antipsychotics for so many of the problems faced by children and their families arriving at the doorstep of our offices. This is the work of the critical ethical practitioner.