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The Ethics and Science of Medicating Children

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Prescriptions for psychiatric drugs to children and adolescents have skyrocketed in the past 10 years. This article presents evidence that the superior effectiveness of stimulants and antidepressants is largely a presumption based on an empirical house of cards, driven by an industry that has no conscience about the implications of its ever growing, and disturbingly younger, list of consumers. Recognizing that most mental health professionals do not have the time, and sometimes feel ill-equipped to explore the controversy regarding pharmacological treatment of children, this article discusses the four fatal flaws of drug studies to enable a critical examination of research addressing the drugging of children. The four flaws are illustrated by the Emslie studies of Prozac and children, which offer not only a strident example of marketing masquerading as science, but also, given the recent FDA approval of Prozac for children, a brutal reminder of the danger inherent in not knowing how to distinguish science from science fiction. The authors argue that an ethical path requires the challenge of the automatic medical response to medicate children, with an accompanying demand for untainted science and balanced information to inform critical decisions by child caretakers.

During the 1990s, prescriptions for psychiatric drugs to children and adolescents skyrocketed (Olfson, Marcus, Weissman, & Jensen, 2002; Zito et al., 2003). Evaluating the records of almost a million Medicaid and HMO youths, one of the largest and most comprehensive studies to date concluded that child and adolescent psychotropic utilization rates nearly tripled from pre-1990s levels (Zito et al., 2003). Total psychotropic prevalence for youths reached as high as 6.3%, rivaling adult rates. According to an IMS Health survey, between 1995 and 1999, the use of antidepressants increased 151% in the 7-12 age group and 580% in the under-6-years-old population. Children under 18-years-old saw a nearly 300% increase in the use of antipsychotic medications such as Risperdal (Diller, 2000). Drug Enforcement Administration records and national physician practice surveys indicate that approximately 4 million children took stimulants in 1998 (Diller).

Even more alarming rates cluster in certain groups. Zito and colleagues found that children in foster care were 16 times more likely to receive a prescription than their non-foster care counterparts (2003). *The Boston Globe* reported that 1 in 8 teens in the state's Medicaid

program was taking psychotropic medications, and 1 in 9 aged 6 to 12 years (8% and 13%, respectively; Barry, 2003). Between 1991 and 1995, pediatricians and psychiatrists wrote record numbers of stimulant, tricyclic antidepressant, clonidine hydrochloride, and SSRI prescriptions for preschoolers (Zito et al., 2000). Prescription rates for methylphenidate (Ritalin) for 2- through 4-year-olds grew by 169%. Zito and associates called such dramatic increases "remarkable in light of the limited knowledge base that underlies psychotropic medication use in very young children" (2000, p. 1026).

In most major surveys of child and adolescent psychotropic use, stimulants are ranked as most popular, and antidepressants are ranked second. The research also points to an increasingly commonplace trend, polypharmacy, prescribing two or more medications simultaneously. According to one study, the rate of co-prescription rose significantly from 4.7% to 11.6% during 1987-1996 (Olfson, Marcus, Weissman, & Jensen, 2002). Children on stimulants for diagnoses of attention-deficit hyperactivity disorder (ADHD) are frequently prescribed clonidine, an antihypertensive for adults, to help with insomnia. These children often take an additional antidepressant along with their amphetamine or methylphenidate. Woolston (1999) remarks:

> Unfortunately, the multiple "comorbid" diagnoses may reify the need for multiple medications: a different medication to treat each different "disorder." Almost weekly I am asked to evaluate and treat children who allegedly have 5 or 6 Axis I disorders and who are receiving as many or more different psychotropic medications to treat each disorder. (p. 1455)

Out of these diverse studies, surveys, and anecdotal reports, a consistent picture emerges. Children and teenagers can hardly be said to live, play, and work in "drug-free zones." The use of drugs to fix their own, their parents', or their school's problems is rampant. IMS, the pharmaceutical industry's own source of information, estimates that as many as 5 million children are taking some form of psychotropic medication (Diller, 2000). Given indisputable trends, widespread marketing, and a growing acceptance of medical intervention, current prevalence is likely far greater.

The news of rising psychiatric prescription rates to children has prompted concern among many. However, reassurance from the medical establishment, including its massive presence in mainstream media, quells much of the public's uneasiness. Popular Web sites, while always advocating therapy interventions, give the most detail for medication treatments. The National Institute of Mental Health (NIMH, 2000) Web page reports that childhood "mental disease," contrary to earlier thinking, can begin at very young ages; early diagnosis means a better prognosis. "We used to think children could not be mentally ill," so the line goes, relegating nonmedicating preferences to the uninformed dark ages when children were left to suffer without the benefit of today's modern medicines. The logic and the emotional appeal are compelling. Concerned parents should "see your [child's] doctor."

In such a climate, legitimate requests for alternatives often meet with formidable resistance. Reports have surfaced of parents facing accusations of neglect by state child protection agencies because of their refusal to medicate their child. Some mental health workers may fear that openly advocating for nonmedical interventions, especially for what are considered severe or chronic conditions, makes them appear ill-informed, radical, or even unethical. Under such conditions, the road to informed consent and free choice by parents, children, and concerned clinicians becomes more and more perilous.

Until recently, childhood psychiatric medications have largely been used "off-label," meaning without the necessary scientific studies to produce FDA approval. Now, this gap is closing, with more and more studies, funded almost exclusively by the medication manufacturers, finding their way into journals and granting scientific legitimacy to what already seemed just common sense.

Scientific backing opens the door to more and stronger arguments in favor of child pharmocotherapy in both lay and professional press. A recent issue of *The Family Therapy Magazine*, the quarterly publication of the American Association of Marriage and Family Therapy, is a case in point. This issue devotes itself to exploring family therapists and medications, with a special article on pediatric psychopharmacology (Walkup, 2003). Walkup states that the accurate depiction of trends in prescribing practices for children fails to "put the increased use in perspective" (p. 35). He argues that many more children are being prescribed medications because:

1. Psychiatric medications work for children's problems.
2. De-stigmatizing psychiatric disorders has freed families and communities to seek medication intervention for troubled children.
3. Medications have become available during the nineties to serve the needs of untreated children.

Our contention is that both common sense and scientific grounding for widespread psychiatric drugging of children is, at best, unconvincing. Let's take each point in turn. First, what evidence do we have for the efficacy of psychotropic medications for safely alleviating children's psychological distress?

ANTIDEPRESSANTS AND KIDS: A SAD STORY

What do we know about the efficacy of antidepressants, the second most widely prescribed psychotropic medication for children and adolescents? The failure of tricyclics (TCAs) to effectively treat children is well documented (see Fisher & Fisher, 1997). During the 1990s, there was great hope for the newer antidepressants, the selective serotonin reuptake inhibitors (SSRIs). However, before 1997, SSRI efficacy studies found little to be hopeful about. A comprehensive 10-year review revealed a dearth of evidence that either TCAs or SSRIs were effective for children and adolescents (Birmaher, Ryan, Williamson, Brent, & Kaufman, 1996). In spite of this, with ever staunch optimism, the reviewers concluded that "psychosocial and pharmacological treatments [for children] are vital" (p. 1581).

Prior to 1997 there was the interesting paradox that at the same time clinicians were prescribing more and more prescriptions for SSRIs, researchers were unable to prove that antidepressants were efficacious for children. All of this changed with the publication of two studies by Emslie and colleagues. The first study (Emslie et al., 1997) was an 8-week, randomized, placebo-controlled, double-blind trial comparing the efficacy of fluoxetine hydrochloride (Prozac) and placebo. This study found:

- A significant difference in response between medication and placebo groups on one of five psychometrically sound outcome measures.
- Self-report scores of participating adolescents and their parents indicated no differences in outcome between the medication and placebo groups.
- Two other clinician-rated measures also showed no difference.

To help guide you though the quagmire of understanding the research jargon, we will use the Emslie study to illustrate the four fatal flaws (Duncan & Miller, 2000; Duncan et al., in press) of drug research. Setting aside the paltry results of just 1 in 5 measures showing superiority over placebo, the four flaws suggest that this study does little to justify the use of antidepressants for children.

EMSLIE AND THE FOUR FLAWS

Client Versus Clinician Ratings of Improvement

In their provocative tour de force, *From Placebo to Panacea* (1997), Seymour Fisher and Roger Greenberg demonstrate that clinicians and clients differ substantially in their reading of how much improvement has actually occurred. For example, in 1992, Greenberg, Bornstein, Greenberg, and Fisher published an extensive meta-analysis of 22 antidepressant studies involving 2230 persons—and compared the effects of a placebo with both "old" (Elavil, for example) and "new" (Prozac) antidepressants. They found that [both old and new] antidepressants showed an advantage [about 20%] over the placebo on clinician-rated measures, but none on client-rated measures. In short, when clients rate their own responses, they often experience no improvement on antidepressants beyond what can be attributed to hope and expectation. If clients don't feel better after taking medications, how meaningful is any improvement other raters think they see? The Emslie study found no difference between the placebo and SSRI groups on the two client-rated measures.

The skepticism researchers have for the perceptions of study participants, even if they are children and adolescents, reflects the mistrust of client views deeply ingrained in mental health discourse. Various explanations have been offered to discount client voices—for example, clients are too impaired by their "illness" to accurately report their condition, or they cannot objectively assess improvement or lack of improvement in the way an observing expert can.

Active Versus Inert Placebo

But how objective are expert observers in drug trials? Greenberg and Fisher (1997) demonstrate that the validity of controlled studies, in which a placebo is compared to a drug, depends upon the participants who rate the outcomes not knowing who is getting the "real" drug and who is getting the placebo. They note that the use of inert sugar pills as the placebo in the vast majority of studies actually makes it possible for most participants and clinicians to tell who is getting the real drug. The level of side effects experienced tips them off: those taking the active medication are more likely to experience the standard side effects—dry mouth, weight loss or gain, dizziness, headache, nausea, insomnia, and so on—clear signals they are taking a powerful drug, while those taking the sugar pill are not. As a result, the "double-blind" study is immediately "unblinded" for those rating outcomes, a fact that seriously compromises any conclusions that can be drawn. This is the second fatal flaw, the issue of an active versus inert placebo—whether or not the study was truly double blinded and included an active placebo that mimicked the side effects of the drug under scrutiny. The Emslie study used a sugar pill placebo and consequently the double blind was likely compromised.

So, because of inactive placebos, it is not a stretch for researchers to accurately guess who is getting a real drug and who isn't. Along these same lines, many drug trial participants in placebo groups have previously been on drug regimens, even some just prior to entering the

trial, and are therefore familiar with the effects of active medications. One review of blindness in antidepressant trials notes that participants are far from passive—they actively read subtle cues or attempt to discover their treatment status and do so with remarkable accuracy (Evan, Siobud-Dorocant, & Dardennes, 2000). This same review notes that simply asking participants to track side effects compromises the blind from the outset.

No active placebo was used in the 1997 Emslie study. The Emslie study researchers, undoubtedly aware of critiques by many of the double blind, attempted to salvage the integrity of the 1997 blind (Hughes et al., 2000). In their assessment, Emslie and fellow researchers determined that the blind "was clearly maintained" (p. 593). When both the Prozac and placebo groups were considered together, without regard to client response, there was no trend in the prediction beyond what would be expected by chance. However, when clients' responses to treatment were considered, clinicians accurately predicted medication for responders (27 out of 31) and placebo for nonresponders (26 out of 35). These represent approximate 87% and 74% rates of accuracy, respectively, far from chance predictions! It is more than interesting that the very efforts to bolster claims about the integrity of the blind ultimately prove that the blind was undermined. The so-called blind procedures in the Emslie study were at best visually impaired, subject to allegiance effects and experimenter bias.

Time of Measurement

The 8 weeks of the Emslie study were obviously an inadequate length of time to draw any conclusions about differences in medication or placebo response. First, antidepressants are almost never prescribed for short periods of time. Second, and more importantly, taking the last measure at 12 weeks provides an inadequate look at the differential efficacy because differences between groups tend to dissolve by 16 weeks (Fisher & Greenberg, 1997). This major design flaw points to the conclusion that longer-term evaluation was avoided, as in nearly all drug studies, because of fear that the effects would wash out.

Compromises to the study's blind and the trial's short time length are far from trivial limitations. The fact that only one clinician-rated measure of five outcome scales showed a difference between active medication and placebo is, at best, marginal evidence of medication superiority. Nevertheless, Emslie and colleagues concluded, "Fluoxetine treatment was superior to placebo in relieving depressive symptoms" (1997, p. 1031).

The importance of the Emslie study as a justification for prescribing SSRIs to juveniles cannot be underestimated. Keep in mind, until 1997 and Emslie's publication, there was virtually no evidence supporting the increasingly widespread prescription of antidepressants for children and adolescents. This study provided enough basis for antidepressant prescription to continue unabated (albeit off-label) for youths and represented the first of two needed to accomplish FDA approval of the medication Prozac for this group.

Conflicts of Interest

Emslie and colleagues completed the Prozac approval sweep in 2002 with the publication of a second placebo-controlled, randomized clinical trial for fluoxetine treatment of child and adolescent depression (2002). The first point of interest is on the first page of this article, which illustrates the fourth fatal flaw of drug studies, namely, who is funding the study and with whom are the authors affiliated.

In May 2000, the editor of the *New England Journal of Medicine* called attention to the problem of "ubiquitous and manifold . . . financial associations" authors of drug trials had to the companies whose drugs were being studied (Angell, 2000, p. 1516). Since this

time, there has been increasing pressure for medical journals to publicize funding sources and author ties to those sources to alert readers to potential conflicts of interest. It is illustrative to note that in the 1997 Emslie article, no author affiliations to drug companies were noted nor was the study's funding source identified. However, under the title of the 2002 Emslie study, readers can note that Drs. Emslie and Wagner were paid consultants for Eli Lilly and Company, who funded the research. The remaining six authors were listed as employees of Eli Lilly and "may own stock in that company" (p. 1205).

Beyond that—same study, different day. Eli Lilly and Company pronounced Prozac to be "well tolerated and effective for acute treatment of major depressive disorder (MDD) in child and adolescent outpatients" adding that "Fluoxetine is the only antidepressant that has demonstrated efficacy in two placebo-controlled, randomized clinical trials of pediatric depression" (Emslie et al., 2002, p. 1205). The primary measure of the study failed to show a significant difference in response; all client-rated and two clinician-rated scales showed no difference. Out of seven, three clinician-rated measures showed significant differences between the experimental drug and placebo. As a 9-week trial, the study did not assess longer-term outcomes. Once again, no active placebo was used, seriously calling into question whether the investigators, either employees or consultants of the company whose drug was under investigation, could, with so much at stake, reasonably remain objective.

Nevertheless, the deed was done—two studies allegedly proving efficacy of Prozac for children and adolescents. Shortly after the second publication, the FDA granted legitimacy to an already well-entrenched prescribing practice. The January 3, 2003, edition of *FDA Talk Paper* prepared by the FDA Press Office announced FDA approval for Prozac for pediatric use to treat depression (Food and Drug Administration, 2003a). The report noted that studies have found side effects similar to those in adult trials. The paper also acknowledged that, after 19 weeks of treatment with fluoxetine, youths in one clinical trial gained an average of 1.1 cm less in height (about 0.5 of an inch) and about 1 kg less in weight (about 2 lb.) compared to youths taking placebo. The FDA report added that, although long-term effects on growth are not known, Lilly had agreed to conduct a Phase IV postmarketing study to evaluate this concern. Unfortunately, the track record for pharmaceutical companies' completion of Phase IV follow-up studies is dismal. For example, of 107 new drugs approved between January 1995 and the end of 1999, not one had been classified by the FDA as having completed Phase IV commitments (Sasich, Lurie, & Wolfe, 2000).

What difference does FDA approval make if child and adolescent antidepressant prescription is already a well-established and growing fact of life? FDA blessing allows the unfettered marketing of these drugs to those who may be concerned about the drug's impact in children's lives. Bestowing the governmental seal of approval quells real fears of parents, clinicians, and clients. It allows the matter of efficacy to be put finally to rest. In an era of evidence-based practice, it can now be said that indeed there is evidence, regardless of how slight, that at least this particular compound works. This "fact" is now repeated in future research articles, mental health Web sites, promotional materials, workshops, classrooms, popular and professional books, ads, and more—media saturation reinforces truth.

For example, Brent and Birmaher (2002), in their most recent review of adolescent depression, unequivocally state the case for SSRIs for adolescent depression: "SSRIs are the most commonly used treatment for adolescent depression, because of the proven efficacy of fluoxetine, citalopram, and paroxetine in placebo-controlled trials, with a response rate of approximately 60% and a favorable side-effect profile" (p. 668). And this "truth" virtually halts inquiry into the actual soundness of the evidence that undergirds a massive child and adolescent pharmaco-mental health industry.

In contrast, but not supported by multibillion dollar corporate entities, psychotherapy for children and adolescents has a strong tradition of proven efficacy (Asarnow, Jaycox, & Tompson, 2001; Curry, 2001; Lewinsohn & Clarke, 1999; Michael & Crowley, 2002; Mufson, Weissman, Moreau, & Garfinkle, 1999). Nevertheless, the political and economic clout of medical psychiatry has allowed childhood psychopharmacology to take its place at the head of the treatment table.

STIMULANTS AND KIDS: THE WRONG KIND OF ATTENTION

ADHD is arguably the most controversial topic in recent mental health history because the ADHD diagnosis is not defined by a biological marker (Leo & Cohen, 2003); it is quite subjective, and is not easily distinguished from the everyday behavior of children (i.e., the diagnosis lacks reliability and validity [Duncan, Miller, & Sparks, 2004]); despite the guidelines of diagnostic prevalence of 3%-5% established by the 1998 National Institute of Health (NIH) consensus panel, diagnostic rates are as high as an astounding 33% in some locations (LeFever, Arcona, & Antonuccio, in press); and despite the lack of evidence for long-term safety and effectiveness, stimulant medication treatment for ADHD has increased significantly in the 1990s (Zito et al., 2003).

Without consideration of design flaws, stimulants, primarily Ritalin, have unequivocally established their efficacy over placebo in small, short-term, randomized clinical trials on narrowly defined ADHD symptoms (not on social or academic measures). To address the criticism that short-term efficacy studies do not address the more important issue of effectiveness—or the success of stimulants on a wider range of outcome measures in real settings over a longer period of time—the Multimodal Treatment Study of Children with ADHD (MTA Cooperative Group, 1999) was conducted. It compared four treatments for ADHD: behavioral treatment (BT), medication management (MM), combined BT and MM, and a community comparison treatment control group. The MTA already has been touted, in both popular and professional publications, as proving that stimulants are more effective than behavioral intervention. Similar to the Emslie studies, and given the impact of the study on prescription practices, it is important to scratch a little below the surface to understand its conclusions.

First, on the positive side, the most unique element of the study is its large sample. Previous studies of ADHD treatment have generally been small, with 1 to 20 participants in each condition. With 144 participants in each group, the MTA was far superior in numbers alone. The MTA also surpassed its predecessors because it evaluated treatment for 14 months instead of the customary 12-16 weeks. Another impressive aspect is the comprehensive nature of the assessments conducted. Rather than the simple clinician-rated outcome measures that characterize most studies, the MTA selected a total of 19 measures from multiple sources (parents, teachers, child, peers, objective tests, and observations) in multiple domains of functioning (ADHD symptoms, peer, and parent-child relationships, classroom behavior, and academic achievement).

Before looking at the specific problems with the MTA, consider the results collected at the 14-month endpoint, as summarized by Pelham (1999), one of the principal investigators:

- All four groups showed dramatic improvement.
- MM was superior to BT on parent and teacher ratings of inattention, and on teacher ratings of hyperactivity, but not on any of the other 16 measures.[1]

- Combined treatment and MM did not differ on any dependent measure; combined treatment was better than BT on parent and teacher ratings of inattention, and on parent ratings of hyperactivity and oppositional behavior, and reading achievement.
- Both MM and combined treatments were superior to community treatments on parent and teacher symptom ratings and on teacher-rated social skills, whereas BT was equivalent to community treatments; the two conditions with BT were superior to community treatment on parent-child relationships. (p. 982)

Let's examine these results in light of the usual design flaws of drug studies. First, as Breggin (2000b) articulates, the study was not placebo controlled or double blinded. The MTA not only lacked a pill placebo control group, but also relied only on evaluations made by teachers and parents who were not blinded to the treatment conditions. Adding emphasis to this criticism, Breggin suggests, is the fact that the only double blind measure (blinded classroom raters) found no difference among any of the treatment groups.

Next, consider the issue of client versus other ratings. Neither the participants themselves (the 7-9-year-old children) nor their peers rated the children as more improved when using medication than when using behavioral or community alternatives. Breggin suggests that the negative findings from the blinded classroom observers, the children themselves, and their peers indicate that stimulant drugs offer no advantages over nonmedication alternatives (2000b).

Finally, recall that the time of measurement is a crucial factor to consider. Here is the key flaw of this study: Assessment occurred at the 14-month endpoint while subjects were actively medicated, but after the fading of therapy. Endpoint measures were taken 4 to 6 months after the last, face-to-face, therapeutic contact! Thus, the endpoint MTA treatment comparison was for active MM treatment versus withdrawn BT. The study's slight drug-favoring results were a foregone conclusion based on the very way it was designed (Pelham, 1999).

Given that the results reflect medication versus withdrawn therapy, the lack of difference on 16 of 19 measures (when MM was compared with BT) and on 19 of 19 measures (when community treatment of mostly medicated children was compared with BT) is even more telling. Also impressive, given the withdrawal, is that 75% of the children in the BT condition were maintained without medication for 14 months, including one half of those who were medicated at study entry (Pelham, 1999).

Two papers addressing the 24-month, follow-up data are under review (W. Pelham, personal communication, April 21, 2003). They show that the group differences are even smaller because the MM and combined groups have lost much of their effect, while the BT and community groups have retained their gains. Further, at 24 months, the majority of parents in the BT group thought their youths were doing well enough that they did not medicate them even after the study had ended (W. Pelham, personal communication, April 21, 2003).

Moreover, the MTA reported that parents significantly preferred the behavioral and combined treatments over medication alone. Even when a preference for medication exists, most parents desire not to medicate their children for the long-term since most ADHD individuals stop taking stimulant medication during late childhood or adolescence (Pelham, 1999). This makes nonmedical intervention particularly important because effects of stimulant medication, though beneficial in the short term, do not last beyond medication termination. This is, of course, why the endpoint measure in the MTA was of active medication and withdrawn BT and not vice versa.

Perhaps parental concern about long-term stimulant use is most fueled by adverse drug reactions (ADRs). In the MTA, an alarming 64% of the children were reported to have some ADRs; 11% of the ADRs were rated as moderate, and 3% as severe, with the latter category representing largely "depression, worrying, and irritability." In his review of the stimulant medication research, Breggin (1998) reports that these troubling reactions to stimulant medications are common across clinical trials.

Finally, emphasizing the importance of parental preference, consider the recent revelation made by one of the principal investigators of the MTA, psychiatrist Peter Jensen. Jensen has been traveling the globe extolling the virtues of stimulants over behavioral interventions. With an audience at a recent APA meeting, Jensen shared that his son is diagnosed with ADHD, and that he and Mrs. Jensen opted for behavioral treatment instead of medication (O'Connor, 2001).

The MTA, as well as all the available evidence regarding stimulants, say nothing that indicates that medication should be privileged over any other option, especially as guided by client preferences. Moreover, and more troubling, the overuse of stimulants is a stopgap measure that locates the problem exclusively in the child (LeFever et al., in press); it creates an "attention deficit" in professionals to responding more creatively to behaviorally demanding children and their less-than-perfect learning contexts. Mental health professionals need to challenge business as usual and encourage a broader discussion of the socioeconomic and cultural issues affecting children and their success in the schools.

On balance, given the less than overwhelming empirical support and apparent medical risks, as well as the nebulousness of the ADHD diagnosis itself (Leo, 2002), the judicious use of stimulants seems warranted. LeFever and associates (in press) make the following (edited) recommendations:

1. Before any treatment, a suspected case of ADHD requires a thorough evaluation that establishes that the symptoms cannot be better explained by other factors, and are inconsistent with developmental level.
2. If a child receives a diagnosis of ADHD during the preschool years, stimulants should be avoided because many problems are resolved by the first or second grade.
3. Behavioral interventions ought to be tried first because of their comparable efficacy and lower medical risks than drug treatment.
4. If the child has not responded adequately after 6 months of therapy, then drug treatment may be considered.
5. Psychotropic medications should not be combined until data from controlled studies support the safety and efficacy of the combination in children. (p. 12)

DE-STIGMATIZATION AND TREATING THE UNTREATED

Putting aside the underwhelming efficacy of both stimulants and antidepressants, Walkup (2003) also argues that de-stigmatization has freed caretakers to use medical means to address children's psychological needs. De-stigmatization would be a good thing, but we find the logic that mental illness is not stigmatizing a bit hard to swallow. Breggin (2000a) states it well:

> Nothing is more stigmatizing than carrying the label of "mental illness" for the rest of your life. It is especially unfair and demoralizing to tell children that they suffer from "brain diseases," "biochemical imbalances" or "crossed wires" when they simply don't. (p. 27)

How benign is a psychiatric label when it means a child must take medicine and must rely on experts rather than on his or her own resources to solve problems? How harmless is it when a diagnosis means a child can forget pursuing a job or career in the armed forces, or may be ineligible to run for political office in the future? Instead, we concur with Breggin that psychiatric diagnosis and its sidekick, medication, create stigma. We prefer to understand children's problems from almost any other frame—lack of maturity, individual temperament, life trauma, or difficulties with relationships—situations that are amenable to time or to the effort of the child guided by those closest to him or her. We also prefer to take into consideration the impact of social conditions beyond the child, family, or school that inhibit the best efforts of all. What might be seen as a brain disease may, in fact, be better described as diseases of poverty, racism, or other forms of marginalization.

Walkup and others, often by omission, paint a relatively benign picture of the side effects of child psychiatric medications. One parent we know questioned the possible effects of Geodon, an antipsychotic, combined with Zoloft (an antidepressant) for her 15-year-old son. The prescribing psychiatrist responded by suggesting that she not read the warnings on the drug insert because "it would just make you crazy." While most professional organizations, including the NIMH, encourage parents to read and to be informed when considering medication for their child, we wonder how often adverse events get lost in the discourse of drug efficacy and benefit?

In reality, the side effects of psychotropic medications for children warrant serious examination. Primarily, the impact of earlier and longer chemical intervention on yet-developed brains represents a significant concern (Vitiello, 1998). There is evidence that the use of neuroleptic and other psychotropic medications makes long-term, if not permanent, changes in brain structure (Breggin & Cohen, 1999). Secondly, too many warning signals point toward an increased risk of mania and suicide brought about by psychotropic medications, specifically the SSRIs (e.g., see Breggin, 2000a). Emslie failed to discuss the implications of the 6% dropout rate due to manic reactions in his 1997 adolescents and Prozac study. If extrapolated to the general population (as are the study's efficacy claims), for every 100,000 children on Prozac, 6,000 would likely experience this serious adverse effect.

Moreover, in a study of paroxetine hydrochloride (Keller et al., 2001), 21 out of 93 (23%) Paxil-takers reported manic-like symptoms, including hostility, emotional lability, and nervousness. (Ten in the Paxil group reported tremor, none in the placebo group.) In real practice, when these medications are taken for much longer periods of time than in clinical trials, rates of serious adverse responses are likely to be even more pronounced. Nevertheless, both of the above mentioned studies proclaim the investigated drugs are "well tolerated" and safe. Meanwhile, reports of children becoming either more violent or more depressed due to medications designed to produce the opposite are abundant (e.g., see Breggin, 2000a; Breggin & Cohen, 1999; Fisher & Fisher, 1997)).

Recently, the United Kingdom's Medicine and Healthcare Products Regulatory Agency (MHRA) stated that Seroxat (paroxetine, also called Paxil in the US) must not be prescribed for anyone under the age of 18 years (Boseley, 2003). According to the MHRA, clinical trials have failed to demonstrate the compound's efficacy for childhood and adolescent depression. More importantly, these trials indicate harmful outcomes as much as 3.2 times greater in the paroxetine group compared to children and adolescents taking placebo, including increased agitation, aggression, self-harm, and suicidality. Glaxo, the drug's manufacturer, denied covering up studies suggesting the drug might

cause damage to youths under 18 years old. Earlier in the year, *The Guardian* revealed that members of the first working group investigating the safety of SSRIs held shares in Glaxo, leading to the group's eventual disbanding.

Nine days later, the FDA issued a similar warning. Stating that it was reviewing reports of possible increased risks of suicide thinking and suicide attempts in children and adolescents being treated with Paxil, the FDA recommended that Paxil not be used by this age group (Food and Drug Administration, June 19, 2003). The FDA's announcement also noted that three well-controlled trials in pediatric patients with MDD failed to show that the drug was more effective than placebo. Once again, how does this sit with the following claim made by the authors of one highly touted trial: "[Paxil] is generally well tolerated and effective for major depression in adolescents" (Keller et al., 2001, p. 762). The Keller and associates' study was funded by GlaxoSmithKline.[2]

The final argument Walkup and others make is that instead of questioning current prescription rates, we should in fact be asking if enough children are "receiving treatment." Fretting over design flaws or even a few unpleasant side effects is missing the bigger picture. This argument cites the Surgeon General's 2001 National Action Agenda for Children's Mental Health (NAACMH), claiming a virtual epidemic of child mental disorders. According to NAACMH, 1 in 10 children or adolescents in the US suffers from mental illness severe enough to impair their life functioning. Sadly, this initiative proclaims, only about one half of these "receive necessary treatment" (Mitka, 2001, p. 398).

In light of these messages, parents and other caretakers are understandably anxious, nervously watching for telltale signs that their child might be the next to succumb. According to Walkup, the most relevant question here is "not the increased use per se, but what percentage of children and adolescents with pharmacologically responsive conditions are actually getting medication treatment" (Walkup, 2003, p. 35). In other words, if only half are being treated, and if evidence now indicates responsiveness for the largest categories of disorders, then current prescription rates for children should practically double. Instead of the 5 million plus children taking psychotropic medications, there should be as many as 10 million or more "receiving treatment."

Missing in the explanations offered by Walkup and others, besides the questionable efficacy of these drugs, are several key questions. How do we know that so many children are "sick"? Have these disorders been hidden from view in past generations, and only now are we able to locate, diagnose, and treat them? If increases in childhood "mental disorders" are a more recent phenomenon, how might we make sense of this? Why are poor children—those on Medicaid, in the foster care system, or in residential settings—more often diagnosed and medicated? What role do simple cultural differences make when the psychiatric establishment is comprised mostly of White, American men (Zito, Safer, dosReis, & Riddle, 1998)? Finally, instead of diagnosable illnesses, are we seeing reasonable reactions to oppressive conditions by those most likely to be under the gaze of "the system"? If so, should we be putting our time, energy, and resources toward larger social agendas, rather than into pills that subdue and stigmatize the very victims of these conditions?

One thing we do know. Pharmaceutical marketing took on new life in the 1990s, and, at the same time, so did a host of mental disorders. With the population "educated" to the symptoms of silent epidemics, the everyday business of living, with its diversity of temperaments and emotional cycles, became subject to "disordering." Who stands to gain the most from promoting a medical versus nonmedical story for children in trouble? We believe that

an ethical path requires posing this question and those raised earlier to the scientific and broader communities in ways that invite clarification of the true options available to children and their families.

ETHICAL CONCLUSION: FIRST DO NO HARM

With all this largesse and publicity raining benevolently down, is it any wonder that people become hypnotically fixated on the brouhaha about a "revolution" in pharmaceuticals and overlook the boring fine print of the drug studies with their more negative implications? Is it any wonder that mental health professionals, who do not have the time to sift through the doublespeak, become beguiled into believing that privileging drugs is a matter of scientific fact? And consequently, how many will know that in the Emslie studies Prozac only outperformed placebo on a few clinician-rated measures, or the sleight of hand presentation of the integrity of the double blind; or the interesting design choice of withdrawing behavior therapy long before endpoint measurement in the MTA?

The time has come to take a long and critical look at the rapid encroachment of drug money and drug marketing influence on those who have the least power to just say no—children. Given that drugs are essentially foisted upon youths without their consent, and the efficacy and safety of drugs for youths has yet to be established, we consider the practice of prescribing drugs to youths as clearly the last resort, and in many cases, unethical, until other options have been discussed. The problem is, in the current pharmaceutical-saturated climate, it becomes increasingly difficult to have other options. The tale of drugs' magical powers to solve life's dilemmas is so compelling, so ubiquitous, there is literally no room for anything else. When faced with the difficult decisions about how best to help, parents, child professionals, and significant caretakers, with all the best intentions, too easily go for the medicine cabinet.

What is required is a shift, or, more likely, a reconnection with what parents and therapists know and have experienced over and over—that most people can and will develop solutions to even the most daunting dilemmas given support and encouragement, that the impetus to health has many avenues and sometimes takes unorthodox routes, and that change will and does occur naturally and universally. At its core is a faith in change and the human tendency to find a way even out of the heart of darkness. Children are no exception. We should not discount the abilities of children to rise to the occasion and to conquer difficult situations in their lives, particularly with the love and support of key adults. Nor should we discount the accuracy of the youngest voices to tell us what is working or what might help. We can protect children, and we can allow them into the equation, giving them a say in their lives (Duncan & Sparks, 2002).

Most often, children trust that adults know and do what is best for them. We must not betray this trust. We simply cannot be blasé about accepting the increasingly automatic medical response, but must demand high quality, untainted science and accurate, balanced information to inform critical decisions by child caretakers. Our ethical position is that families should make the decisions they believe will be most helpful for their youngest members. At the same time, we believe professionals are duty bound, by the ethics of our various professions, to ferret out the good science from the bad and to learn to critically analyze claims in Web sites, brochures, press releases, and scientific studies regarding medications for children. We recommend a vigorous critique of what has come

to be everyday understanding of what works for children and teenagers as they navigate sometimes difficult paths to adulthood. We are obligated to be purveyors of this information to those who must make the final choice, the families themselves.

Finally, we believe therapists are obligated to not take the easy road by abandoning tried and true counseling skills in favor of a "quick fix." Being up-to-date on the latest pediatric psychopharmacology at the expense of adding to or strengthening other practices only bolsters medical dominance and diminishes the choices we can offer. When concerned parents approach us, we should be ready and willing with a range of nonmedical strategies. We assert that heroic youths and heroic parents should have a full range of options for making this journey on their own terms. Only then can we claim that we first do no harm.

NOTES

1. Although Pelham reports that MM was superior to BT on parent and teacher ratings of hyperactivity, the table on page 1082 in the 1999 MTA paper says that according to the teachers the students were better off in terms of inattention but not hyperactivity. This has been pointed out by authors not affiliated with the MTA study (Leo, 2003, personal communication), but has never been clarified in print by any of the MTA researchers.

2. The lead author of the study, Martin Keller, according to *The Boston Globe* (Kong & Bass, 1999), earned over one half million dollars in consulting fees in 1998, mostly from pharmaceutical companies whose drugs he touted in medical journals. The story reported that neither Brown University, where Keller is a professor, nor Keller reported these payments to the government as required of grantees under federal regulations designed to prevent research bias.

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