

Just Say 'No' to Drugs as a First Treatment for Child Problems

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When children and teens present with behaviour and emotional problems the lure of a quick fix is understandable and drugs present a ready-made solution. Therapists are often hesitant to talk about medication and defer to medical professionals. In this paper DUNCAN, SPARKS, MURPHY and MILLER highlight the explosion in the use of psychotropic medications for children and teens. This trend flies in the face of the American Psychological Association's recommendation of the use of psychosocial interventions as the first intervention of choice with children and teens. The reliability and validity of psychiatric diagnoses is questioned, in particular against a background of fluctuations in child development and social adaptations, and a compelling critique is provided of the current research findings on the effectiveness of psychotropic medications including antidepressants and ADHD medications. Therapists are urged to shed their timidity and discuss openly the risks and benefits of medication with the knowledge that there is empirical support for psychosocial interventions as a first line approach. Recommendations are offered to engage clients as central partners in developing solutions—medical or non-medical—that fit each child and each situation.

A mother has a moment of panic, spying her daughter's arms crisscrossed with red cuts.

A harried teacher does a double take when the behaviour of a typically disruptive middle schooler takes a bizarre turn. Young parents are at a loss to explain the uncontrollable rages of their five-year old. In each case, the spectre of mental illness hovers, whispering an urgent command to "*get professional help!*" Psychotherapists are often the first stop for help—we, like our clients, feel the pressure to solve the problem rapidly with the best standard of care. And, more and more, that standard has become synonymous with psychiatric medication.

With daily pressure on therapists to manage youth behaviour and emotional problems, the lure of a quick fix is understandable, and drugs seem a ready-made solution. But beyond referring families for psychiatric consultations, therapists are often hesitant to talk about

medication with the families they see, choosing instead to defer to medical professionals. But to *not* talk about psychiatric drugs in today's world of ubiquitous chemical imbalances and glossy advertising remedies is to ignore the proverbial elephant in the living room. Prescriptions of psychotropic drugs for children and adolescents have skyrocketed. To skip a discussion of medication is to disregard a growing reality that impacts on children and their families. The *Rx* (medical prescription) elephant won't go away just because we don't talk about it.

Our reticence is mirrored in parents and children who are reluctant to offer an opinion or ask a question about other options or side effects. The end result is that children, parents, and therapists are often shut out of the loop—their questions, ideas, and solutions take a back seat. But how can therapists broach this topic—after all, we are not medical experts, or as the joke goes, we are not 'real' doctors.

Aren't we stepping out of our expertise and professional role to discuss medications with clients?

While we may be stepping out of our comfort zones, we are not travelling beyond the boundaries of our expertise to discuss options regarding treatment approaches for young people in distress. We need not fear these conversations or feel timid in the face of medical opinion; the data speak clearly about just how safe and effective psychiatric drugs are for children. The empirical evidence supporting the benefit of child medication is far from substantial, while concerns about safety continue to surface. Therapists can use this knowledge to confidently assist with medication decisions—they can help children and parents get the facts about risks and benefits, and make clear the take-home message that there are many paths to preferred ends.

It is not our aim to discredit individual preferences for or experiences with medication, or to

claim that psychiatric drugs are not ever helpful. We are not wide-eyed anti-drug zealots. Instead, we are anti-privileging drugs as a first-line solution—especially for children and adolescents. And while we are adamant about putting clients in charge of the decision to medicate and have been writing passionately about the lack of demonstrated efficacy of drugging children for nearly ten years, we are actually in the mainstream of current scientific thinking, *The American Psychological Association Working Group on Psychotropic Medications for Children and Adolescents*, 2006 states:

'It is the opinion of this working group that...the decision about which treatment to use first...should be guided by the balance between anticipated benefits and possible harms of treatment choices... For most of the disorders reviewed herein, there are psychosocial treatments that are solidly grounded in empirical support as stand-alone treatments. Moreover, the preponderance of available evidence indicates that psychosocial treatments are safer than psychoactive medications. Thus, it is our recommendation that in most cases, psychosocial interventions be considered first.' (p. 175, emphasis added)

The report further points out: *'Ultimately, it is the families' decision about which treatments to use and in which order. A clinician's role is to provide the family with the most up-to-date evidence, as it becomes available, regarding short- and long-term risks and benefits of the treatments.'* (p. 175)

The APA is hardly an organization known for going out on a limb or taking risky liberties with the data! This knowledge means that when children experience difficulties, discussions about solutions can be open, creative, and evolving, and encompass a range of views about change based on each person's concerns, circumstances, and preferences. While medication may be useful for some children, it does not have to dominate intervention strategies or monopolize talk about change. Therapists can expand the range of options, and their clinical roles, even in circumstances that typically trigger prescriptions.

Explosion in the use of psychotropic medication for children and teens

Jess, a 15-year old girl enters school through the front door, proceeds down the hallway and out the back, another no-show for the day. Jess finds it difficult to attend to classroom work, preferring to hang out with the pony she helps care for as a part-time job. At the school meeting, Jess's mother states that she found marks on her daughter's arms, apparently self-inflicted with her father's pen knife. A referral to

a psychiatrist is made and Jess is prescribed an antidepressant.

Jess is not alone. The past decade has seen an explosion of psychotropic medication prescriptions for children and teens (Zito et al., 2003). In the United States prescriptions for antidepressants have increased at a rate of 11 per cent each year from 1994 to 2000, and five per cent each year since, a total of over eleven million prescriptions written annually. The number taking antipsychotic medicines soared 73 per cent in the four years

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Illustration: Shannon Rose

ending in 2005, far outpacing the increase in adults—over 2.5 million youth in the US per year are prescribed antipsychotics (dosReis, Zito, Safer, Gardner, Puccia & Owens, 2005). Spending on drugs like Ritalin for behavioural problems exceeds any other category for the first time, including antibiotics. The number of kids taking one or more prescription medicines to treat mental health-related conditions has hit nearly nine per cent. If Jess

to neuro-imaging research as proof positive of the biology of behavioural and emotional problems. A highly publicized study claimed to show that the brains of ADHD-diagnosed children were smaller than their non-ADHD counterparts (Castellanos et al., 2002). However, anatomy Professor Jonathan Leo and researcher David Cohen report that the control group was two years older, heavier, and taller than the ADHD diagnosed children,

Yeab...I told my mom about Nick (Jess's boyfriend). She knows we broke up.

Therapist: *Is that what's bothering you the most now?*

Jess: *Yeab. That, and school sucks.*

Jess, her mom and the therapist talk about how Jess cuts herself to help with the emotional hurt. They also talk about Jess's boredom with her classes and her desire to work more to earn money and not 'waste time' at school. They listen to Jess and value that she feels comfortable enough to let them into her world. All agree that the first order of business is for Jess to be safe. Since Jess is adamant about not wanting medication, they agree to set up a safety plan. The practitioner ensures that Jess is the primary architect of the plan, prompting her to identify strategies that she believes will work. Instead of cutting at night when she felt down, Jess planned to listen to music, get in her mom's bed or call her friends. Jess writes the strategies down and signs an agreement to tell her mom or call the therapist if she feels like it is not working.

There are many ways to reach desired ends. Not every child is Jess and not every parent will react the same way. What will work can only be known one child and one family at a time after an open consideration of options.

Validity and reliability of psychiatric diagnosis

Michael, age 13, is home from residential treatment and recently reunited with his mother who is now attending regular Narcotics Anonymous meetings. When confronted about his 'clowning' in math class, Michael makes a beeline for the door and is found hanging halfway up the flagpole like a frightened monkey. In short order, Michael's diagnosis is changed from ADHD to early onset bipolar disorder. His medication is changed from stimulants to anticonvulsant and antipsychotic medications.

'Early onset bipolar disorder' has an ominous ring to it. At first glance medication seems the most logical intervention for preventing a slide into more distress and coping with the disorder. Diagnosis, as the sole gateway to medications, provides the official rationale for medical

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lived in a foster home, she would be 16 times more likely to be medicated; if the diagnosis ended up bipolar disorder or ADHD, her chances of being on more than one medication at the same time would be as much as 87 per cent (Duffy et al., 2005).

The push to medicate young people is fueled partially by the belief that problems are biological and require medical intervention. Web pages, doctor's office brochures, magazine articles and TV advertisements describe depression, ADHD, mood swings, and the like as brain dysfunctions. Even when we know they are promotions from drug companies, pictures of neurotransmitters or talking serotonin cartoons are powerful, lasting images. This biological perspective is also backed up by impressive sounding clinical studies. Social explanations and solutions are not accorded the same weight in the media as medical ones and are a distant second when it comes to research funding and marketing. As a result, claims are rarely questioned and the assumption that child and adolescent problems have a biological basis has become accepted fact.

Cartoons notwithstanding, biochemical imbalances and other so-called mind diseases remain the only territory in medicine where diagnoses are permitted without a single confirmatory test (Duncan, Miller & Sparks, 2004). Many point

undermining any conclusion about brain size and ADHD (Leo & Cohen, 2003). Despite fifty years of efforts to find one, no reliable biological marker has ever emerged as the cause of any psychiatric 'disease'.

Knowing there is no irresistible scientific justification to medicate, the therapist is free to put other options on the table and draw in the voices of Jess and her mother.

Mother: *Jess, you can't keep doing this.*

I don't want you to hurt yourself.

What's wrong? What do you want?

Jess: (Shrugs shoulders and looks down.)

Therapist: *Jess, we just want to make sure you're safe? What do you think will help?*

Jess: *I don't know.*

(Everyone just sits for a while. There is genuine puzzlement and concern from everyone in the room—there does not seem to be a way out of the dilemma.)

Mother: *Jess, do you want to take the medicine that Dr. Stevens gave you? He said you were clinically depressed and that it would help.*

Jess: *No! I don't want to take any pills. I've got to do this myself.*

Mother: *Okay.*

Therapist: *Jess, do you want to talk with me and your mom, or maybe just one of us alone, about some of that stuff we talked about last week?*

Jess: (after a lengthy pause, thinking)

intervention. The belief that diagnosis can provide accurate identification of discreet disorders is a key assumption that underlies medication prescription. Therapists may feel that they have little choice but to assume that a diagnosis explains what is wrong and provides a solution.

In spite of its widespread acceptance, the validity and reliability of psychiatric diagnosis is suspect (Duncan et al, 2004; Sparks, Duncan & Miller, 2006). In particular, diagnostic validity is questionable when it comes to children. According to the World Health Report, 'Childhood and adolescence being developmental phases, it is difficult to draw clear boundaries between phenomena that are part of normal development and others that are abnormal' (World Health Organization, 2001). The notion of stable, fixed psychiatric syndromes does not fit the fluctuations of child development and adaptation to social environments—children change continually with age and context.

Reliability has to do with whether or not clinicians looking at the same array of symptoms will come up with the same diagnosis. If there is independent agreement on a diagnosis amongst professionals, it is considered reliable. Robert Spitzer, the primary architect of the DSM, commented on the ability of the DSM to provide consistent agreement in clinical diagnosis: 'To say that we've solved the reliability problem is just not true... It's been improved. But if you're in a situation with a general clinician it's certainly not very good. There's still a real problem, and it's not clear how to solve the problem' (Spiegel, 2005, p. 63). In other words, Michael might well be diagnosed with depression if he were seen by a different clinician, or may not have received a diagnosis at all. A bipolar diagnosis can last a lifetime; out-of-the ordinary child behaviours tend to be time-limited. Recognizing the potential negative effects, the American Counseling Association's Ethical Code supports counsellors who refrain from making a diagnosis.

Returning to Michael, consider the therapist's response to his diagnosis:

Therapist: Hey, Michael, how's it going?

Michael: Not so good. The doctor says I have some kind of... I forget. Anyway, he gave me these new pills to take. I didn't

like the old ones, but these are even worse. Mom says I should take them, but they make me feel weird!

Therapist: I saw what the doctor said in the report he sent me. It says that it seems like your moods kind of go up and down. Does that seem right to you?

Michael: Yeah. Kind of. I never know if mom is going to, you know, go off again. It's hard to sit there in class when I keep thinking about that, so I just start joking around. Then Mr. Riley gets on my case, and I haven't even done anything so I say 'I'm outta here!'

Therapist: Wow. That makes a lot of sense. No wonder you wanted to do something to get that thought out of your mind for a while.

Michael: So, you mean I'm not crazy?

It was important for Michael to make sense of his own experience and actions, and to understand these as reactions to stressful events. The therapist refused to allow the diagnosis or his situation at home to get him off the hook. They brainstormed ways that Michael could deal with his stress without getting in trouble. The therapist returned to the pills because Michael expressed discomfort with them. Referring to the outcome measure the therapist was using, the practitioner suggested that Michael monitor his response to the medication to determine whether it was working or making him feel worse.

Instead of certain diagnoses resulting in knee-jerk prescriptions, troubling behaviour can be validated

as making sense within the context of the child's life. And if medication is a part of treatment, children can monitor whether medication is useful and, with the help of adults, can be in the driver's seat in medication decisions.

Are research findings on the effectiveness of psychotropic medication reliable?

Six-year old Kyle, according to his parents, 'flies into a rage at the drop of a hat.' They note that Kyle's rages occur when playing with his three-year old sister and they fear that he may hurt her. Kyle's mother shares with a therapist her concern that Kyle might have a mental illness and wonders whether medication could help. When parents hear that even young children can be mentally ill and that problems result from undiagnosed disorders, it makes sense that they may adopt this point of view when other explanations and options are not readily available.

The decision to pursue psychotropic drugs is based largely on the belief that they work. People assume that Prozac and similar drugs are the intervention of choice for child and adolescent depression, and that stimulant medications are consistently effective for children labeled with ADHD. Pediatricians and family doctors also endorse such assumptions based on published evidence from clinical trials.

The clinical trials most often cited for medication effectiveness include: the two clinical trials that gained



Prozac FDA approval for childhood depression conducted by psychiatrist researcher Graham Emslie of the University of Texas Southwestern Medical Center and colleagues (1997, 2002) (hereafter called the Emslie studies); and the Multimodal Treatment of ADHD (MTA) examining the efficacy of Ritalin versus behavioural and combined intervention (MTA Cooperative Group, 1999, 2004ab).

The gold standard for research is the randomized, double blind, placebo controlled trial. In this design, two groups are formed, presumably similar since they are selected randomly from the initial pool of applicants. One group gets the drug being tested; the other, a placebo. In this design, neither study participants, researchers, nor assisting clinicians, should know who is in which group—that is, who is taking the real drug and who is getting the dummy pill. This helps eliminate the bias that comes when participants and researchers know who is in each group, and weeds out factors like hope and expectancy that could interfere with determining what is actually responsible for any differences found between groups. The validity of the trial depends upon the ‘blindness’ of participants who rate the outcomes.

However, most studies do not use active placebos—pills that mimic the effects of real drugs. Rather, they use inert sugar pills as the placebo which makes it possible for most participants and clinicians to tell who is getting the medication. Inert sugar pills, or inactive placebos, do not produce the standard side effect profile of actual drugs—dry mouth, weight loss or gain, dizziness, headache, nausea, insomnia and so on. Study participants are likely to be on the alert for these types of events and, since most have been on medications before, many are familiar with these effects. As a consequence, these subjects are likely to identify correctly which group they are in (Fisher & Greenberg, 1997; Sparks & Duncan, in press).

Researchers interview participants throughout the study to collect information about change and side effects. On-going interviews that listen for or are active in asking about side effects can reveal the active versus

inactive pill takers easily, effectively un-blinding the study and skewing results. In support of this theory, a meta-analysis conducted by psychiatrist researcher Joanna Moncrieff of the University College of London found that when studies used active placebos, little or no differences were found between the dummy pill and the drug (Moncrieff, Wessely & Hardy, 2004). The Emslie studies used inactive, sugar pill placebos drawing into question the integrity of the study’s double blind. Evidence of the compromised double blind were apparent in the drug manufacturer’s own records where *‘it was not uncommon to see notations defining the patient’s blinded treatment, or in some cases to find fluoxetine (Prozac) plasma concentration results’* (FDA, 2001, June 25, p. 19).

The instruments chosen as primary measures in drug trials are clinician-rated. Frequently, client ratings of improvement differ from clinician’s, often in ways that run counter to findings of drug effectiveness. In both clinical trials that resulted in FDA approval of Prozac, no client-rated measures indicated superiority of the drug over placebo. However, both studies concluded that Prozac outperformed placebo. How valid can an assessment of improvement be if the client does not agree with it? In the first Emslie study, two out of four clinician-rated measures indicated a difference between the placebo and SSRI groups. Two client-rated measures found no difference. Similarly, the primary measure of the second study failed to show a significant difference—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. If children and their parents do not detect improvement over placebo, how effective are the drugs?

Standard time frames for clinical drug trials are 8 to 12 weeks. In contrast, most prescriptions for youth psychiatric medication assume that the drug will be taken for much longer. Assessing how well a drug does in an 8 to 12-week period cannot portray an accurate picture of the drug’s performance in real life. Differences

between medication and placebo groups tend to dissolve by 16 weeks. Without longer term follow-ups, researchers cannot make accurate conclusions about effectiveness in everyday life. The Emslie studies were of eight weeks duration, calling into question their usefulness in real-world decision making.

A key component of evaluating any drug trial is learning who paid for it and what the authors’ potential conflicts of interest are. The pharmaceutical industry’s influence over scientific inquiry has, in some ways, become almost a cliché. In May of 2000, the editor of the *New England Journal of Medicine*, Marcia Angell called attention to the problem of *‘ubiquitous and manifold... financial associations’* of authors to the companies whose drugs were being studied (Angell, 2000, p. 1516). Why is it important to know who sponsors a study? One recent review (Heres, Davis, Maino, Jetzinger, Kissling & Leucht, 2006) looked at published head-to-head comparisons of five popular antipsychotic medications. In nine out of ten studies, the drug made by the company that sponsored the study came out on top.

Without an appreciation of the role industry influence plays in how the study is designed, carried out, and disseminated, it would be easy to accept bottom line conclusions as fact. However, recent regulations now require authors to fully disclose their affiliations, allowing a more critical appraisal of any study’s conclusions. The first Emslie study, published prior to disclosure requirements, did not identify author affiliations. However, FDA data indicate that Eli Lilly sponsored the study. The second and approval-clinching trial of Prozac for child and adolescent depression lists author affiliations on the first page. Here, readers learn that Emslie is a paid consultant for Eli Lilly, who funded the research and whose product was being investigated. The remaining authors are listed as employees of Eli Lilly and *‘may own stock in that company’* (p. 1205). Combining this information with the ‘unblinding’ that results from inactive placebos seriously calls into question whether the researchers, either employees or

consultants of the company whose drug was under investigation could, with so much at stake, remain objective.

Recent pooled analyses of both published and unpublished trials of SSRIs for the under-18 age group reveal that, as far as how well they work, these drugs, plain and simple, do not deserve a blank cheque. An

(the 7–9 year old children) rated themselves as no more improved when using medication than when using behavioural or community alternatives. Of interest, peer ratings concurred with this assessment. The fact that neither blinded classroom observers, the children themselves, or their peers found that medication was better than

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analysis by researcher Jon Jureidini found that, out of 42 reported measures in six published trials, only 14 showed a statistical advantage. None of the youth and parent measures in this sample indicated any advantage of the drug over a sugar pill—only the doctors reported improvement. They also discovered that the effect size for the drug over placebo was quite modest (0.26), amounting to only a 3 to 4 point difference on scales which had ranges from 17 to 113 as possible scores. This may be statistically significant, but fails the test of clinical significance—that is, fails to tell us anything meaningful about the client sitting in front of us, much less serve as a mandate, or ‘best practice’. Unpublished trials fared much worse—only one in nine showed a statistical advantage for the drug over placebo (Jureidini, Doecke, Mansfield, Haby, Menkes & Tonkin, 2004).

The Multimodal Treatment Study of Children with ADHD (MTA), the major trial supporting the superiority of ADHD medication, not only didn’t use an active placebo, it lacked a pill placebo control group altogether (MTA Cooperative Group, 1999). As a consequence, it relied on evaluations made by teachers, parents, and clinicians who were not blinded to the intervention conditions. The only double-blind measurement (made by classroom raters) found no difference among any of the intervention groups. In fact, the subjects themselves

behavioural interventions suggests that stimulant drugs offer no advantages over non-medication alternatives.

With regard to time frames, the MTA surpassed its predecessors because it evaluated outcomes at 14 months instead of the customary 8–12 weeks. The assessment occurred at the 14-month endpoint while subjects were actively medicated. However, behavioural intervention had long since stopped—endpoint measures were taken four to six months after the last face-to-face contact. Thus, the endpoint MTA comparison was between active medication and withdrawn behavioural intervention. This made the comparison hardly a head-to-head contest, making the slight superiority of medication (on 3 of 19 unblinded measures) a foregone conclusion. A 24-month follow-up of the MTA shows that the improvements of children on medication deteriorated (up to 50 per cent) while the behavioural intervention group retained their gains. All advantage of the combined group over the behavioural intervention also dissipated (MTA, 2004a).

Finally, consider the conflicts of interest. For those studies conducted before the disclosure requirement, a little sleuthing can help. An online database published by a non-profit health advocacy group (*Integrity in Science*, www.cspinet.org/integrity/) reveals that lead MTA investigator Peter Jensen and at least five other

MTA authors have significant ties to drug companies. Specifically, Jensen is listed as a consultant to Novartis, the makers of Ritalin, the drug under investigation in the MTA.

When practitioners know what to look for—does the study have a true double blind, are outcome measures clinician or client rated, how long did the study last, who funded the study and what are the authors’ industry affiliations—they realize that medication should not be privileged over other psychosocial options (Sparks & Duncan, in press). Equipped with this information, therapists also have a powerful method for evaluating future studies without having to take the word of the latest headline or sound byte on the evening news.

Kyle and his family are at a crossroads. It would not be hard to start down a path that saw his difficulty as the early signs of mental illness. Through this lens, a proactive approach might make sense, warding off a potential downward spiral before it becomes entrenched and intractable. However, knowing also that such an approach most likely means medication with its attendant risk and unproven efficacy, it also makes sense to explore other ways to understand and to resolve his and his family’s dilemma.

Therapist: *I can certainly see that you have some concerns here. I really appreciate how you’re trying to make sure that you know what’s going on so that you can take action sooner rather than later. Usually, it’s a lot easier to head things off at this age, rather than wait until the child is 8 or 9 when it is a lot harder.*

Mother: *Exactly! That’s what we [with Kyle’s dad] thought too. That’s why I wanted to speak to you. You know, since we moved here, and the new baby came, and starting the business and all, we hardly have time to sleep.*

Therapist: *Well, it says a lot about you that you could make the time to get in here today!*

Mother: *Thanks. What you said about doing something now rather than later, did you think we should have him see a doctor, or have some kind of evaluation, maybe some medication or something?*

Therapist: *Well, that is certainly something that could be done. But, we don’t really know if that will be needed at this point. Most of the time, we can*

work with the schools and also recommend things at home, that can move things in a better direction. Children of Kyle's age typically respond well to behaviour plans. We can observe what's working for him and what we can do to build in some rewards for when things are going well. It would be helpful if you could do the same—see what is working or what isn't at home. Would you note the times that Kyle is getting along with his sister and when things are going well? (Mother nods in agreement) If we can meet again next week, we might have some better ideas of what's going on and where to go with things. Does that make sense?

Mother: *Yes, it does. Problem is, his dad and I are so busy, and the baby takes up so much of my time, we hardly pay much attention to Kyle these days except to tell him to do things, like get ready for bed or to stop doing things. Come to think of it, we don't even have time to get him in bed like we used to, with his favorite game and story.*

Kyle's mother and the therapist detailed concrete steps that could be implemented at school and home. A follow-up meeting was scheduled to review progress and develop a behavioural plan based on the mother's and the teacher's observation of what was working. Diagnosis and medication, while not discounted, were not the primary discussion topics. Instead, other ways to view and address the problem emerged from a therapeutic partnership to explore options.

Safety

Jess's mother was torn. On one hand, she feared for her daughter's life and would do whatever it took to protect her. On the other, she was leery of medications and, in particular, ones not approved for children. Michael was placed on an antipsychotic and an anticonvulsant. All he knew was that he didn't feel right. His teacher noted that Michael no longer disrupted class, but instead put his head on the desk a good portion of the day. Many popular drugs are viewed as safe for children. However, safety is often tied to a lesser-of-two-evils argument. Many are willing to accept certain risks when the possible alternative is a child's school failure, drug abuse, crime or suicide.

Most psychiatric medications for

children are prescribed 'off label'. This means that the majority of drugs prescribed frequently do not have the requisite two clinical trials that show they are safe and effective. Included in off label medications are the new antipsychotics and all anticonvulsants. Additionally, there are no studies to support the efficacy or safety of

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prescribing multiple medications. All antidepressants, with the exception of Prozac, are prescribed off label for child and adolescent depression. The window of approved drugs for children is very narrow—more narrow than what might justify the robust prescription rates. Even approved medications often have risks that are minimized in the decision-making process.

As the APA report noted, a thoughtful weighing of risk versus benefit is at the heart of any medication decision. Much of the data that has been collected raises concern. A systematic evaluation of 82 medical charts of children and adolescents treated with SSRIs found that 22 per cent experienced some type of psychiatric adverse event (PAE), typically a disturbance in mood (Wilens, Biederman, Kwon, Chase, Greenberg & Mick, 2003). Estimates of PAEs in child and adolescent studies is complicated by inconsistent collection methods for side effects data, and benign or misleading assessments of data actually reported. In the first Emslie study, six per cent of participants taking Prozac dropped out due to manic reactions compared with two per cent in the placebo group. If extrapolated to the general population, for every 100,000 children on Prozac, as many as 6,000 might be expected to experience this serious adverse effect. In addition, according to FDA documents, at least two

participants receiving Prozac in this study attempted suicide (FDA, 2001, June 25).

After a review of published and unpublished trials, the FDA issued a black box warning for all antidepressants for children, alerting consumers and providers to increased risk of suicidality and

clinical worsening (FDA, October, 15, 2004). The Medicines and Healthcare Products Regulatory Authority (MHRA) in the United Kingdom took it further, banning all antidepressants (except Prozac, which can only be used with children over eight years when talk therapies have failed). Growth suppression and adverse cardiac effects have been noted as well (FDA, 2001, June 25; FDA, 2003, January 3).

ADHD drugs also have troubling records when it comes to side effects. Sixty four percent of the children in the MTA reported adverse drug reactions: 11 per cent were rated as moderate and three per cent as severe. In March of 2006, an FDA safety advisory committee called for stronger warnings on ADHD drugs, citing reports of serious cardiac risks, psychosis or mania, and suicidality. Stimulant medications have also been associated with increased emergency room visits. A recent study conducted by the U. S. Centers for Disease Control and Prevention found that thousands of children taking stimulants wind up in the ER with chest pain, stroke, high blood pressure, fast heart rate, and overdose (Johnson, 2006, May 25). Finally, the MTA also revealed that the average height suppression for older children was about 1 cm per year, while younger children averaged 1.4 cm per year height loss with a 20 per cent reduction in growth rate.

Children like Michael, diagnosed with pediatric bipolar disorder, are taking antipsychotic medications in record numbers (Duffy et al., 2005; Staller, Wade, & Baker, 2005). Side effects for these drugs in adults are well known, including irreversible movement disorders, obesity and the risk of diabetes. Given that one in five visits to a psychiatrist by a young person results in an antipsychotic prescription, a six-fold increase in recent years, it's hard not to be alarmed at what these risks might mean for children (Olfson, Blanco, Liu, Moreno & Laje, 2006).

Conclusion

The decision of whether or not to medicate a child is one of the most difficult any family can face. A medical path is always a choice, and its pros and cons can be explored with medical and non-medical professionals. Therapists can feel free to shed their timidity and discuss openly the risks and benefits of medication, with the knowledge that there is empirical support for psychosocial intervention as a first line approach. The following are recommendations for engaging clients as central partners in developing solutions—medical or non-medical—that fit each child and each situation.

- Gather input from multiple sources including the child, parents, teachers, school records, and other community care-givers.
- Develop multiple frameworks of understanding the problem based on the perspectives of the youth, parents, teachers, and significant others. Include developmental, familial and environmental explanations.
- Develop a concrete plan of action. If medication is part of the plan, make sure that all involved, including the youth, are aware of potential risks, adverse events, the meaning of off label prescription, and the lack of studies supporting combining medications. Suggest resources for obtaining additional information about risks and benefits. Include discussion of a time frame for discontinuation of medication.
- Work with the child, parents, teachers and others to implement the plan and modify it based on

systematic feedback on an outcome measure that is understood easily by all (like the *Child Outcome Rating Scale*—free download at www.talkingcure.com.) If medication is part of the plan, invite the youth and others to monitor the effects and use the results as a basis for discussion with medical professionals. Invite the youth and others to view positive change as resulting from their efforts—'Given that some take meds and they don't work, how is it that you made them work for you?' These kinds of questions encourage people to take ownership for successful outcomes.

Lack of critical awareness takes on greater weight where children are concerned because children trust adults to make good decisions on their behalf. We hope that knowing about the APA recommendations, the lackluster empirical support for drugging children as a first-line intervention, and the attendant safety risks has bolstered your confidence to talk about medication, raise concerns about robotic prescription practices and side effects, and offer alternatives. An awareness of the relationship between a profit-driven industry and science, and what that science actually reveals, enables therapists to assist families to make intervention decisions—not only permitting a fuller picture from which to construct solutions, but also an appreciation that a child constantly changes with the ebb and flow of life, and is indeed like a river. You cannot step in the same river twice.

References

- American Psychological Association Working Group on Psychoactive Medications for Children and Adolescents. (2006). Report of the working group on psychoactive medications for children & adolescents. Psychopharmacological, psychosocial, and combined interventions for childhood disorders: Evidence base, contextual factors and future directions. Washington, DC: American Psychological Association. Retrieved Sept. 22, 2006 from <http://www.apa.org/pi/cyf/childmeds.pdf>.
- Angell, M. (2000). Is academic medicine for sale? *The New England Journal of Medicine*, 341(20), 1516–1518.
- Castellanos, F. X., Lee, P. P., Sharp, W., Jeffries, N. O., Greenstein, D. K., Clasen, L. S., Blumenthal, J. D., James, R. S., Ebens,

- C. L., Walter, J. M., Zijdenbos, A., Evans, A. C., Giedd, J. N. & Rapoport, J. L. (2002). Developmental trajectories of brain volume abnormalities in children and adolescents with attention-deficit/hyperactivity disorder. *JAMA*, 288(14), 1740—1748.
- dosReis, S., Zito, J. M., Safer, D. J., Gardner, J. F., Puccia, K. B., Owens, P. L. (2005). Multiple psychotropic medication use for youths: a two-state comparison. *Journal of Child & Adolescent Psychopharmacology*, 15(1), 6877.
- Duncan, B., Miller, S., & Sparks, J. (2004). *The Heroic Client*. San Francisco: Jossey-Bass.
- Duffy, F. F., Narrow, W. E., Rae, D. S., & West, J. C., Zarin, D. A., Rubio-Stipec, M., Pincus, H. A. & Reiger, D. A. (2005). Concomitant pharmacotherapy among youths treated in routine psychiatric practice. *Journal of Child and Adolescent Psychopharmacology*, 15(1), 12–25.
- Emslie, G. J., Heiligenstein, J. H., Wagner, K. D., Hoog, S. L., Ernest, D. E., Brown, E., Nilsson, M. & Jacobson, J. G. (2002). Fluoxetine for acute treatment of depression in children and adolescents: A placebo-controlled, randomized clinical trial. *Journal of the American Academy of Child and Adolescent Psychiatry*, 41(10), 1205–1215.
- Emslie, G.J., Rush, A.J., Weinberg, W. A., Kowatch, R. A., Hughes, C. W., Carmody, T. C. & Rintelmann, J. R. (1997). A double-blind, randomized, placebo-controlled trial of fluoxetine in children and adolescents with depression. *Archives of General Psychiatry*, 54(11), 1031–1037.
- Fisher, S., & Greenberg, R. P. (1997). *From Placebo to panacea: Putting psychiatric drugs to the test*. New York: Wiley.
- Heres, S., Davis, J., Maino, K., Jetzinger, E., Kissling, W., & Leucht, S. (2006). Why Olanzapine beats Risperidone, Risperidone beats Quetiapine, and Quetiapine beats Olanzapine: An exploratory analysis of head-to-head comparison studies of second-generation antipsychotics. *American Journal of Psychiatry*, 163(2), 185–194.
- Johnson, L. A. (2006, May 25). ADHD drugs linked to scores of ER visits. *Chicago Tribune*, p. 6.
- Jureidini, J. N., Doecke, C. J., Mansfield, P. R., Haby, M. M., Menkes, D. B., & Tonkin, A. I. (2004). Efficacy and safety of antidepressants for children and adolescents. *British Medical Journal*, 328, 879–883.
- Leo, J., & Cohen, D. (2003). Broken brains or flawed studies? A critical review of ADHD neuromimaging research. *The Journal of Mind and Behavior*, 24(1), 29–56.
- Moncrieff, J., Wessely, S., Hardy, R. (2004). Active placebo versus antidepressants for

depression. *The Cochrane Database of Systematic Review: The Cochrane Library*, 2, Oxford: Update Software.

MTA Cooperative Group. (2004a) 24-month outcomes of treatment strategies for attention deficit/hyperactivity disorder (ADHD): The NIMH MTA follow-up. *Pediatrics*, 113, April, 754–761.

MTA Cooperative Group (2004b). Changes in effectiveness and growth during the follow-up phase of the multimodal treatment study of children with attention deficit/hyperactivity disorder. *Pediatrics*, 113, April, 762–769.

MTA Cooperative Group (1999). A 14-month randomized clinical trial of treatment strategies for attention-deficit/hyperactivity disorder. *Archives of General Psychiatry*, 56 (12), 1073–1086.

Olfson, M., Blanco, C., Liu, L., Moreno, C. & Laje, G. (2006). National trends in outpatient treatment of children and adolescents with antipsychotic drugs. *Archives of General Psychiatry*, 63(6), 679–685.

Sparks, J. A. & Duncan, B. L. (in press). Do no harm: A critical risk/benefit analysis of child psychotropic medication. *Journal of Family Psychotherapy*.

Sparks, J. Duncan, B. & Miller, S. (2006). Integrating psychotherapy and pharmacology: Myths and the missing link. *Journal of Family Psychotherapy*, 17, 83–108.

Spiegel, A. (2005). The dictionary of disorder: How one man redefined psychiatric care. *The New Yorker*, January 3, 56–63.

Staller, J. A., Wade, M. J., & Baker, M. (2005). Current prescribing patterns in outpatient child and adolescent psychiatric practice in central New York. *Journal of Child and Adolescent Psychopharmacology*, 15(1), 57–61.

U. S. Food and Drug Administration (2001, June 25). Medical review. Retrieved July 3, 2004 from http://www.fda.gov/dcer/foi/nda/2003/18936SO64_Prozac%20Pulvules_medr.pdf

U. S. Food and Drug Administration (2004, October 15). FDA launches a multi-pronged strategy to strengthen safeguards for children treated with antidepressant medications. Retrieved October 30, 2004 from <http://www.fda.gov/bbs/topics/news/2004/NEW01124.html>

Wilens, T. E., Biederman, J., Kwon, A., Chase, R., Greenberg, L. & Mick, E. (2003). A systematic chart review of the nature of psychiatric adverse events in children and adolescents treated with serotonin reuptake inhibitors. *Journal of Child and Adolescent Psychopharmacology*, 13, 143–152.

World Health Organization (2001). World Health Report, 2001. Available at <http://www.who.int/whr/2001/en/>

Zito, J. M. & Safer, S. J. (2005). Recent child pharmacoepidemiological findings. *Journal of Child and Adolescent Psychopharmacology*, 15(1), 5–9.

Zito, J. M., Safer, S. J., dosReis, S., Gardner, J. F., Magder, L., Soeken, K., Boles, M., Lynch, F. & Riddle, M. A. (2003). Psychotropic practice patterns for youth: A 10-year perspective. *Archives of Pediatric & Adolescent Medicine*, 157(1), 17–25.

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