Challenging Automatic Prescription: Listening to Data, Talking with Families, Honoring Client Preferences

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When money speaks, the truth stays silent.

–Russian Proverb

The decision to pursue psychotropic drugs is largely based on the belief that they work and are safe. Family therapists and clients alike often assume that selective serotonin reuptake inhibitors (SSRIs) are the intervention of choice for child and adolescent depression, and that stimulant medications are consistently effective for children labeled with Attention-Deficit Hyperactivity Disorder (ADHD). 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. A thoughtful weighing of risk versus benefit is at the heart of any medication decision.

Web pages, doctor's office brochures, magazine articles, and TV ads describe depression, ADHD, mood swings, and the like as brain dysfunctions needing medical treatment. Even when we know they are promotions from drug companies, pictures of neurotransmitters or talking serotonin cartoons

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are powerful, lasting images. Pediatricians and family doctors, influenced by clinical trials detailed by pharmaceutical reps, increasingly prescribe psychotropic medication for children and adolescents. 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.

Given the disparity of resources and press, a family therapist's office may be one of the few places to openly discuss options, as opposed to biological imperatives, with families struggling with a troubled youth and the decision to medicate. But family therapists have been hesitant to talk about medication, choosing instead to defer to medical professionals. But to not talk about psychiatric drugs in today's world of ubiquitous glossy ad remedies and rising prescription rates is to ignore the proverbial elephant in the living room.

When therapists understand research–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. Knowing that there is no irresistible scientific justification to medicate, family therapists are free to put other options on the table and draw in the voices of their clients. There are many ways to reach desired ends. What will work can only be known one family at a time after an open consideration of options, and the systematic monitoring of the results (Duncan & Sparks, 2002).

Sparks and Duncan (this issue) advocate for a critical risk/benefit analysis, suggesting that family therapists become informed so that they can assist families with decisions about medication. 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. Family therapists can use this knowledge to confidently facilitate 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.

While some may accuse us of stepping beyond our areas of competence (see below), we are not traveling beyond the boundaries of our expertise to discuss options regarding treatment approaches for young people in distress. After an exhaustive (245 pages) review of the evidence, the American Psychological Association, the same organization seeking prescription privileges, 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*. (APA Working Group on Psychoactive Medications for Children and Adolescents, 2006, p. 174, 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. 174)

The APA is hardly known for taking risky liberties with the data! Knowing this means that when children experience difficulties, discussions about solutions can be open, creative, and evolving, encompassing 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. Family therapists can expand the range of options, and their clinical roles, even in circumstances that typically trigger prescriptions.

DIAMOND AND RYNN: "THEIR POSITION WILL NOT MOVE OUR FIELD FORWARD"

> One should treat as many patients as possible with a new drug while it still has the power to heal.
>
> –Sir William Osler

In their thoughtful response, Diamond and Rynn (this issue) agree with our critique of the pharmacological research, and even cite a review that punctuates the continued weak empirical support of the efficacy of SSRIs–although, they, like drug studies, minimize the risk, commenting only on the low probability of the increased risk for suicide. They disagree

with our interpretation of the research and liken our critique, although sympathetically at times, to "conspiracy theory." Diamond and Rynn justify poorly designed studies containing well-known and avoidable flaws (despite vast resources) on the basis that research is "just damn hard."

They also defend pharmaceutical research by noting the checks and balances that exist at the IRB, journal publishing, and governmental regulatory levels. Based on the track record so far, we do not share their faith in the system. At the journal level, for example, Keller et al. (2001) boldly concluded in a top tier journal, "Paroxetine (Paxil) is generally well-tolerated and effective for major depression in adolescents" (p. 762)–after finding no effect on the primary measures, after a 28% drop-out rate, after 23% of the participants reported manic-like symptoms, including hostility and emotional lability, and after 11 adolescents incurred serious adverse events versus 2 in the placebo group (Duncan, Miller, & Sparks, 2004; Jureidini et al., 2004). Since this is unfortunately the rule rather than the exception, we are left wondering about the checks and balances of a peer review process that would allow such a glaring misrepresentation to see the light of day. In addition, despite the lauded checks and balances, conflicts of interest remain a serious obstacle to interpreting results reported in journal publications. For example, a recent review (Heres et al., 2006) looked at published head-to-head comparisons of five popular antipsychotic medications. In 9 out of 10 studies, the drug made by the company that sponsored the research came out on top.

After concerns arose about a possible link between children taking SSRIs and suicide-related behavior, the FDA began an investigation. When the FDA scientist Andrew Mosholder revealed that children taking SSRIs had twice the incidence of suicidal behaviors, the FDA chose to keep it secret despite growing public concern (Shogren, 2004). The FDA's official position was that there was not adequate data to support a link between SSRIs and possible suicide. You be the judge: Mosholder reviewed clinical trials of eight antidepressant drugs involving over 4,100 children and found 108 suicide-related events–74 on SSRIs and 34 on placebo (Shogren, 2004)–mirroring the already reported results of the FDA's British counterpart, the Medicines and Healthcare Products Regulatory Agency. These examples do not inspire our faith in the system of checks and balances that Diamond and Rynn so confidently report.

They also suggest that we should not criticize pharmacological studies because psychotherapy research also has flaws. Of course, but the flaws of psychotherapy research have no relevance to a risk/benefit analysis of psychotropic drugs for children. At last check, there were no black box

warnings on family therapy nor has it been connected to suicide, permanent neurological dysfunction, growth suppression, cardiac abnormalities, or sudden outbursts of aggressive behavior. Differing with our position because we only cover psychopharmacological research misses the entire point of our article–that we first do no harm by becoming informed about the minimal benefits of drugs compared to their potential for adverse events to enable a discussion of the full range of options with our clients.

Finally, and perhaps the meat of their disagreement with our paper, Diamond and Rynns suggest that our take-home message is antimedication, which in their view doesn't fit a best practice perspective or serve the best interests of our field. We are not conspiracy theorists or wide-eyed antidrug zealots. It is not our aim to discredit individual preferences for or experiences with medication, to claim that psychiatric drugs are not ever helpful, or to imply that we don't support families when they choose psychiatric drugs. Instead, we are antiprivileging drugs as a first-line solution–especially for children and adolescents. We are passionate about putting clients in charge of the decision to medicate based on a risk/benefit analysis and their own preferences. And, contrary to the suggestion that we are flying in the face of best practice, *we are actually in the mainstream of current scientific thinking as evidenced by the APA exhaustive analysis.*

While Diamond and Rynn's suggestions for addressing medication with families demonstrate their concern for families and preference for starting with psychotherapy, their comments sometimes read like a drug company ad rather than a discussion of options–containing inaccurate information and persuasion to choose drugs. For example, Diamond and Rynn say: "Unfortunately, unlike for adult depression medications have not been as extensively studied and have not consistently shown to be effective for adolescents. It appears that some adolescents benefit from it and some don't." Given by their own admission that 80% (12 of 15) of the studies about SSRIs found no benefit of taking the drug over placebo on primary measures (Hammad, Laughren, & Racoosin, 2006), and that none of the studies found that parents or youth saw any effect beyond a sugar pill, their statement represents a gross misrepresentation. A far more accurate account of the data might be, "It appears that some adolescents benefit from it but most do not." Contrary to their stated opinion, psychotherapy fares much better than these meager results (APA Working Group on Psychoactive Medications for Children and Adolescents, 2006; Kazdin, 2004).

Furthermore, when the client is not responding to treatment, the data do not justify a knee-jerk response to sell medication as the only other option ("But some time you are so weighted down by the depression that it is hard for you to fight for a better life. If you could get a little more sleep, eat a bit more, feel less on edge, then I think you can accomplish the things we set out to do here. At this point, medication may help us win this war."). Rather, a transparent discussion of all the possibilities, including a change in type of treatment (including medication), a different therapist, another venue of service, or any other client idea would better tailor the service to the family as well as flow more directly from best practice research.

We agree that medication is an option and can be part of the discussion based on client's preferences. A medical path is always a choice, and its pros and cons can be explored with medical and nonmedical professionals. We would never stand in the way of a client considering medication. If clients believe medication will help, feel more hopeful at the possibility of trying it, and are making an informed choice, then medication can be beneficial. We passionately disagree that it will not move the field forward to transparently discuss options with clients. Putting clients in charge of the decision to medicate, and encouraging a frank discussion of the pros and cons, would not harm the field–such a conversation positions us side by side with families rather than apart from them mired in professional concerns about marginalization or a loss of market share because we take an unpopular perspective with our medical colleagues. The implication that to move the field forward requires complicity with an approach with "weak" empirical support as well as significant risks seems not only misguided, but also questionable at many levels.

EVERETT AND TOFF: "HURRIED, DRAMATIC AND SWEEPING CONCLUSIONS"

> He's the best physician who knows the worthlessness of most medicines.
>
> –Benjamin Franklin

Much like drug research, the response by Everett and Toff (this issue) contains so many inaccuracies, unsubstantiated claims, reference mistakes, and quantum leaps from the actual data, it is impossible to address

them all. First, they argue that family therapists don't have the knowledge, time, or access to materials to evaluate clinical trials, and suggest that discussions about medications with clients open therapists to liability and regulatory risks. The implications here are insulting to family therapists, and the use of fear tactics to discourage frank conversations with clients is disheartening. We cannot disagree more strongly–family therapists can feasibly and knowledgeably engage in critical analysis of the drug trial literature and the role it plays in professional guidelines, training mandates, and media.[1] Our hope for our article is to empower clinicians with the view that, given the keys, most will have little difficulty unlocking the underpinnings of clinical trials–that we do not have to leave it up to the experts, like Everett and Toff, who, like others, make bold claims regarding the safety and efficacy of stimulants that do not even vaguely approximate the data.

Everett and Toff report that our analysis relies on but a single study, the MTA, and suggest that the FDA provides the needed oversight should safety concerns arise–they argue that our conclusion that psychosocial interventions be considered first ignores the evidence of a favorable risk/benefit profile for these drugs. Our purpose was not to provide a literature review, but to illustrate our analysis using those studies that form the pivotal infrastructure of medication prescription. Therefore, we chose to strike at the very heart of the support for stimulant prescription for children. Those well versed in the ADHD literature know that the National Institute of Mental Health ADHD Treatment (MTA) study (MTA Cooperative Group, 1999, 2004a, 2004b) is the largest, most complexly designed trial examining stimulants for ADHD, and is most often cited as proof of the superiority of stimulant medications over psychosocial intervention. Including 600 children at multiple sites, it is the only study with three treatment arms, including psychosocial intervention, and of longer term effects. The MTA is the virtual ADHD trial "mother lode" in terms of its size, methodology, and longevity. Our choice to examine the MTA was clear–a five flaws analysis of the MTA not only provided the perfect backdrop to illustrate our critical method, the analysis itself revealed the blemished underbelly of even the most sophisticated trials and effectively cast doubt on repeated claims of stimulant superiority and safety.

Everett and Toff ask if readers are aware that trials supporting the effectiveness and safety of stimulants far outweigh those that do not. The MTA was one such trial that "supported" stimulant use, but on closer examination, the MTA, like other stimulant studies, does not provide evidence for privileging stimulants over safer alternatives. As our article

suggested, one just needs to scratch below the surface. Case in point: Everett and Toff cite (although incorrectly) research to support their claim that favorable studies far outweigh those that raise concerns–a study of the effectiveness and safety of Adderall XR (see, Biederman, Lopez, Boellner, and Chandler, 2002)[2]. Using a five flaw analysis, we find that the makers of Adderall, Shire Pharmaceuticals, funded this study (Flaw # 4); this information is easily located at the end of the article prior to references. Lead author, Biederman, is well known to the pharmaceutical industry, receiving research support from Shire, Eli Lilly, Wyeth, Pfizer, Cephalon, Janssen, and Noven, and is on the speakers bureau for at least seven drug companies (this information is easily accessed at www.integrityinscience.com). This placebo-controlled trial did not use an active placebo (Flaw #1). This is even more important in this study since 66% of the participants (children aged 6–12) had previously taken stimulant medications and had positive responses–previous non-responders were excluded from the study in addition to another 67 children who were dropped after the placebo washout procedure. It is likely that these treatment savvy children and parents–the majority of participants–could discern whether they were receiving an active or inactive substance based on prior experience.

Most conspicuous, however, is Flaw # 3 "time of measurement." The Biederman et al. (2002) Adderall XR trial was–drum roll please–3 weeks in length! This, it seems, is a strange way to design a study that hopes to make any claims about effectiveness and safety, and begs the question about why end point measurements occurred at 3 weeks. In light of this, any results must be considered suspect at best, especially given the study's bias toward participants who had already responded to stimulants–hardly worth the status Everett and Toff (and most likely many others without the benefit of critical analysis) grant it. Moreover, a consideration of adverse events (Flaw #5) in this 3-week trial reveals that 70% of the Adderall groups reported adverse events (AE). Significant differences were found with placebo regarding AEs such as anorexia, insomnia, abdominal pain, and emotional lability. The benefits reported in this trial, when considered in the context of a likely spoiled double blind, the 3-week duration, and the difference with placebo regarding serious adverse AEs, offers a risk/benefit profile that does not support stimulants as a first-line treatment.

Everett and Toff also cite McGough et al. (2005), a 24-month, open label, extension of the Biederman trial as proof of the long-term safety and efficacy of stimulant medications. The authors acknowledge that

"without controlling for a placebo response in the current study, it is possible that results were subject to observer bias" (p. 536). There were no restrictions on concomitant psychosocial treatment in this study, prompting investigators to admit that any benefits that might have accrued from these treatments were not assessed. Without a placebo arm, there is no way of determining whether the effects detected were due to the drug, to psychosocial treatment, some other event or simply the passage of time.

Continuing Flaw #5 and our discussion of whether Everett and Toff's cited study supports a favorable risk/benefit analysis, in this Shire Pharmaceutical funded study, 52% of study participants dropped out before completing the 24-months. Over the course of the study, 96% reported some AEs–63% mild, 34% moderate, and 3% serious. Children averaged almost a 5 kilogram decrease in expected weight gain based on Center for Disease Control and Prevention normative growth charts, with similar results evident for height. While this just scratches the surface, one can see how easy it is to question the take-home message– "once-daily doses of 10–30 mg of MAS XR were persistently effective in reducing ADHD symptoms and were well tolerated over a 2-year treatment period in children with ADHD" (p. 536).[3] Given that only 48% of participants remained in the study, and 37% experienced at least moderate AEs, the assertion that these studies support a favorable risk/benefit analysis for stimulants represents an egregious misrepresentation of the actual data. In addition, the very studies that Everett and Toff cite cast significant doubt on their bold claims of 75% or better efficacy, exposing these assertions as gross exaggerations of the efficacy of stimulants that severely distort any risk/benefit analysis.

Everett and Toff seem content to rely on the FDA and "the professionals" (Texas Children's Medication Algorithm Project) to protect our youngest clients from the adverse effects of stimulant medications. In March of 2006, the Drug Safety and Risk Management Advisory Committee of the FDA urged stronger warnings on ADHD drugs, citing reports of serious cardiac risks, psychosis or mania, and suicidality for children taking them. The review found 1,000 reports of psychosis or mania possibly linked to the drugs from January 1, 2000 through June 30, 2005 (Dooren). Despite the advisory committee's black box recommendation, the FDA eventually decided to forgo a black box for all ADHD drugs (Adderall has a black box for cardiac risk and Strattera for suicidality), and, instead, to highlight risks on the label and include an information guide for parents with each prescription. Challenging this decision, 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).

We find less comfort than Everett and Toff regarding the FDA's oversight of stimulants given that the FDA ignored their own advisory committee recommendations. Even less reassuring to us are the oversight of "the professionals," the Texas Children's Medication Algorithm Project (TCMAP), the best practice guidelines promoted by the *American Academy of Child and Adolescent Psychiatry* recommending stepwise medication regimens (interestingly, of the higher priced drugs) for most children's behavioral and emotional complaints. Disclosure statements for prominent academics and researchers involved in TCMAP span nearly an entire printed page. Drug company investment in the Texas Medication Algorithm Project, parent of TCMAP, has paid huge dividends to pharmaceutical companies whose drugs are featured. For example, Pfizer invested 232 thousand dollars while gaining 233 million in sales; Lily reaped the most profit with a 109 thousand dollar investment turning 328 million in sales (Wilson, 2004). We are concerned that the best interests of children will not prevail knowing that so much profit is at stake.

Everett and Toff assert that our conclusion that stimulants should not be privileged for children's ADHD-type problems is "hurried" as well as "sweeping and dramatic." We base our conclusion on the most prestigious child stimulant study to date, the MTA, as well as a "five-flaws" perspective of drug research and a review of the extensive safety literature. Paradoxically, the studies Everett and Toff cite to support a favorable risk/benefit profile for stimulants not only do not refute our conclusion, but actually endorse it. Moreover, the same conclusion was reached by the APA working group:

> There is no evidence that stimulants produce effects that maintain over years, generalize after medication is stopped, and/or alter long-term outcomes of treated individuals. There is growing concern that growth suppression may be an iatrogenic effect of stimulants that will reliably accompany long-term use. As discussed above, very little is known about the long-term risks of stimulants in other domains (e.g., potential elevation of risk for substance use). With regard to use over a period of 2–3 years, *the risk-benefit analysis of stimulant medication does not appear to be favorable because beneficial effects appear to dissipate while side effects (e.g., growth) do not.* (APA Working Group on Psychoactive Medications for Children and Adolescents, 2006, p. 52, emphasis added)

Finally, Everett and Toff suggest that we offer little guidance for day-to-day practice, and instead recommend a "more ethically sound" model that family therapists can use for "balancing the use of medication with ongoing therapy." Our article provided simple guidelines for clinicians that put families, not pharmaceutical companies, at the forefront of decision making. We believe it to be unethical not to mention, for example, that the use of multiple medications for children is an untested, unapproved practice. Nor would we be squeamish about informing our clients that behavioral interventions have a strong track record for helping with symptoms of ADHD–in fact, moderate to large effect sizes (see APA Working Group for Strength of Evidence for Psychosocial Interventions), and that the efficacy and safety of stimulant medications over time are not known while studies do point to growth inhibition and the possibility of cardiovascular risk, among other side effects. This is knowledge clearly within our professional domain and accessible for any who care to look. Primarily, however, we would support the informed preferences of our clients, and would not advise clients to take or not take medications. Whatever the client's decision, including child and caregiver, we want them to be informed and to be "in the driver's seat" in determining the best use, or nonuse, of any drug.

We applaud the use of teams in assisting families facing child behavioral problems. However, when a medical team fits every situation, we cannot help but see this as an example of medication being the automatic solution. In the scenario provided by Everett and Toff, the advantages of medications are extolled: families are told that stimulants are "helpful" or "quite beneficial" and that medication and therapy can be "quite effective." Everett explains that children often require medication to benefit from therapy and that "substantial improvement" in self esteem often occurs as well–both statements are not supported by research nor is the suggestion that risks have diminished. Although side effects are mentioned, neither Everett nor Toff mentions the probable risk of growth suppression.

While we recognize that this limited transcript leaves much to the imagination, the families' voice seems strangely absent, leaving them as but cardboard cutouts listening to the experts telling them what to do. We find nothing in their model that would create a level playing field–that medication may not work or that there is an equally valid nonmedication option available. Moreover, Everett and Toff's model does not validate the pivotal role clinicians can play in helping ameliorate ADHD symptoms without medication. Their model virtually enshrines the automatic prescription of

stimulants (and perhaps particularly Adderall since it is mentioned and referenced exclusively) and bypasses the informed choice of consulting families. In addition, it overlooks the diversity of cultural and environmental influences that shape child behavior and preferences for help while collapsing oppressive conditions into a single, child-owned diagnosis.

Our professional and ethical mandates demand that, instead, we help clients make medication decisions based on a thoughtful, empirically sound, and balanced risk-benefit analysis. The decision of whether or not to medicate a child is one of the most difficult any family can face, and therapists can provide invaluable input and support guided by client preferences. Medication remains an option, just not a privileged one. We hope that knowing about the APA recommendation, the lackluster empirical support for drugs as a first-line intervention, and the safety risks bolsters family therapists' confidence to talk about medication, raises concerns about robotic prescription practices, and offers alternatives. An awareness of the relationship between a profit-driven industry and science, and what that science actually reveals, enables therapists to assist families in making treatment decisions–permitting a fuller picture from which to construct solutions. Let us first do not harm by collaborating with families in a thoughtful risk/benefit analysis of psychiatric drugs. Let us ask the tough question: How many children need to benefit to justify one child being harmed?

NOTES

1. We find it curious that, while family clinicians are encouraged to become conversant in psychopharmacology–the drugs and side effects for different disorders–the fairly straightforward approach we offer may be considered too rigorous, or beyond the expertise of everyday family therapists. We cannot help but notice that this view supports the forgone conclusion of the inevitability of medication for a growing array of presenting problems and stifles attempts to consider the rampant involvement of the pharmaceutical industry in clinical trials (Antonnucio, Danton, & McClanahan, 2003; Melander, Ahlqu-vist-Rastad, Meijer, & Beerman, 2003) and the establishment of clinical guidelines (Choudhry, Stelfox, & Detsky, 2002).

2. We could not locate a 2005 study of these authors that fits the reference description given by Everett and Toff. The 2002 study by these authors (see complete citation in our reference list) best matches their description of a study involving over 500 children. Biederman is the lead author in a 2005 study (different secondary authors) that matches the reference publication, issue, and pages provided by Everett and Toff in their references list. However, this study is entitled "Efficacy and safety of modafinil film-coated tablets in children and

adolescents with attention-deficit/hyperactivity disorder: results of a randomized, double-blind, placebo-controlled, flexible-dose study," clearly not the Adderall XR study Everett and Toff are presenting in their commentary. Additionally, we do not examine the study alluded to ("one of these trials involved 600 patients") as no references citation was given for it.

3. Everett and Toff mention another trial as evidence of the long term safety of stimulant medication–(Spencer et al., 2006). This study is a 4-week, controlled trial examining the efficacy and safety of mixed amphemtamine salts, again extended release Adderall XR. As such, it does not examine long-term safety factors.

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