In this Commentary, which also appeared in The Journal of Clinical Psychiatry (2007;68:1963–1970), 5 experts on attention-deficit/hyperactivity disorder (ADHD) discuss the diagnosis and treatment of complicated ADHD in children and adolescents. This topic is particularly relevant to our readers because individuals with complicated ADHD often first seek help from their primary care physician before consulting a psychiatrist.

Larry Culpepper, M.D., M.P.H.

PHYSICIANS DISCUSS HOW TO DIAGNOSE, ASSESS, AND TREAT COMPLICATED ATTENTION-DEFICIT/ HYPERACTIVITY DISORDER.

Complicated attention-deficit/hyperactivity disorder (ADHD) is a unique problem for physicians to confront. Patients with complicated cases tend to have comorbid disorders that confuse and obscure diagnosis and make treatment difficult. Several factors should be considered when assessing patients for ADHD, such as family and patient history and the role of psychological testing. After diagnosis, physicians should educate both the patient and the family about ADHD and its treatment options.

On February 20, 2007, Robert L. Findling, M.D., a Director of the CME Institute of Physicians Postgraduate Press, Inc., and a nationally recognized expert in child psychiatry, assembled a group of experts to discuss complicated ADHD and associated diagnostic and treatment issues. Their discussion appears here.

This special Commentary is another in a series of independent projects undertaken by the CME Institute of Physicians Postgraduate Press, Inc., as a service to its members and the broader academic and clinical community. Visit www.psychiatrist.com/issues/ to listen to audio selections from this discussion.

Faculty affiliations and financial disclosures appear at the end of this Commentary.

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Diagnosing and Managing Complicated ADHD

Robert L. Findling, M.D. (Chair); L. Eugene Arnold, M.D., M.Ed.; Laurence L. Greenhill, M.D.; Christopher J. Kratochvil, M.D.; and James J. McGough, M.D.

Dr. Findling: The purpose for this roundtable on the diagnosis and management of complicated attention-deficit/hyperactivity disorder (ADHD) is to help clinicians distinguish ADHD from comorbid psychiatric disorders and to compare strategies, both pharmacologic and nonpharmacologic, for managing complicated ADHD.

Factors That Complicate ADHD

Dr. Findling: What are the key factors that complicate ADHD?

Dr. Arnold: One factor that complicates ADHD is comorbidity. In fact, ADHD may sometimes be a complication of another primary disorder. Disorders that commonly co-occur with ADHD, and sometimes may even be mistaken for ADHD, are conduct, oppositional-defiant, anxiety, depressive, bipolar, and substance use disorders. ^{2,3}

Dr. McGough: Another factor that can complicate ADHD is a child's social situation.⁴ Physicians tend to be preoccupied with reducing symptoms via medication but often fail to recognize the context in which the behavior is exhibited. Although ADHD may not be primarily driven by environmental factors, sometimes clinicians fail to recognize severe family chaos, parental discord, abuse, and other issues of psychosocial distress that can have an impact on a child, which can create a complicated presentation of ADHD.

Dr. Arnold: Abuse is an important issue to recognize. Child abuse and ADHD have a higher-than-expected overlap,^{5–7} which could be bidirectional; children with ADHD sometimes seem to invite abuse by their behavior, and abuse could aggravate or even cause symptoms of ADHD.⁸ Alternatively, an abused child may have posttraumatic stress disorder (PTSD), which can be mistaken for ADHD because children may be distant and fail to pay attention, as well as having interference with their cognitive functioning.

Dr. McGough: Another complication that has come into focus recently is that of youngsters who have difficulties of impulse control and mood lability. Community practitioners tend to label these severely impaired children with ADHD as having bipolar disorder. Ongoing controversy surrounds whether that diagnostic label is proper or not, 13–15 but nonetheless, severely impulsive, labile children confound treatment decisions.

Is ADHD Overdiagnosed?

Dr. Arnold: I see history repeating in an analogy. The recent diagnostic view that more children may be presenting with bipolar disorder has developed over the years in the same way that more ADHD diagnoses

Table 1. Summary of DSM-IV Diagnostic Criteria for ADHDa

Criterion	Description
A	Patients must exhibit 6 to 9 symptoms of inattention or 6 to 9 symptoms of hyperactivity-impulsivity that have persisted for at least 6 months
В	Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years
С	Some impairment from the symptoms is present in 2 or more settings (eg, at school [or work] and at home)
D	There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning
Е	The symptoms do not occur exclusively during the course of a pervasive developmental disorder, schizophrenia, or other psychotic disorder and are not better accounted for by another mental disorder (eg, mood disorder, anxiety disorder, dissociative disorder, or a personality disorder)

developed. I remember when ADHD was considered a rare disorder. But following a tremendous groundswell of recognition and diagnosis, some people worried that ADHD was overdiagnosed.¹⁶ We may be experiencing the same situation with bipolar disorder, whereby, although once thought to be rare or nonexistent in kids, it is now an increasingly recognized disorder, it is increasingly diagnosed, and some now worry that it may be overdiagnosed in some quarters.

Dr. Findling: Is ADHD overdiagnosed?

^aBased on American Psychiatric Association. ¹⁷

Dr. Arnold: If clinicians rely only on symptom counts and ignore the other criteria in the DSM-IV (Table 1)¹⁷—particularly criterion E, which states that symptoms cannot be better explained by another mental disorder—they can tend to overdiagnose ADHD. Some children may not require any diagnosis; if a patient has symptoms of ADHD but no functional impairment (as stated in criterion D),¹⁷ then a diagnosis may not be necessary.¹⁸

Dr. McGough: Jensen¹⁶ found substantial underdiagnoses of ADHD in the United States, and of those children who had been diagnosed with ADHD, many received inadequate treatment. So, I think the accusation that ADHD is overdiagnosed is generally unfounded.

Dr. Findling: What factors prevent people who need treatment from getting treatment?

Dr. Arnold: One factor is simply coverage for the financial burden of treatment. Even though ADHD drugs are not as expensive as drugs used to treat some other mental disorders, families without prescription coverage are often in a financial situation in which the monthly cost of treatment is a hardship for the whole family.

Diagnosing ADHD in Young Children

Dr. Findling: Dr. Greenhill, in your work with preschoolers, ^{19,20} have you found that group of young people to be complicated to assess and evaluate?

Dr. Greenhill: One of the biggest issues with hyperactive preschoolers is judging how much of the hyperactivity is a delayed resolution of the normal developmental hyperactivity of toddlers and how much is actual pathology. Hyperactivity among preschoolers may be associated with speech disorders; if a child has a speech delay, then the resolution of their developmental hyperactivity could be delayed.

Dr. Findling: So, speech and language disorders may confound accurate diagnoses of ADHD in young people.²¹ Issues with speech and language or difficulties with social skills can cause concerns about pervasive developmental disorders (PDDs). Are PDDs other disorders that may be mistaken for ADHD?

Dr. Arnold: Children with autism and other PDDs are usually fairly active and inattentive to instructions or questions, but generally present also with other problems such as the inability to relate socially, stereotyped behavior, and language impairments. Of course, children with ADHD can also have language impairments, which can cause similar problems to those of PDDs. DSM-IV technically does not allow diagnosing ADHD in the presence of PDD, but if it did, over half of children with PDD would probably qualify for ADHD as a second diagnosis.

Another complication or comorbidity of ADHD that used to help in diagnosing ADHD but lately has been ignored is developmental coordination disorder, or problems with hand-eye coordination. ²² Clinicians tend to neglect examining hand-eye coordination when evaluating a child for ADHD, even though this complication interferes with writing, reading, and other academic skills that are independent of the problems with associated attention span.

Dr. Findling: In other words, physicians should be broader in their diagnostic considerations when faced with young people suspected of having ADHD but who are not responding to treatment or who do not fit the diagnosis.

Assessing Patients With Complicated ADHD

Dr. Findling: When faced with a youngster with complicated ADHD, what approaches are the most effective to examine what may be going on in that person's life?

Dr. Kratochvil: This may sound simplistic, but I find that one of the most important approaches is to take the time to systematically assess the patient. Systematically address all of the diagnostic criteria for ADHD to ensure that the patient indeed has ADHD, and also systematically assess for comorbid conditions since comorbidity is the rule rather than the exception. There is no substitute for a careful, thorough assessment of these patients.

The use of rating scales can certainly facilitate this process. Scales can help to assess for symptoms of ADHD and screen for other disorders. Several scales for screening ADHD with comorbid disorders are available at no cost; for example, the Vanderbilt Assessment Scale is a part of the American Academy of Pediatrics ADHD toolkit²³ can be accessed on the National Initiative for Children's Healthcare Quality web site (www.nichq.org) after registering as a member.

Dr. Greenhill: Another approach is to check to see if the child's parents are going through any personal crises of their own—for example, whether the mother, the father, or both, are depressed. Parental depression can have quite an impact on a child.

Dr. Findling: Family history is important; you may find that a parent or a parent's sibling had the same problems in childhood as the patient does. Also, I spend a substantial amount of time assessing ADHD, not only cross-sectionally, but longitudinally as well. ADHD has a longitudinal course that is reasonably predictable since it is a chronic condition.

So when I assess a young person, instead of asking his or her parents about the difficulties the child is currently experiencing, I ask when they first started having concerns about their child or hearing about concerns from teachers or others caring for their child. The child's difficulties may not become problematic until he or she first goes to school. These difficulties then continue to be present and get worse over time as the demands on the youngster increase. Conversely, I will sometimes assess a youngster who clearly has had ADHD according to his or her history, but then an event occurs around 8 or 9 years of age—perhaps an important stressor or change in a youngster's life—and a comorbid disorder develops, which could be a mood or an anxiety disorder.

Dr. Arnold: Tracing out the history of the disorder in the individual case is a good idea as long as it does not degenerate into "archaeology" (commiserating over the past without learning from it). I also agree about extending the history to the parents. If one parent has ADHD, which is often likely, it may be undiagnosed. Tracing what happened in the case of a parent may offer insight into the probable illness course for the child, suggest possibilities for psychosocial therapeutic interventions, such as the parent using his or her experience to support the child, or highlight critical junctures that may influence the illness course.

Dr. Kratochvil: Additionally, the more complicated the presentation of a child, the more useful I find collateral sources of information. For example, teachers can be very valuable in giving a developmental perspective of how a child is performing in the classroom and in clarifying diagnostic issues.

Dr. Findling: What about the role of pediatricians as well?

Dr. Arnold: Pediatricians can provide insight into medical complications associated with behavioral problems. In cases in which medical problems influence a child's behavioral problems (e.g., children with allergic

stigmata such as eczema or asthma), physicians need to pay attention to the physical aspect. Outlining a child's medical history can illustrate when behavior problems are aggravated, such as during certain seasons or when the child is exposed to certain irritants.

Dr. Findling: Many pediatricians and family doctors are privileged in that they have watched these children grow up and can often relate behavioral concerns or suspicions they may have to a specialist, which may further clarify the long-term history of the child.

Childhood Learning Difficulties and Psychological Testing

Dr. Findling: How do you approach assessing children for a history of a learning disability or a learning disorder?

Dr. Arnold: Learning difficulties and disabilities are problems in managed care. Most insurance plans will not pay for a psychoeducational assessment because these assessments are supposed to be provided for free by the school system. Conversely, trying to get an assessment from the school system can also be problematic. If there are hints that a child may have a learning disorder in addition to ADHD, physicians can apprise the parents of the child's rights to get such an assessment.

Dr. Findling: Remember, there was a time when children were not even ascribed an ADHD diagnosis unless extensive psychological testing was given, which is no longer the case in routine clinical practice. In our own practices, how do we differentiate children who could benefit from psychological testing versus those who do not necessarily need it?

Dr. Greenhill: The practice parameters for ADHD²⁴ now specify that psychological testing is not mandated as a requirement for evaluation. However, they should be considered if the patient, relative to his or her intellectual ability, shows a disparity between their high scores on aptitude tests and their low classroom achievement in mathematics or language.

Dr. Findling: How do you determine when testing is most indicated in clinical practice? What are the key red flags you hear in a child's history that suggest testing is needed? For me, a red flag for a youngster who clearly has ADHD could be an inconsistency of performance, such as doing well in some school subjects but not particularly well with math or reading. In my practice, I ask both general questions about academic performance and specific questions about aspects of learning and learning styles (Table 2); the answers to these questions can be helpful in determining which children have the highest priority for psychological testing. However, sometimes it is useful to treat a young person with ADHD prior to psychological testing because the ability to complete a psychological test for a child with significant ADHD symptomatology can be compromised.

Table 2. Questions About Academic Performance to Ask Parents of Children With ADHD

How well does your child do in school?

Do you think your child is living up to his/her potential in school? If you think your child is underachieving, why do you and his/her teachers think this is happening?

Does your child do better in some subjects than in others? Is there a specific subject or subjects with which your child has particular difficulty?

Does your child do better when material is presented to him/her in a particular way?

Dr. Arnold: That is a good point. Another point to add is that trouble in reading but not in math could indicate a learning disorder rather than ADHD. Math requires attention to detail, whereas difficulties with attention are not likely to cause complete reading failure because a reader can skim to get the gist of what is written.

Dr. Findling: Parents want to know whether laboratory, psychological, or neuroimaging tests provide a definitive diagnosis, even though these tests are not necessary for a diagnosis of uncomplicated ADHD. What is the role for the more sophisticated or technologically advanced assessments?

Dr. McGough: In research studies, clinical assessment is the gold standard by which imaging techniques are measured, and people should understand that neuroimaging findings are not specific to ADHD. They are fascinating because they allow us to understand what is happening in the brains of children with ADHD, but the predictive power of those tests in terms of actually diagnosing someone is negligible. We need to continue educating clinicians and the public alike that, while neuroimaging tests can show the biology involved, they are not at all definitive, and ADHD remains a clinical diagnosis.

Dr. Kratochvil: Precisely; these tests are not indicated for differentiating between psychiatric disorders or making a psychiatric diagnosis.

Substance Use, Abuse, and Misuse in ADHD

Dr. Findling: Do issues related to substance abuse or misuse, particularly in teenagers, play a role assessing ADHD?

Dr. McGough: Individuals with ADHD do seem to be at particular risk for getting involved with substances to a degree that is not normal for their developmental stage.²⁵ Most teenagers do experiment some with illicit drugs, but children or adolescents with ADHD and comorbid conduct disorder are especially prone to start using these drugs earlier and having subsequent difficulties with them.²⁶ So I think in the adolescent patient, consideration of substance abuse or misuse is wise.

Dr. Greenhill: One of the biggest problems that complicates ADHD is smoking.²⁷ Once adolescents start smoking, cigarette use is high and difficult for these ado-

lescents to stop. But, smoking has become more restricted in this country and these adolescents often clash with authority figures because of a strong desire to smoke.

Dr. Findling: What do you think is driving that desire?

Dr. Greenhill: Some theoretical assumptions have been made about the connection between nicotine receptors and dopamine in ADHD.²⁸ Patients claim they both feel calmer and have better attention on nicotine, and the subjective response they get from smoking is stronger than the response these patients have experienced with stimulant medications.

Dr. Findling: With the expansion of coffee houses, do you see many kids with ADHD drinking a lot of caffeinated beverages as well?

Dr. McGough: Caffeinated beverages are very popular among all ages. Research²⁹ has suggested that children with ADHD are adrenergically dysregulated. While treatment can restore some homeostasis, if dopamine is still dysregulated, people will seek out in their environments what they need, which may create an increased risk for experimentation and addiction.

Dr. Arnold: Nicotine has been suggested to be a useful drug with a deadly delivery system. But, that raises an interesting question of whether nicotine gum or patches should be given to adolescents with ADHD who smoke in order to lessen the health risks of smoking. Additionally, has nicotine dependence been shown to be a gateway for illicit drugs such as marijuana?

Dr. Findling: Opinions vary concerning cause and effect, so it is hard to know. Do these young people have ADHD and comorbid oppositionality and conduct-related problems first, and then are drawn toward substance use and smoking as a result? We certainly see lots of youngsters who abuse substances but do not smoke and do not have ADHD. Often, high rates of substance abuse are associated with mood disorders, particularly depression, instead of ADHD. Young people who have depression and who abuse substances will often be misdiagnosed with ADHD in middle school or early high school.

Parent and Patient Education About ADHD and Treatment

Dr. Findling: Do adherence- or compliance-related issues confound the management of complicated ADHD?

Dr. Kratochvil: Adherence and compliance can be tremendous issues. When working with patients with ADHD and their families, it is important for physicians to spend time to educate everyone involved about what ADHD is, what causes it, and what we know about treatments. Helping the family get a better understanding of ADHD and partnering with the patient and the family to better address the ADHD can greatly facilitate

compliance. But even in the best situations, compliance can be difficult.

Dr. Arnold: Oppositional behavior can interfere with medication compliance. It is important to keep medication from becoming part of a parent-child power struggle; a medication contract has to be directly negotiated with the child. The most common comorbidity with ADHD is conduct disorder or oppositional-defiant disorder. ^{2,3} In fact, oppositional defiant disorder is so common that the public tends to link ADHD symptomatology with aggression and oppositional behavior even though neither is part of the diagnostic criteria for ADHD.

Dr. Findling: You are alluding to the fact that many families come in with misinformation or misconceptions about ADHD. Which misconceptions do you all find most common and problematic when trying to work with these young people and their families?

Dr. Kratochvil: Some basic misconceptions that physicians need to address with the family include the idea that ADHD is not a real disorder, that it does not have biological underpinnings, that treatments are not safe, and that treatments are overused.

Dr. Findling: Do you address these misconceptions when a diagnosis is made as well as at the initiation of treatment?

Dr. Kratochvil: Absolutely. That dialogue should start early and continue throughout treatment.

Dr. Findling: How do you address their misconceptions?

Dr. Kratochvil: We are fortunate to now have a tremendous scientific database to demonstrate the biological underpinnings of ADHD. Physicians can now explain to the families that ADHD is a neurobiological disorder, and that neuroimaging findings can help understand what ADHD is and how we think the treatments work. And of course, physicians need to explain the data to the families in an understandable way. Some of them may not agree initially, but if we can work together with the families, everyone can generally come to a meeting of minds.

Dr. Findling: One of the key issues when formulating a risk-benefit analysis for treatments is the associated risks of having untreated ADHD. Families are often unfamiliar with the acute and long-term consequences of ADHD, as well with the potentially unsatisfactory outcomes of patients. Do these issues arise when discussing treatments with parents?

Dr. McGough: Most parents are often aware that if their child is not doing as well as he or she is capable, that child is at increased risk for frustration, low self-esteem, peer problems, and problems at school. Then, it is easy to describe how children could become isolated and join less desirable social networks as they get older. It is also important to mention the health risks as these impulsive individuals get older, e.g., having problems

with driving, making poor lifestyle decisions, and getting involved in other risky and dangerous activities such as substance abuse. Most parents, even when they are worried about getting their children addicted to a medication, are willing to allow a trial treatment when they realize that there is a high risk of their child getting involved with illicit substances if the ADHD is left untreated.

Stimulant Effects on Children's Growth

Dr. Findling: What other issues do you raise when educating the families?

Dr. Greenhill: I share the evidence that suggests that stimulants³¹ and atomoxetine³² are associated with a reduction in growth rates. For example, some children show a lower rate of height and weight gain.³¹ Patients should be carefully monitored on age corrected growth charts, and if they drift more than 10 percentile points lower than their baseline growth percentiles, treatment dose or type should be reexamined. Amphetamine-like drugs produce the most slowdown in growth, followed by methylphenidate and atomoxetine, which are associated with weaker growth slowdown.

Dr. Arnold: Data from the Multimodal Treatment Study for ADHD³³ found continued growth slowing during 2-year follow-up, but 36-month data show no further growth loss after 2 years.³⁴ Data about whether stimulant-treated patients with ADHD ultimately reach their expected height are not yet available.

Dr. Kratochvil: Colleagues and I are systematically collecting longitudinal data on children with ADHD. We have a large atomoxetine database³⁵ that showed after the initial growth deceleration, the data suggests that the children do eventually catch up. The group of children still taking atomoxetine at the 5-year follow-up has actually caught up to their initial percentile.

Pharmacologic and Nonpharmacologic Treatment Options for ADHD

Dr. Findling: When faced with children with complicated ADHD, do you first initiate treatment with medicine, with nonpharmacologic interventions, or the combination?

Dr. McGough: Clinicians should never ignore events in the child's life. If there is something that is clearly aberrant or dysfunctional, it should be addressed in whatever clinical way possible. But having said that, the recently modified Texas Children's Medication Algorithm Project³⁶ offers clinically relevant, evidence-based guidelines for which pharmacologic steps to take with the most complicated ADHD conditions. Specific algorithms for uncomplicated ADHD, depression, tics, and aggression were developed by consensus to treat simple, uncomplicated ADHD, as well as ADHD with comorbid depression, tic disorders, and aggression. Reasonable evidence exists for first- and second-tier treatment approaches in

these comorbid conditions, but after that, the evidence wanes.

Dr. Arnold: However, I think that cases of complicated ADHD would not depend on medication alone.

Dr. McGough: If a patient has a response to ADHD medications but still experiences symptoms, clinicians should look for complicated etiologies, particularly social etiologies.

Dr. Findling: And employ some nonpharmacologic interventions.

Dr. Arnold: I have a case right now that illustrates that. Teachers report that the patient is getting an excellent pharmacologic response to the study medication at school, but the parents report no improvement at home. The ADHD is still a problem, which causes conflict among the family members. So, I referred them for family therapy. If the problems are not due to short attention span, impulsivity, and overactivity—in other words, something else is going on—then no medication is going to cure that.

Dr. Findling: In many ways, medicines are limited because they really only treat certain core symptoms. Other problems require other forms of intervention and consideration.

ADHD Treatment Complications

Dr. Arnold: Side effects of medications are another complication that sometimes occurs when treating ADHD. Target symptoms may respond well to pharmacologic treatment but a side effect can be intolerable for the patient, which makes the overall value of the treatment questionable. By combining behavioral treatments with medication, clinicians may be able to lower the dose and possibly take the edge off the side effects but still retain the benefits of the medication.

Dr. Findling: In many of our practices, common pharmacologic side effects that parents are often concerned about are weight loss and insomnia. For weight loss, clinicians can discuss with parents the importance of a good breakfast and a bedtime snack. We often hear about insomnia, which I think can be both overstated and understated: overstated because some sleep difficulties early in the treatment course will frighten parents if they are not warned ahead of time, but understated because some patients do have chronic difficulties with sleep that can complicate the treatment.

Dr. Arnold: For insomnia, it is important to get a baseline measure of how many sleep problems the patient is already having. Another side effect that I have found to be of concern to parents is affective flattening—zombie-like behavior that is associated with certain pharmacologic treatments. I would adjust the dose for affective flattening as much as I would for problems with appetite.

Dr. Findling: Another issue is that young people sometimes say they feel "different" while being treated with

ADHD medications, even if their appearance to others has not changed. This is a problem because it is difficult to understand exactly what their subjective experience is and it can affect treatment adherence.

Dr. Greenhill: Adolescents will sometimes report that their friends do not find them as being much fun as they once were, which may reflect that they are not the class clown anymore, and they may feel that the attention they get is worth everything to them, even if it is not particularly good attention.

Dr. Kratochvil: In order to enhance adherence, clinicians must open a dialogue with parents and patients, letting them know that if problems occur, the dose could be titrated or the medication could be switched, and not to discontinue treatment before talking it over together.

Dr. Findling: Taking a collegial, collaborative approach may be a more efficacious way to open a dialogue with the parents and patient, rather than the authoritarian, paternalistic approach to treatment.

Take-Home Points

Dr. Findling: What are key take-home tips for practitioners regarding the assessment, diagnosis, and treatment of complicated ADHD?

Dr. Greenhill: I agree with my colleagues about the need for a thorough, comprehensive evaluation, which includes understanding the family history of the presence of psychological difficulties and psychiatric problems in the parents and how these issues might impact the child directly and indirectly through complications and problems in delivering a treatment. I also agree that families should be clearly warned about both subtle and dramatic medication side effect problems that they might run into during the treatment.

Dr. McGough: I would encourage physicians to be sure they have considered the whole context of the child's and the family's behavior before moving toward complicated pharmacotherapies.

Dr. Kratochvil: One recommendation I have is to identify useful rating scales. Implementing tools like that into clinical practice can be very useful.

Dr. Arnold: Also, remember to take enough time to really understand the patient and the family. This is difficult because managed care tends to pressure physicians to make a rather quick diagnosis and treatment plan, but there is no substitute for reserving enough time to really do a thorough patient evaluation.

Dr. Findling: I agree with all of those points. Thank you for your time.

Drug names: atomoxetine (Strattera), methylphenidate (Concerta, Ritalin, and others).

Disclosure of off-label usage: The chair has determined that, to the best of his knowledge, no investigational information about pharmaceutical agents that is outside U.S. Food and Drug Administration—approved labeling has been presented in this article.

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