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Perspective

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Pediatric Mental Health Care Dysfunction Disorder?

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In February, the American Psychiatric Association released draft revisions for the next iteration of its diagnostic manual (the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* [DSM-V]).

One of the draft's most talked-about features is a new diagnostic category for children: temper dysregulation disorder with dysphoria (TDD). The addition has been praised by some as a verdict on one of the hottest questions in child psychiatry: Is the dramatic increase in the number of children with a diagnosis of bipolar disorder appropriate? The answer appears to be no. But the creation of this new category raises another question: Will the TDD diagnosis advance what everyone agrees should be the ultimate goal of psychiatric classification — helping troubled children to flourish? Sadly, the answer to the second question is also no, unless we get serious about reforming pediatric mental health care.

The hallmark of bipolar disorder in adults is a manic episode: a distinct period of abnormally and persistently elevated, expansive, or irritable mood, with accompanying symptoms, lasting at least 1 week. In the mid-1990s, a small but influential group of child psychiatrists began to argue that most children with bipolar disorder do not have discrete episodes of mania but instead have chronic and very severe irritable mood as manifested by explosive, aggressive outbursts or rapid cycling between elevated and depressive moods in a single day. Between the mid-1990s and 2003, as reported by Moreno and colleagues,[1] the number of children with a diagnosis of bipolar disorder visiting outpatient clinics increased by a factor of 40. These children, some preschoolers, were primarily being treated with mood stabilizers and a new generation of antipsychotic drugs.

No one disputes that these children — who can be explosively angry, irritable, frantically active, suicidal, or even homicidal — are troubled. No existing DSM diagnosis conveys the appropriate severity and complexity of these children's moods and behaviors; the "bipolar disorder" label was meant to provide a home for children who were "diagnostically homeless." Rather, the dispute has been about whether bipolar disorder is the right diagnostic home.

If the proposed change to the psychiatric manual stands, most

Key Differences between a Manic Episode as Defined in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), and the Proposed Definition of Temper Dysregulation Disorder with Dysphoria (TDD) in DSM-V.

Characteristic	Manic Episode	TDD
Mood symptoms	Episode of elevated, expansive, or irritable mood	Temper outbursts that are grossly out of proportion and inconsistent with developmental level, interspersed with persistently negative mood
Additional symptoms	Three symptoms (if elevated or expansive mood present) or four symptoms (if irritable mood present) of seven additional symptoms: grandiosity, decreased need for sleep, pressured speech, flight of ideas, distractibility, psychomotor agitation, and excessive involvement in pleasurable activities with high potential for painful consequences	
Duration of mood symptoms	At least 1 wk	Three or more outbursts per week for at least 12 mo
Degree of impairment	Marked impairment in one setting	Outbursts or negative mood is present in two settings or is severe in one setting
Age at diagnosis	None specified	At least 6 yr
Age at onset	None specified	Under 10 yr

children who recently received the bipolar label because of their explosive outbursts could now receive the TDD label instead. (A very small number of children do meet the manual's criteria for a strictly defined episode of mania.) That change is a good thing. Bipolar disorder is a lifelong condition requiring continuous management with medication. When applied broadly to children, the diagnosis has three problems. It gives the impression that physicians know what is wrong and how to treat it. It presumes that the outcome of the childhood condition is bipolar disorder in adulthood. And if wrongly applied, it keeps the child from getting help for what really is wrong. The TDD label more accurately describes these children's behaviors (see table) and acknowledges what we do not know, including the outcome of their condition. The new label will assist researchers studying the causation, treatment, and outcomes of a serious behavioral and mood disturbance. Such clarity is badly needed so that researchers can be confident that they are studying the same thing and so that clinicians can be confident that they are using the same treatments for similarly afflicted patients.

But switching from the bipolar label to the TDD label will not by itself decrease the rate of psychopharmacologic treatment. If applied trivially to children with any kind of temper tantrum, it will actually increase medication use. Insofar as children who have outbursts frequent and severe enough to warrant this diagnosis may live in stressful households and have other conditions such as attention-deficit disorder, depressive or anxiety disorders, or learning and language disorders, focusing solely on medication risks overlooking problems that require nonpharmacologic solutions.[2] And although psychiatrists attempt to make relatively fine discriminations among the clusters of symptoms used to identify psychiatric disorders, the pharmacologic tools available for treating those symptoms are often blunt. Children with the TDD label will probably receive many of the same medications currently prescribed for children with a diagnosis of bipolar disorder. These medications have been shown to decrease aggression in children and are part of published treatment algorithms (such as the Texas Children's Medication Algorithm). But children with TDD will also be at risk for clinically significant side effects associated with the use of atypical antipsychotic agents, such as dramatic weight gain, metabolic and endocrine abnormalities, and cognitive dulling.

The medications are also far less effective than anyone would wish. As Thomas Insel, director of the National Institute of Men-

tal Health, put it, "The unfortunate reality is that current medications help too few people to get better and very few people to get well."[3] Although the medications given to children with a diagnosis of bipolar disorder have been effective at managing the symptoms of adult bipolar disorder, a 2007 "practice parameter" from the American Academy of Child and Adolescent Psychiatry described evidence for their efficacy in children as "sparse at best." Even with the addition of treatment trials published in the intervening 3 years, our knowledge base is still very small and seldom extends to children younger than 10 years of age.

The same 2007 practice parameter strongly recommends that psychotherapeutic treatments should accompany medications for almost all children diagnosed with bipolar disorder. Some physicians go further, arguing that psychosocial, educational, or behavioral therapy should be the first-line treatment, especially for young children with mental health problems.[4] It is widely agreed that treatment with medications alone is seldom sufficient. Yet a recent study of large databases of privately insured individuals showed that most young children who were prescribed antipsychotic medications did not receive adjunctive psychosocial treatment.[5] The exact reasons for this failure to provide children with recommended comprehensive mental health care are complicated; causes include a paucity of well-trained therapists, insurers' reluctance to cover nonpharmacologic treatments, and the time-intensive nature of the treatments. The mere addition of diagnostic categories such as TDD does not address the pressing need to transform our systems of delivering mental health care to children.

The good news is that the addition of TDD to the psychiatric manual may lend some clarity to the debate about the most appropriate diagnostic home for some deeply troubled children. The bad news is that our understanding of the nature of these children's heterogeneous disturbances is in its infancy. The risk–benefit ratios of the medications used to treat severe outbursts have not been established. And though effective nonpharmacologic treatments are being developed, it's probable that too few children will receive these interventions. Troubled children, regardless of their diagnostic label, deserve better.

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Gene Patenting — Is the Pendulum Swinging Back?

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Are human genes and the process of comparing DNA sequences patentable? These questions were raised by a group of researchers, pathologists, patients with cancer, and medical professional organizations challenging some of Myriad Genetics' patents covering the *BRCA1* and *BRCA2* genes and their use in screening for elevated risks of breast and ovarian cancer. On March 29, in a startling decision, a federal district court judge invalidated many of Myriad's patent claims,[1] reigniting a long-simmering debate about the patentability of genes.

The Patent Act permits exclusive control for a limited time (currently 20 years) of any "process, machine, manufacture, or composition of matter," and since its inception, the U.S. Patent and Trademark Office (USPTO) has granted patents on new pharmaceuticals and medical devices. However, as recently as the 1970s, the view among many medical researchers and legal scholars, as well as members of the USPTO, was that DNA sequences were not patentable, primarily because DNA is a naturally occurring substance