

Backlash on bipolar diagnoses in children

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MGH psychiatrist's work stirs debate

By Scott Allen, Globe Staff | June 17, 2007

No one has done more to convince Americans that even small children can suffer the dangerous mood swings of bipolar disorder than Dr. Joseph Biederman of Massachusetts General Hospital.

From his perch as one of the world's most influential child psychiatrists, Biederman has spread far and wide his conviction that the emotional roller coaster of bipolar disorder can start "from the moment the child opened his eyes" at birth. Psychiatrists used to regard bipolar disorder as a disease that begins in young adulthood, but now some diagnose it in children scarcely out of diapers, treating them with powerful antipsychotic medications based on Biederman's work.

"We need to treat these children. They are in a desperate state," Biederman said in an interview, producing a video clip of a tearful mother describing the way her preschool daughter assaulted her before the child began treatment for bipolar disorder. The chief of pediatric psychopharmacology at Mass. General, he compares his work to scientific break throughs of the past such as the first vaccinations against disease.

But the death in December of a 4-year-old Hull girl from an overdose of drugs prescribed to treat bipolar disorder and attention deficit hyperactivity disorder has triggered a growing backlash against Biederman and his followers. Rebecca Riley's parents have been charged with deliberately giving the child overdoses of Clonidine, a medication sometimes used to calm aggressive children. Still, many wondered why a girl so young was being treated in the first place with Clonidine and two other psychiatric drugs, including one not approved for children's use. Riley's psychiatrist has said she was influenced by the work of Biederman and his protege, Dr. Janet Wozniak.

"They are by far the leading lights in terms of providing leadership in the treatment of children who have disorders such as bipolar," said J. W. Carney Jr., lawyer for Dr. Kayoko Kifuji, a Tufts-New England Medical Center psychiatrist who temporarily gave up her medical license after Riley died on Dec. 13, 2006. "Dr. Kifuji subscribes to the views of the Mass. General team."

Part of the criticism of Biederman speaks to a deeper issue in psychiatry: the extensive financial ties between the drug industry and researchers. Biederman has received research funding from 15 drug companies and serves as a paid speaker or adviser to seven of them, including Eli Lilly & Co. and Janssen Pharmaceuticals, which make the multi billion-dollar antipsychotic drugs Zyprexa and Risperdal, respectively. Though not much money was earmarked for bipolar research, critics say the resources help him advance his aggressive drug treatment philosophy.

Numerous psychiatrists say Riley's overdose suggests that bipolar disorder is becoming a psychiatric fad, leaving thousands of children on risky medications based on symptoms such as chronic irritability and aggressiveness that could have other causes. Riley's father, for example, had only recently returned to the home after being accused of child abuse, according to police. Since the girl's death, state officials have stepped up a review of the 8,343 children taking the latest antipsychotic medications under the Medicaid program for conditions including bipolar disorder, to be sure the treatment is appropriate.

Psychiatrists too often prescribe these medications, which carry side effects such as weight gain and heart disease risk, without addressing problems in the children's lives, said Dr. Gordon Harper, director of child and adolescent services at the state Department of Mental Health. He likened the approach to "tuning the piano while the subway is going by."

Aggressive treatment

Biederman's critics chide him for not speaking out against misuses of a diagnosis that he has helped inspire. Among leading authorities on bipolar disorder, the Mass. General team has proposed the most aggressive treatment for the broadest group of children, they say, and Biederman should take responsibility when treatment goes wrong. At a conference on bipolar disorder at Pittsburgh's Point Park University last weekend, one speaker, Dr. Lawrence Diller, a California behavioral pediatrician, contended that Biederman bears some blame for Riley's death.

"I find Biederman and his group to be morally responsible in part," said Diller, whose popular book, "Running on Ritalin," accused psychiatrists of over treating another childhood condition, attention deficit hyperactivity disorder. "He didn't write the prescription, but he provided all the, quote, scientific justification to address a public health issue by drugging little kids."

Biederman rejects the idea that Riley's death is a cautionary tale, accusing critics of exploiting a tragedy to fan fears about psychiatry, a profession that has long faced prejudice. "The fact that she had XY drug or XY treatment is irrelevant to what happened. . . . If this child had the same outcome from treatment for asthma or seizures, we wouldn't have this frenzy," said Biederman in an interview at Mass. General's Cambridge mental health clinic.

Though Biederman acknowledges that distinguishing bipolar disorder from ordinary crankiness and flights of fancy in young children is challenging, he insists there is no ambiguity in the patients at his practice. "People have to wait a long time to see me or my colleagues. . . . It's not that somebody comes to me after their child has a temper tantrum. They do things for years that are dangerous. These are things that profoundly affect the child," said Biederman, putting them at risk of academic failure or even suicide.

Biederman dismisses most critics, saying that they cannot match his scientific credentials as co author of 30 scientific papers a year and director of a major research program at the psychiatry department that is top-ranked in the "US News & World Report" ratings.

The critics "are not on the same level. We are not debating as to whether [a critic] likes brownies and I like hot dogs. In medicine and science, not all opinions are created equal," said Biederman, a native of Czechoslovakia who came to Mass. General in 1979 after medical training in Argentina and Israel. He now lives in Brookline.

Struggle for research funds

Biederman's thinking on bipolar disorder grew out of his work in the early 1990s, when he observed that many children referred to Mass. General's psychiatric clinic seemed to have periods where they were extremely aggressive, deeply depressed, or angry. And they were not getting better from taking medications such as Ritalin, which is prescribed for attention deficit hyperactivity disorder.

At the time, psychiatrists considered bipolar disorder a condition that typically revealed itself around age 20, and rarely in children under 12, but Biederman believed that many of his patients met the definition normally applied to adults. Working with Wozniak, he published an influential paper in 1995 reporting that one out of six children at his clinic might be bipolar and that the rate was even higher among children with ADHD.

Biederman was already quite successful as an ADHD researcher, establishing close ties with companies that manufactured drugs such as Ritalin to fund research projects that the federal government would not pay for. He also received payments for giving speeches about mental health issues and serving on scientific advisory boards that typically meet a few times annually to discuss research. He declined to say how much he receives, but said that all of the income was approved by both Harvard Medical School and the hospital.

Biederman's boss said he does not believe the money affects Biederman's judgment.

"I think a pharma person would not dare to tell Joe what to say," wrote Dr. Jerrold Rosenbaum, chief of psychiatry at Mass. General, in an e-mail. "And if they made that mistake, it would be only once. . . . For Joe, it is his ideas and mission that drive him, not the fees."

Biederman said he quickly discovered that drug companies were less interested in bipolar disorder than the more established ADHD. He and Wozniak, who did not respond to a request for an interview, struggled to get

funding for research on bipolar children. "The more controversial a diagnosis is, the harder it is to get funding from conventional sources," he explained.

Contrasting viewpoints

Occasionally, they received small grants from drug companies or private philanthropies to test drugs on children, but Biederman admits these studies are not enough to prove the drugs are safe and effective. Nonetheless, the Mass. General studies were enormously influential: their 2001 study, in which 23 children diagnosed as bipolar received the drug Zyprexa for eight weeks, became one of the most frequently quoted articles in the history of the Journal of Child and Adolescent Psychopharmacology. The study showed that the drug eased outbreaks of aggression, though children typically gained more than 10 pounds.

Biederman was disappointed that he could not do more comprehensive studies, but he saw no reason to delay treatment. "At least the line of drugs I'm talking about gives some relief," he said. "The only way to understand the side effects is in the context of the seriousness of the illness."

As bipolar disorder received increasing media attention, Biederman and Wozniak's research was often cited as the scientific rationale for diagnosing and treating the disease aggressively. Another leading researcher, Dr. Barbara Geller of Washington University in St. Louis, adopted a more restrictive view, requiring that children have a series of specific symptoms such as reduced need for sleep before she would diagnose the disorder. But the Mass. General team used broader categories, saying that children who are extremely irritable or aggressive might be bipolar. Skeptics said those symptoms were too common, leaving too much room for dispute over who is really sick.

Dr. Biederman's staff "can do the same diagnostic interview on 100 children and come up with five or 20 bipolar disorders, and I might do the same thing and find only one or none," said Dr. Jon McClellan, a psychiatrist at the University of Washington who chaired a panel of the American Academy of Child and Adolescent Psychiatry that recently concluded there is no proof that children under 6 can be diagnosed with the disorder. He says he has received no money from the pharmaceutical industry for years.

A surge in diagnoses

Biederman's work helped fuel a surge in the number of children diagnosed with bipolar disorder over the past 15 years. A national study of community hospitals found that the percentage of mentally ill children diagnosed as bipolar quadrupled from 1990 to 2000.

The rapid rise raised concerns at the National Institute of Mental Health, prompting its top officials to convene leading specialists, including Biederman, to urge them to come up with diagnosis and treatment standards. The resulting guidelines, released in 2001, acknowledged that Biederman was right: Bipolar disorder can strike before puberty. However, the guidelines also stated that identifying the disease among children is challenging because normal children are prone to be irritable, aggressive, or giddy.

Dr. Steven Hyman, who was then director of the mental health institute and is now provost at Harvard University, said he remains very concerned about the growing use of "big gun" antipsychotic drugs such as Zyprexa, Risperdal, and Seroquel on children. In the Massachusetts Medicaid program, the number of people under 18 receiving at least one of the "atypical antipsychotic" drugs rose from 6,943 in 2002 to 9,123 in 2005, a 31 percent jump, before declining to 8,343 in 2006. Hyman says that none of the drugs has the approval of the Food and Drug Administration for use in bipolar children, and doctors prescribe them based on their individual judgment.

"We don't know the first thing about safety and efficacy of these drugs even by themselves in these young ages, let alone when they are mixed together," said Hyman.

Rebecca Riley's treatment

Kifuji was careful in treating Rebecca Riley, meeting the child six times before diagnosing bipolar disorder, according to Carney. Based on the child's behavior and family history, Kifuji prescribed three drugs to the 3-year-old child, including the antipsychotic medication Seroquel and Clonidine, a high blood pressure medicine that is often prescribed to calm aggressive children. Last year, Clonidine was prescribed to 1,195 children under age 7 served by the Massachusetts Medicaid program, including Riley.

Police charge that her parents, Carolyn and Michael Riley , repeatedly convinced Kifuji to give them extra Clonidine, ultimately accumulating dozens of extra pills that they used to control the little girl. Long before the child finally died on the floor beside her parents' bed, the police report said, teachers and school nurses noticed that she had become lethargic like a "floppy doll" on a nurse's lap.

Carney said his client, who is not practicing while the investigation continues, did nothing wrong in writing the prescriptions for the girl. Although some were shocked that the child was taking so much medication, Carney said Kifuji was practicing mainstream psychiatry for a very troubled child. He observed that Biederman's "research and teaching validates Dr. Kifuji's work with patients."

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