

November 19, 2008

Use of Antipsychotics in Children Is Criticized

By [GARDINER HARRIS](#)

WASHINGTON — Powerful antipsychotic medicines are being used far too cavalierly in children, and federal drug regulators must do more to warn doctors of their substantial risks, a panel of federal drug experts said Tuesday.

More than 389,000 children and teenagers were treated last year with Risperdal, one of five popular medicines known as atypical antipsychotics. Of those patients, 240,000 were 12 or younger, according to data presented to the committee. In many cases, the drug was prescribed to treat attention deficit disorders.

But Risperdal is not approved for attention deficit problems, and its risks — which include substantial weight gain, metabolic disorders and muscular [tics](#) that can be permanent — are too profound to justify its use in treating such disorders, panel members said.

“This committee is frustrated,” said Dr. Leon Dure, a pediatric neurologist from the [University of Alabama](#) School of Medicine who was on the panel. “And we need to find a way to accommodate this concern of ours.”

The meeting on Tuesday was scheduled to be a routine review of the pediatric safety of Risperdal and Zyprexa, popular antipsychotic medicines made, respectively, by Johnson & Johnson and Eli Lilly & Company. [Food and Drug Administration](#) officials proposed that the committee endorse the agency’s routine monitoring of the safety of the medicines in children and support its previous efforts to highlight the drugs’ risks.

But committee members unanimously rejected the agency’s proposals, saying that far more needed to be done to discourage the medicines’ growing use in children, particularly to treat conditions for which the medicines have not been approved.

“The data show there is a substantial amount of prescribing for [attention deficit disorder](#), and I wonder if we have given enough weight to the adverse-event profile of the drug in light of this,” Dr. Daniel Notterman, a senior health policy analyst at [Princeton University](#) and a panel member, said when speaking about Risperdal.

Drug agency officials responded that they had already placed strongly worded warnings on the drugs’ labels.

“I’m a little puzzled about the statement that the label is inadequate,” said Dr. Thomas Laughren, director of the agency’s division of [psychiatry](#) products. “I’m anxious to hear what more we can do in the labeling.”

Kara Russell, a spokeswoman for Johnson & Johnson, said, “Adverse drug reactions associated with Risperdal use in approved indications are accurately reflected in the label.”

But panelists said the current warnings were not enough.

While panel members spoke at length about Risperdal, they said their concerns applied to the other medicines in its class, including Zyprexa, Seroquel, Abilify and Geodon.

The committee's concerns are part of a growing chorus of complaints about the increasing use of antipsychotic medicines in children and teenagers. Prescription rates for the drugs have increased more than fivefold for children in the past decade and a half, and doctors now use the drugs to settle outbursts and aggression in children with a wide variety of diagnoses, even though children are especially susceptible to their side effects.

A consortium of state [Medicaid](#) directors is evaluating the use of the drugs in children on state Medicaid rolls to ensure that they are being properly prescribed.

The growing use of the medicines has been driven partly by the sudden popularity of the diagnosis of pediatric [bipolar disorder](#).

The leading advocate for the bipolar diagnosis is Dr. Joseph Biederman, a child psychiatrist at [Harvard University](#) whose work is under a cloud after a Congressional investigation revealed that he had failed to report to his university at least \$1.4 million in outside income from the makers of antipsychotic medicines.

In the past year, Risperdal [prescriptions](#) to patients 17 and younger increased 10 percent, while prescriptions among adults declined 5 percent. Most of the pediatric prescriptions were written by [psychiatrists](#).

From 1993 through the first three months of 2008, 1,207 children given Risperdal suffered serious problems, including 31 who died. Among the deaths was a 9-year-old with attention deficit problems who suffered a fatal stroke 12 days after starting therapy with Risperdal.

At least 11 of the deaths were children whose treatment with Risperdal was unapproved by the F.D.A. Once the agency approves a medicine for a particular condition, doctors are free to prescribe it for other problems.

Panel members said they had for years been concerned about the effects of Risperdal and similar medicines, but F.D.A. officials said no studies had been done to test the drugs' long-term safety.

Dr. Dure said he was concerned that doctors often failed to recognize the movement disorders, including [tardive dyskinesia](#) and [dystonia](#), that can result from using these medicines.

"I have a bias that extra-pyramidal side effects are being under-recognized with these agents," Dr. Dure said.

Dr. Laughren of the F.D.A. said the agency could do little to fix the problem. Instead, he said, medical specialty societies must do a better job educating doctors about the drugs' side effects.