FDA vetoes black box warning for ADHD drugs

(continued from page 2)

Meanwhile, the Canadian government is warning people with high blood pressure, cardiovascular problems, or overactive thyroids not to take Ritalin, Adderall XR, Concerta, Dexedrine, or Strattera, all drugs prescribed for ADHD disorder and related conditions. Health Canada notes, "All ADHD drugs stimulate the heart and blood vessels.... The effects are usually mild or moderate, but in some patients this stimulation may—in rare cases—result in cardiac arrests, strokes, or death."

The FDA's Pediatric Advisory Committee did call for stimulant drugs to carry warnings that the drugs can cause hallucinations. Committee member Thomas Newman estimated that between 2 and 5 of every 100 patients treated with stimulants will suffer a severe psychotic episode.

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"FDA panel: no black box warning for ADHD drugs," Richard A. Sherer, *Psychiatric Times*, May 2006.

—and—

"Heart patients should avoid ADHD drugs: Health Canada," CBC News, May 26, 2006.

—and—

"Panel advises disclosure of drugs' psychotic effects," Gardiner Harris, *New York Times*, March 23, 2006.

ADDITIONAL DRUG WARNINGS:

PAXIL GlaxoSmithKline is notifying doctors that the antidepressant drug Paxil (paroxetine) can increase the risk of suicide attempts in young adults. The company's analysis showed that 11 of 3,455 adults taking Paxil for depression attempted suicide, compared with 1 in 1,978 taking a placebo. Most patients who attempted suicide were young adults, and the risk was highest during the first few weeks of treatment.

While antidepressants have been linked to an increased risk of suicide in children and adolescents, this is the first study to implicate them in adult suicide.

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ACE INHIBITORS: ACE inhibitors, used to reduce blood pressure, cause severe birth defects in seven percent of babies exposed to the drugs in utero, according to a new large-scale study. One-third of the defects affect the heart, one-quarter affect the face or limbs, and one-tenth affect the brain or spinal cord. The most severe defects can cause permanent disability or mental retardation. The drugs were already known to be dangerous in later stages of pregnancy, but the new data reveal that they are unsafe in the first trimester of pregnancy as well.

Brain's "daydreaming" network abnormal in autism

The neural networks we use when we daydream or let our minds wander during restful times do not work normally in autistic individuals, according to a recent functional magnetic resonance imaging (fMRI) study. This finding, the study's authors say, suggests that the internal thoughts of autistic individuals may be far different from those of other people.

Kennedy and colleagues note that several regions of the resting network are particularly susceptible to damage during early development because of their high metabolic rates.

Daniel Kennedy and colleagues note, "Several regions of the brain (including medial prefrontal cortex, rostral anterior cingulate, posterior cingulate, and precuneus) are known to have high metabolic activity during rest, which is suppressed during cognitively demanding tasks." To see if this pattern held true in autism as well, the researchers compared 15 individuals with high-functioning autism or Asperger syndrome to 14 non-disabled controls, measuring energy usage in the "resting network" when the participants relaxed and when they performed a cognitively demanding task.

The non-disabled controls exhibited a normal pattern of deactivation of the resting network during the task, Kennedy and colleagues report, while the brains of autistic participants failed to demonstrate this deactivation effect. "The resting network shuts down in normal subjects, because it was already running high during rest," Kennedy says. "We didn't see a similar shutdown in autistic subjects—because it wasn't ever there to begin with."

In addition to allowing the brain to process internal thoughts during "down time," the resting network is believed to play a key role in self-awareness, and Kennedy notes that it also "supports thinking about other people, emotional processing and the processing of familiar faces—all things that we know are abnormal in autism at a behavioral level."

The researchers' tests also showed that the medial prefrontal cortex, one region of the resting network, functioned abnormally during a test of emotion processing. This suggests, they say, "that there is abnormal functioning of the midline resting network in autism during rest and emotion processing, which we speculate may reflect a more general failure to engage in the types of internally directed thoughts that normally recruit this network." They also found that the degree of abnormality in deactivation of the medial prefrontal cortex during cognitively demanding tasks correlated with the degree of social impairment of autistic individuals.

The researchers say, "A particularly intriguing behavioral study found that individuals with autism spectrum disorders report very different internal thoughts than control subjects, lending support to our interpretation that an absence of this resting activity in autism may be directly related to abnormal internal thought." They suggest that the absence of normal internal thought processes may be related to the obsessive interests and preoccupations of autistic individuals, or that "perhaps hypersensitivity to their external environment constantly interrupts the full emergence and elaboration of internally directed thoughts."

Kennedy et al. note that several regions of the resting network are particularly susceptible to damage during early development because of their high metabolic rates. "Furthermore," they say, "because these highly active midline regions are richly connected with numerous cortical and subcortical regions, an early insult affecting any one of these areas may have devastating, widespread consequences on brain connectivity and subsequent functionality."

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"Failing to deactivate: resting functional abnormalities in autism," Daniel P. Kennedy, Elizabeth Redcay, and Eric Courchesne, *Proceedings of the National Academy of Sciences*, Vol. 103, No. 21, May 23, 2006, 8275-80. Address: Daniel P. Kennedy, Department of Neurosciences, University of California at San Diego, 9500 Gilman Drive, La Jolla, CA 92093, dkennedy@ucsd.edu.

—and—

"Mind's 'daydream' centers may hold clues to autism," *HealthDay*, May 11, 2006.

QUOTABLE:

"There are very powerful people in positions of great authority in Britain and elsewhere who have staked their reputations and careers on the safety of MMR and they are willing to do almost anything to protect themselves."

Peter Fletcher, former chief scientific officer at the British Department of Health, quoted by Dan Olmsted in "The age of autism: but is Wakefield right?," Washington Times*, June 13, 2006*

"The use of potent antipsychotic drugs to treat children and adolescents for problems like aggression and mood swings increased more than fivefold from 1993 to 2002, researchers reported yesterday....

"'We are using these medications and don't know how they work, if they work, or at what cost,' said Dr. John March, a professor of child and adolescent psychiatry at Duke University. "It amounts to a huge experiment with the lives of American kids, and what it tells us is that we've got to do something other than we're doing now' to assess the drugs' overall impact."

"Use of antipsychotics by the young rose fivefold," Benedict Carey, *New York Times*, June 6, 2006