FDA hearing: Five hundred suicides in children given antidepressants?

An advisory committee of the Food and Drug Administration urged at a public hearing in February 2004 that the FDA warn doctors and consumers that newer antidepressants such as Paxil, Zoloft, and Effexor, often given to autistic children, can increase the risk of suicidal thoughts or behavior in teens and children.

In addition, experts testifying at the February 2 hearing expressed frustration that pharmaceutical companies had mislabeled reports of suicidal behavior under the mislcading heading "emotional lability" in order to disguise the problem.

Prior to the hearing, a controversy erupted when a scientist at the FDA was initially barred from publicly presenting his findings. FDA researcher Andrew Mosholder was scheduled to outline the results of a safety analysis of antidepressants, a project he was assigned following warnings last December by the FDA, as well as by British regulators, that antidepressants are linked to suicide in children. (The British regulators have called for an end to the use of certain antidepressants for pediatric patients, while FDA officials are still "studying" the issue.)

Mosholder's review of data from 20 clinical trials involving eight different antidepressants and more than 4,100 children concluded that the drugs do indeed increase the risk of suicidal behavior. However, the FDA removed his name from the hearing agenda. According to one FDA source who spoke to the *San Francisco Chronicle*, an FDA official told Mosholder that "he wasn't going to be able to present [his report] because he had reached a conclusion and therefore was biased." Another FDA official claimed that Mosholder's research was not yet "finalized" and thus not ready for presentation.

One skeptical FDA official who requested anonymity asked the *Chronicle*, "Why is the agency sitting on its hands and acting as if there isn't a risk when their own scientists have looked at the data and concluded that there is?"

After much negative publicity resulted from the incident, The FDA reconsidered its action and some of Mosholder's data were presented at the February hearing, which also included the testimony of family members of children who committed suicide following antidepressant treatment.

David Healy, a psychiatrist whose own research strongly implicates antidepressants as a risk factor for suicide, says drug-company-sponsored studies make antidepressants appear more benign than they are. The FDA itself acknowledged to the panel in a January 24, 2004 briefing that its review of the results from company-controlled clinical trials revealed a "preponderance of negative studies of antidepressants in pediatric populations," with at least 12 of 15 trials failing to show any benefits.

"What you're seeing," Healy told the FDA panel, "is one of the greatest divides in medicine, between what published articles and their authors say, and what the data actually show." Healy estimates that about 500 U.S. children have committed suicide as a result of antidepressant treatment.

Editor's Note: The FDA also claims vaccines are safe. Does anyone believe them?

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"Drug report barred by FDA; scientist links antidepressants to suicide in kids," Rob Waters, *San Francisco Chronicle*, February 1, 2004.

—and—

"FDA links antidepressants, youth suicide risk, Shankar Vedantam, *Washington Post*, February 3, 2004.

—and—

"Youth, meds, and suicide," Benedict Carey, *Los Angeles Times*, February 2, 2004.

—and—

"Advisory committee tells FDA: strength warnings on SSRI drug labels now," news release, Alliance for Human Research Protection, February 4, 2004.

New study again implicates thimerosal, MMR vaccine

A new paper by David and Mark Geier again strongly implicates the thimerosal in vaccines as a factor in the current epidemic of autism, and suggests that the measles vaccine plays a role as well.

The researchers used data from the Department of Education and the Centers for Disease Control and Prevention to identify the prevalence of autism in several birth cohorts (children born in 1981 through 1985, and 1990 through 1996), and to calculate the average amount of mercury each child was administered through vaccines. A similar analysis was performed for the measles-mumps-rubella (MMR) vaccine using data for birth cohorts from 1982, 1985, and 1991 through 1996.

Geier and Geier report that "as the prevalence of autism increased from the birth cohorts from the late 1980s through the early 1990s, a corresponding increase in the average mercury dose per child occurred. A maximum occurred in the birth cohort of 1993 in both the average mercury dose per child and the prevalence of autism." Moreover, as the average mercury dose per child decreased from 1993 through 1996, the prevalence of autism decreased as well. They report, "[T]here were statistically increased odds ratios for the prevalence of autism that correlated with increasing doses of mercury from thimerosal-containing childhood vaccines in comparison to a baseline measurement."

The researchers' data also showed that the increase in the number of children given the MMR vaccine from the mid 1980s to the early 1990s correlated with the increase in the prevalence of autism, indicating that the MMR vaccine "potentially contributed to a rise in the prevalence of autism in the United States during the 1980s."

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"A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism," David A. Geier and Mark R. Geier, *Medical Science Monitor*, Vol. 10, No. 3, March 2004, 133-39. Address: Mark R. Geier, 14 Redgate Ct., Silver Spring, MD 20905, mgeier@comcast.net.

Atkins diet can reduce seizures—but is it safe?

The popular Atkins diet may curb epilepsy, according to a recent study, but one physician group is cautioning about the risks of the low-carbohydrate diet.

Researchers at Johns Hopkins placed six individuals, including three under the age of 13, on the Atkins diet for a minimum of four months. By the end of the trial, two children and one young adult were seizure-free and on reduced doses of anticonvulsive drugs.

Eric Kossoff and colleagues say the Atkins diet is similar to the ketogenic diet, a very strict low-carbohydrate and high-fat diet currently used to treat epilepsy, in that both diets can lead to ketosis (in which the body produces ketones, a chemical metabolite of fat that appears to inhibit seizures). While they note that their study is very small, and caution against switching from a ketogenic diet to the Atkins diet, the researchers say, "By learning more about how the Atkins diet works to control seizures, we should learn more about which patients may benefit best from either or both of these diets. It may be, for example, that some of those who can't tolerate the restrictiveness of the ketogenic diet could be helped with Atkins."

Another group of researchers, however, is warning that the Atkins diet can be dangerous even for young people. The Physicians Committee for Responsible Medicine (PCRM) recently held a news conference to release data on the deaths of two people (including one teenager) who suffered cardiac arrest while following the Atkins plan. PCRM warns that the Atkins diet can significantly increase the risk of osteoporosis, kidney stones, colorectal cancer, cardiovascular disease, impaired renal function, and diabetic complications.

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"Atkins diet may reduce seizures in children with epilepsy," news release, Johns Hopkins Children's Center, December 9, 2003.

—and—

"Atkins diet alert," website of the Physicians Committee for Responsible Medicine, www.atkinsdietalert.org/physician.html