

Federal Officials Launch Major ADHD Study on Cardiac Risk

BY MARY ELLEN SCHNEIDER
New York Bureau

Officials at the Food and Drug Administration and the Agency for Healthcare Research and Quality are launching a large-scale study aimed at determining whether the medications used to treat attention-deficit/hyperactivity disorder expose patients to an increased risk for cardiovascular problems.

The study is a retrospective review of about 500,000 children and adults who took ADHD medications before the end of 2005. Of the 500,000 patients included in the analysis, about 80% represent pediatric use and 20% adult use, according to the FDA. The evaluation will build on preliminary work performed by the FDA that included information from large health care databases on prescription drug use, outpatient treatment, health outcomes, and death.

The federal study will include all drugs currently being marketed for the treatment of ADHD. The study is expected to be completed in about 2 years.

The launch of the study follows reports of sudden death in treated patients with underlying serious heart problems, and reports of stroke and heart attack in treated adults with certain risk factors. As a result of these reports, in 2006 the agency directed ADHD drug manufacturers to revise their product labeling for physicians to include concerns about cardiovascular problems. And earlier this year, FDA officials also directed drug manufacturers to develop patient medication guides to alert patients to possible cardiovascular risks from ADHD medications.

At that time, the FDA also recommended that physicians obtain a health history and assessment of possible cardiovascular problems before starting patients on ADHD medications.

"It's an important study to do," said Dr. Martin T. Stein, professor of pediatrics at the University



of California, San Diego. Dr. Stein is the recipient of unrestricted educational grants from Eli Lilly and Co., which makes Strattera, and is a member of the Strattera Pediatric Advisory Board.

The main question that pediatricians will be looking to have answered is whether children with an underlying structural heart disease or an arrhythmia are at increased risk for cardiovascular problems when taking these medications, Dr. Stein said. The 2006 reports of sudden death have raised public awareness, but the jury is still out on the risks of taking medications for ADHD in association with a cardiovascular disorder. The federally funded study has the potential to lay some of these concerns to rest, he said.

The jury is still out on the risk of taking ADHD meds in association with cardiovascular disorders.

DR. STEIN

But for most physicians who treat a lot of ADHD, there is no doubt about the safety of these medications, said Dr. Steven R. Pliszka, chief of the division of child and adolescent psychiatry at the University of Texas at San Antonio. Despite increases in prescriptions for these drugs among children, there has been no documented increase in cardiovascular disease, he said. Dr. Pliszka has conducted research for McNeil Pediatrics, Shire, and Eli Lilly and Co., which manufacture ADHD drugs.

ADHD affects 3%-5% of school-age children and about 4% of adults in the United States, according to estimates from the National Institute of Mental Health. ADHD medications are widely prescribed to children and adolescents, according to government data. Three ADHD drugs (Concerta, Strattera, and Adderall) were among the top five drugs prescribed for children 17 years and younger in 2004, according to the AHRQ. And the agency estimates that the national price tag for those three medications was about \$1.3 billion in 2004.

In addition to providing information for physicians and families, federal officials expect that the results of the study will also influence reimbursement for drugs under Medicare, Medicaid, and the State Children's Health Insurance Program. ■

Number of Uninsured U.S. Children Is Growing

BY MARY ELLEN SCHNEIDER
New York Bureau

The number of Americans without health insurance reached 47 million last year, up from 44.8 million in 2005, according to new data released by the U.S. Census Bureau.

The percentage of individuals without health insurance also rose from 15.3% in 2005 to 15.8% in 2006.

This rise includes an increase in the number of uninsured children.

The percentage and number of children under age 18 without health insurance increased from 8 million (10.9%) in 2005 to 8.7 million (11.7%) in 2006.

Much of the increase in the uninsured rate for children can be attributed to a decline in private coverage, David Johnson, chief of the division of housing and household economic statistics at the Census Bureau, said during a news conference.

Overall, the percentage of individuals covered by any type of private insurance plan dropped from 68.5% in 2005 to 67.9% in 2006.

And among children, the percentage with private coverage fell from 65.8% in 2005 to 64.6% in 2006, Mr. Johnson said.

At the same time, coverage by government insurance was also down from 27.3% in 2005 to 27% in 2006.

The data are compiled from the 2007 Current Population

Survey Annual Social and Economic Supplement.

The increase in the number of uninsured individuals between 2005 and 2006 is "pretty shocking," said Karen Davis, Ph.D., president of The Commonwealth Fund, especially in a year when states have been under less financial pressure and many have been trying to expand coverage.

The deterioration of dependent coverage among private plans is particularly disturbing

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and points to the importance of reauthorizing the State Children's Health Insurance Program (SCHIP) with adequate funding, she said.

The number and percentage of uninsured children had been falling consistently between 1998 and 2004 but that progress began to reverse in 2005, said Robert Greenstein, executive director of the Center on Budget and Policy Priorities.

These latest data from the Census Bureau show that the country is "losing significant ground" in insuring children, he said, and he called on President Bush to rethink his position on funding for SCHIP. ■

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