Hyperactivity Drugs to Be Studied for Heart Risk (Update4)

By Rob Waters

Sept. 17 (Bloomberg) -- Drugs used by 5 million children and adults in the U.S. to treat attention-deficit hyperactivity disorder will be studied by U.S. health agencies to determine whether they raise heart risks.

The study will examine data from 500,000 patients who have taken the medications from 1998 to 2005, the Food and Drug Administration said in a statement today. The drugs, including Shire Plc's Adderall, Johnson & Johnson's Concerta and others, generated about $1.9 billion in sales during the first six months of 2007, according to IMS Health Inc., a Norwalk, Connecticut- based market research company.

Most ADHD drugs are central nervous system stimulants that can increase heart rate and blood pressure, and some reports have spurred concern about their potential to cause heart attacks and strokes. Last year, the FDA asked makers of all ADHD drugs to alert doctors and patients about these risks.

While case reports have described the heart complications, ``it is unknown whether or not these events are causally related to treatment," said Gerald Dal Pan, director of FDA's office of surveillance and epidemiology, in a statement posted on the FDA's Web site. ``The goal of this study is to develop better information on this question."

Drugs in this category include Adderall, from Basingstoke, England-based Shire; Concerta, made by New Brunswick, New Jersey- based J&J; Focalin, made by Basel, Switzerland-based Novartis AG; and Metadate CD made by UCB SA, based in Brussels.

Trouble Concentrating

People with ADHD have trouble concentrating or controlling fidgety behavior. Drugs to treat these symptoms are used by 5 million people in the U.S., including 3.3 million under the age of 19, according to Medco Health Solutions Inc., the Franklin Lakes, New Jersey, drug benefits manager.

Use of the medications has surged among people of all age groups and both genders, according to Medco. About 4.3 percent of children took ADHD drugs last year; boys between 10 and 19 used them the most, with 7.8 percent taking them last year.

In May, 2006, the FDA ordered drugmakers to include warnings about the drugs' potential to cause cardiovascular problems and psychiatric symptoms in their prescribing information, said Sandy Walsh, an FDA spokeswoman, in a telephone interview today. In February this year, the agency directed the companies to issue medication guides describing the risks to be given to patients when they pick up their prescriptions at pharmacies.

A report by FDA staff members released in March, 2006, found 30 cases of psychiatric, neurological and cardiovascular side effects among children who took Adderall between October, 2004 and November, 2005. Three of the children died from heart-related problems.

Emergency-Room Visits

A May, 2007 report by the U.S. Centers for Disease Control and Prevention said that 2,500 children went to hospital emergency rooms in 2004 after taking ADHD drugs, most due to accidental overdoses. About one in four children had

symptoms or tests suggesting serious heart or blood pressure symptoms including palpitations, chest pain or fainting, the CDC said.

Most drugs used to treat attention deficit disorder are stimulants. Drugs in this category had sales of $1.6 billion in the first half of 2007, according to IMS Health. Eli Lilly & Co's Strattera, the only non-stimulant approved to treat ADHD, had sales during that period of $281 million.

The new study will be conducted by the FDA and the Agency for Healthcare Research and Quality. It follows on the heels of an earlier, FDA-sponsored effort that compiled information on prescription drug use, inpatient care, outpatient treatment, and health outcomes, including death, the agency said.

In that study, researchers identified people who took ADHD drugs during a seven-year period ending in 2005. The new study will take about two years to complete, the FDA said.

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