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25 deaths linked to ADHD drugs

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Twenty-five persons died and 54 more suffered serious cardiovascular problems after taking drugs to treat attention-deficit (hyperactivity) disorder between 1999 and 2003, the government says.

Children accounted for 19 of the deaths and 26 of the cases of nonfatal cardiovascular problems, including heart attacks, strokes, hypertension, palpitations and arrhythmia, according to a Food and Drug Administration (FDA) report released yesterday.

The FDA report also includes data on 26 other deaths between 1999 and 2003 in ADHD-drug patients. Those include death by suicide, intentional overdose, drowning, heatstroke and from underlying disease.

The report's release preceded an FDA panel discussion today to discuss new ways of examining the potential cardiovascular risks of the drugs, which include amphetamines such as Adderall, and methylphenidates, sold as Ritalin, Concerta, Methylin and Metadate.

The few studies that have looked at longer-term use of ADHD drugs provide little information on those risks, the FDA said.

Sales of drugs to treat ADHD have increased sharply in recent years, with use growing at a faster rate among adults than children, according to a recent study by Medco Health Solutions, a prescription benefit manager. Spending on ADHD drugs soared from \$759 million in 2000 to \$3.1 billion in 2004, according to IMS Health, a pharmaceutical information and consulting firm.

According to the Centers for Disease Control and Prevention (CDC) and the Mayo Clinic, about 7.5 percent of U.S. school-age children have ADHD. Reports estimate that the number of American children who take Ritalin, Concerta, or similar anti-ADHD drugs at about 6 million.

Death and injury reports led the FDA's Canadian counterpart, Health Canada, to yank the ADHD drug Adderall XR from the market for six months last year.

A Canadian panel eventually concluded there was inadequate evidence of increased harm from Adderall XR compared with other available therapies, a conclusion that the FDA also reached based on data on hand.

The FDA review released yesterday found fewer than one adverse event -- that is, a death or serious injury -- per 1 million ADHD drug prescriptions filled, with the sole exception of the 1.79 cases per million of nonfatal cardiovascular or cerebrovascular problems reported in adults treated with amphetamines.

Also, in some of the cases, the children who died later were found to have had undiagnosed heart conditions. And in three of the five cases of death in adults receiving amphetamine treatment, the patients had pre-existing hypertension.

That suggests that hypertension "may be an important risk factor for sudden death in the adult population," according to the report.