TODAY, IN 1775

Patrick Henry made his famous call for American independence from Britain, telling the Virginia Provincial Convention, "Give me liberty, or give me death!"

New hyperactivity drug label rejected

Advisers instead urge clearer wording

By Andrew Bridges
Associated Press

WASHINGTON — Federal health advisers said yesterday that Ritalin and other drugs for attention deficit hyperactivity disorder should not carry strong "black box" warnings about potential cardiovascular and psychiatric risks.

Rather, the Food and Drug Administration advisory committee recommended that the drug labels be written so people can understand them. "I wouldn't use the word 'tougher,' said panel chairman Dr. Robert Nelson. " 'Clearer.' "

By voting against the black box warnings, the pediatric advisory panel broke with another committee that voted just last month to include them on the drugs' labels.

The agency isn't required to follow the advice of its advisory committees, but usually does.

Nearly 3.3 million Americans age 19 and younger used a hyperactivity drug last year, according to Medco Health Solutions Inc., a prescription drug benefit program manager.

Psychiatrists and others had urged the committee to move cautiously before recommending stronger warnings of heart attacks, hallucinations and other potential risks associated with the drugs.

In February, the FDA's Drug Safety and Risk Management advisory committee voted to recommend that the agency add the strongest possible warning to some of the drugs to alert doctors, patients and parents of the uncertainty regarding the risk they may pose to the cardiovascular system.

The FDA then asked the pediatric panel to examine that issue, as well as reports that psychosis or mania can occur in some juvenile patients at normal doses of any drug used to treat hyperactivity disorders.

Adding black-box warnings to some or all the drugs, which also include Adderall and Strattera, could cause more harm than good, some experts told the panel prior to the vote.

The FDA has struggled since last year with the question of how to communicate the potential risks associated with the drugs.

Psychiatrists and mental health advocates said leaving the disease untreated could rival the risks the drugs may pose.

"It is important to not let the discussion of ADHD medications overshadow the public health crisis of untreated mental health disorders in children," said Cynthia Wainscott of the National Mental Health Association.

FDA officials say patients and doctors should be aware that the small number of reported psychiatric events could represent side effects of the drugs, although they cannot point to a definitive link. However, they noted a "complete absence" of similar reports in children treated with dummy pills during dozens of clinical trials of the drugs. In many children, the events ceased once they stopped taking the drugs — and resumed in some once they restarted.

Ritalin is manufactured by Novartis Pharmaceuticals Corp. and in generic form by other companies; Adderall is made by Shire Pharmaceuticals Inc.; and Strattera is produced by Eli Lilly and Co.