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AMA to consider stand against warning labels on antidepressants

BY BRUCE JAPSEN

CHICAGO - (KRT) - The American Medical Association will consider taking a stance against a controversial Food and Drug Administration decision to add stiff warnings about antidepressant use among teens and children at its conference in Chicago this month.

Those behind the proposal say it is designed to combat a recent, rapid decline in prescriptions and ensure children and adolescents are getting proper treatment for depression.

But critics predict confusion will reign if the nation's largest doctor's group opposes the FDA and declares the agency has been too stern on antidepressants - especially during a time the agency is under criticism for lax oversight of drug safety.

Last fall the FDA ordered drug makers to place the highest warning, a so-called "black box" label, on antidepressants after a public outcry and government hearings in which some parents said they believed the drugs played a role in their children's suicide. The new label warns of increased "suicidal thinking and behavior" in children and adolescents being treated with antidepressants.

Since the FDA began reviewing widely prescribed drugs such as Prozac, Zoloft, Paxil and Celexa antidepressant usage is down more than 10 percent among patients under age 18, according to a study by Medco Health Solutions Inc. The pharmacy benefit company found usage down 16 percent for the same age group in the fourth quarter, "traditionally the time of the year when antidepressant use peaks," the Medco study said.

The decline concerns Dr. David Fassler, who is on the board of the American Psychiatric Association and is a voting AMA delegate representing the American Academy of Child and Adolescent Psychiatry.

"Are the right kids getting the right treatment?" said Fassler, adding that he didn't feel the decision was supported by available scientific data. "I worry that it will reduce access to effective and appropriate treatment for children and adolescents suffering from depression."

Fassler's group, the 36,000-member American Psychiatric Association, is among those concerned about the affects of the black-box warning. The large organization could have some clout with the AMA's 543-member policy-making House of Delegates when it meets the week of June 19 in Chicago to discuss the proposal, one of dozens the group will consider. The House represents nearly 250,000 doctor members of the AMA.

Though the resolution's prospects are unknown, some observers say it is irresponsible of the AMA to even consider the proposal.

"For the AMA to move on this issue is irresponsible and confusing," said Dr. Sidney Wolfe,

director of Public Citizen's health research group. "It is extraordinarily demeaning to both doctors and patients that a black box warning, that would lead to safer use of the drugs, is not a good idea. The black box warning is an attempt to balance out the known risks with the benefits of the drug and decrease the chance of a patient having an adverse reaction."

A black box warning does not prevent doctors from prescribing a certain medication. It highlights risks and typically makes physicians think twice about using the product.

Any move to water down the labeling or eliminate the black box warning is sure to meet stiff opposition from some doctors, particularly pediatricians who fought for the new warnings last year.

"I think the black box warning is very reasonable and factually correct, and I don't see any reason to change it," said Dr. Thomas Newman, a pediatrician and University of California at San Francisco professor of epidemiology and biostatistics. He was on the FDA advisory panel that recommended the agency add the new warning labels.

Reached Wednesday, two of the largest makers of antidepressants, Pfizer Inc., the maker of Zoloft, and GlaxoSmithKline Plc. the maker of Paxil, declined to comment on the proposal before the AMA.

The drugs certainly have support among the medical profession, particularly in the field of psychiatry. And a report from the AMA's Council on Scientific Affairs recently completed a report concluding that the FDA should re-evaluate the impact of its decision.

"This product labeling should not be interpreted in such a way that would decrease access to patients who might benefit from these drugs," the report said.

The AMA forum could lead to a more unified voice among doctors regarding the controversial use of antidepressants among children, some doctors said.

"Are the right kids getting the right treatment?" Fassler asked. "That is where we need to place the emphasis."

Others, meanwhile, say parts of the AMA report advocating additional studies will also be a valuable exercise to put before the FDA.

"The FDA should evaluate the impact of the changes that it makes," said University of California-San Francisco's Dr. Newman. "The FDA takes actions with certain goals in mind and it would be a good idea for them to evaluate whether they accomplish the goals they were intended to accomplish."

If doctors support the idea, it would be a tug in the opposite direction for the FDA - an agency recently criticized for not being vigilant enough in ensuring the safety of drugs after they hit the market in the wake of the withdrawals of pain medications Vioxx and Bextra.

Merck & Co. pulled Vioxx from the market last fall after a study found it increased a patient's risk of heart attack and stroke. In April, Pfizer pulled Bextra, because of similar concerns, as regulatory scrutiny heightened. The FDA reportedly knew of heart risks from Vioxx years before.