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Jim Spencer from Wichita, Kan., holds anti-abortion signs behind the Academic Building Monday afternoon. **Spencer** has been a part of the organization Justice All since 1996.

FDA urges monitoring for antidepressant users

By Lauran Neergaard
THE ASSOCIATED PRESS

WASHINGTON — Doctors who prescribe some popular antidepressants should monitor their patients closely for warning signs of suicide, especially when they first start the pills or change a dose, the government warned Monday.

The Food and Drug Administration asked makers of 10 drugs to add or strengthen suicide-related warnings on their labels.

The agency insists it's not yet clear whether the drugs actually spur suicide on occasion — or whether the underlying mental illness is to blame. But FDA bowed to pressure from anguished families who, at an emotional meeting last month, blamed the pills for their loved ones' suicides and pleaded for better warnings.

It's a difficult issue to sort out because depression itself can lead to suicide, and studies clearly show that antidepressants have helped many people recover from depression.

Still, until the question is settled, FDA's own scientific advisers had urged stronger warnings that certain antidepressants may cause agitation, anxiety and hostility in a subset of patients who may be unusually prone to rare side effects.

Monday, FDA followed that recommendation, stressing that the most vulnerable time is when a patient starts therapy or changes the dose.

"We think this is good advice whether the drugs increase the risk or not," said FDA medical policy chief Dr. Robert Temple. "There's a reason people are put on therapy — their depression is worse or somebody's worried about it. Maybe that's what drives it (reports of suicides) or maybe it's the drugs. In either case, you really need to pay attention in the early days."

While FDA's investigation into the possible suicide link initially focused on children and teenagers, Monday's warning includes adults, too. The FDA had investigated reports of suicide among adult antidepressant users in the early 1990s and concluded there was no link — but on Monday revealed that it is reanalyzing that question.

The drugs of concern are newer generation antidepressants: Prozac, Paxil, Zoloft, Effexor, Celexa, Lexapro, Luvox, which are called SSRIs or SSRI-like drugs, and Remeron, Serzone and Wellbutrin, which operate differently.

Manufacturers didn't immediately say if they'd comply.

British health authorities sounded the alarm last year, saying long-suppressed research suggests serotonin-affecting antidepressants might sometimes increase the risk of suicidal behavior in children and teenagers. Excepting only one drug, Prozac, that has been proven to alleviate pediatric depression, Britain declared the other six SSRIs or SSRI-like drugs unsuitable for depressed youth. Britain didn't mention the other three drugs listed in the U.S. notice.

FDA issued a caution on pediatric use last year but says it doesn't yet have proof the drugs are to blame. Among 25 studies of the suspect medications involving 4,000 children and teens, there were no completed suicides. Some 109 patients experienced one or more possibly suicide-related behaviors or attempts — but the studies varied dramatically in what was considered suicidal behavior. For example, among 19 patients classified as cutting themselves, almost all were superficial, with little bleeding.

But critics flooded an FDA meeting last month demanding stronger action — and days later the issue again made headlines when a 19-year-old woman taking part in a study of Eli Lilly & Co.'s experimental new antidepressant duloxetine hanged herself in a company-run facility.

Most antidepressant labels already contain some fine-print statement about suicide, usually that the possibility is inherent with depression.

FDA asked Monday for explicit explanations of worrisome behavior changes to be placed in bold print under the prominent "warnings" section of those labels: agitation, anxiety, irritability and recklessness. Doctors spotting those signs should consider prescribing a lower dose or stopping the drug, FDA said.

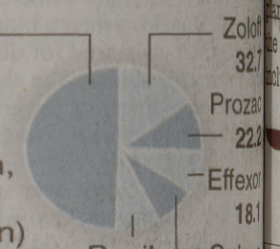
The drugs are used for many conditions other than depression; the warning applies regardless of the reason for use.

Critics welcomed the change but said such complaints first were raised many years ago.

Antidepressants, use with caution

The Food and Drug Administration recommends that certain antidepressants include a warning for worsening depression or suicidal thoughts. There were over 213 million dispensed prescriptions for antidepressants in 2003.

Dispensed prescriptions for antidepressants, 2003
in millions



SOURCE: IMS Health