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Safety Alerts Cite Cholesterol Drugs' Side Effects

By GARDINER HARRIS

Federal health officials on Tuesday added new safety alerts to the prescribing information for statins, the cholesterol-reducing medications that are among the most widely prescribed drugs in the world, citing rare risks of memory loss, diabetes and muscle pain.



Federal health officials said these widely prescribed drugs could cause elevated blood sugar and problems with memory.

It is the first time that the Food and Drug Administration has officially linked statin use with cognitive problems like forgetfulness and confusion, although some patients have reported such problems for years.

Among the drugs affected are huge sellers like Lipitor, Zocor, Crestor and Vytorin.

But federal officials and some medical experts said the new alerts should not scare people away from statins. "The value of statins in preventing heart disease has been clearly established," said Dr. Amy G. Egan, deputy director for safety in the F.D.A.'s division of metabolism and endocrinology products. "Their benefit is indisputable, but they need to be taken with care and knowledge of their side effects."

Diabetes patients and even those who develop diabetes while taking statins should continue taking the medicines, said Dr. Steven Nissen, chairman of cardiovascular medicine at the Cleveland Clinic, who has studied the medicines extensively.

"These are not major issues, and they really do not alter the decision-making process with regard to statins," Dr. Nissen said.

Last year, nearly 21 million patients in the United States were prescribed statins. Whether that number of users is too high or too low has been debated for years. While advice on whether to take statins involves a complex mix of factors like age, family history and blood pressure, some experts have suggested that those with total cholesterol levels around 200 would benefit from treatment. Others have argued that treatment should not start until a cholesterol level of 240 or higher, all other factors being equal.

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Dr. Sidney M. Wolfe, director of Public Citizen's health research group, is among those who contend statins are overused. He said the new alerts about risks provided more reasons that otherwise healthy people with cholesterol levels less than 240 "should not be taking these drugs."

The F.D.A. said that routine monitoring of liver enzymes in the blood, once considered standard procedure for statin users, was no longer needed because the liver injury associated with statin therapy was so rare.

Reports about memory loss, forgetfulness and confusion span all statin drugs and all age groups of patients, the F.D.A. said. Dozens of well-controlled trials of statins have offered few hints that the drugs cause any kind of cognitive impairment, Dr. Egan said. Still, the F.D.A. has received many reports over the years that some patients felt unfocused or "fuzzy" in their thinking after taking the medicines.

Officials in the F.D.A. debated whether such reports were truly worrisome, Dr. Egan said. But in recent years, the F.D.A. — criticized for waiting too long to issue some safety alerts — has become more willing to be public about possible drug risks, even when the evidence is uncertain

"We are trying to be as transparent as possible with our alerts and labeling," Dr. Egan said, even though the alert on the possibility of fuzzy thinking "is not overly helpful."

Statins seem to increase blood sugar levels in some patients by small amounts, and when millions are treated, that change leads to a diagnosis of diabetes for more people.

The F.D.A. had already placed an alert about diabetes risks on the label of Crestor, a big-selling statin made by AstraZeneca, because a Crestor trial showed an increased risk. The agency decided to extend that alert to all drugs in the class with the exception of Pravachol, an older medicine manufactured by Bristol-Myers Squibb.

A well-controlled trial of Pravachol previously showed that it reduced the risks of developing diabetes by 30 percent, but other trials have found Pravachol less effective in reducing cardiac risks.

Dr. Egan suggested that doctors check the blood sugar levels of patients after starting them on statin therapy.

That statins can cause muscle pain, particularly at high doses, has long been known, but in its new alert the F.D.A. reminded doctors that some other medications increase the likelihood that statins linger in the body longer than normal and increase the risk of muscle pain. Among the drugs that conflict with statins are H.I.V. protease inhibitors like telaprevir and boceprevir and the antibiotics erythromycin and clarithromycin.