

FDA Declines OTC Status for Merck Cholesterol Drug Again

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Government advisers on Thursday rejected Merck & Co.'s bid for over-the-counter sales of Mevacor, the granddaddy of the famed cholesterol-lowering drugs.

Too many of the wrong people would use the drug if it no longer required a prescription, advisers to the Food and Drug Administration concluded in a 10-2 vote against nonprescription sales of the medication.

"The patients couldn't figure out whether the drug was for them," said one FDA adviser, Dr. William Shrank of Harvard Medical School.

Merck argued that offering a low dose of Mevacor on open drugstore shelves, next to the aspirin, would persuade millions of people with moderately high cholesterol levels to take a pill that might prevent a first heart attack.

"This is a real opportunity," said Edwin Hemwall, executive director of Merck's worldwide OTC regulatory and scientific affairs. After the meeting, Hemwall said, "We are disappointed. We felt we presented a compelling case."

The FDA's advisers, however, were struck by how many people, in a study of almost 1,500 potential customers, wanted to buy the drug even though they were bad candidates.

One-quarter of people who wanted the pill did not have a high enough risk of heart disease to qualify, meaning they would face unnecessary side effects.

Worse still, 30 percent of very high-risk people -- those who have heart disease or diabetes or had survived a stroke -- wanted Mevacor; these are people who should be under a doctor's care. Merck says many of them are not seeing a doctor and that a little treatment is better than none.

Yet more than 30 percent of patients already taking prescription cholesterol-lowering drugs said they wanted the over-the-counter version. One-half said they would drop the more potent drug in favor of low-dose Mevacor. To the FDA advisers, that raises big questions about previously protected people setting themselves up for a heart attack.

"That's not good," said Dr. Kenneth Burman of Washington Hospital Center. "They're not getting monitored, they're not getting other medications and they're not getting counseling."

Arthur Levin, director of the Center for Medical Consumers in New York, told Merck: "What I keep hearing from you is, 'It's good to be on a statin, it's good to be on a statin.' Don't you think that's a risk, that they may misdiagnose themselves and take too low a dose?"

The FDA is not bound by its advisers' recommendations, but usually follows them. Twice since 2000 the FDA has said no to over-the-counter Mevacor.

Britain allows nonprescription sale of the cholesterol-lowering statin Zocor, but only if customers get it directly from a pharmacist -- meaning behind-the-counter sales.

Merck wants Mevacor to be sold over-the-counter, arguing that with heart disease still the nation's No. 1 killer, people have become sophisticated enough about artery-clogging cholesterol to try.

If such sales were allowed, Mevacor might become the most complex over-the-counter drug available.

Unlike OTC remedies for headaches or allergies, high cholesterol causes no outward symptoms. People would need a laboratory blood test to know if their cholesterol was high enough to qualify and follow-up tests to make sure the pills were working.

The FDA advisers questioned if people would do that. They also noted that at \$1 to \$1.50 a day, an over-the-counter version would cost more for the insured than the typical \$4 to \$15 for a month's supply of numerous statins.

Doctors are divided about the request. The American Heart Association is remaining neutral, while the American College of Cardiology opposes OTC Mevacor, for the same reasons the FDA panel cited.

But others told the advisers that a drug known to have few serious side effects should have a shot at reaching the millions of people now getting no treatment for high cholesterol.

"We're still failing to prevent this epidemic. It's time to take bolder action, to try new approaches," said Dr. Valentine Burroughs of New York's Mount Sinai Medical School, a Merck consultant.

"You should put this drug in the drinking water," said Dr. David Nash of Philadelphia's Thomas Jefferson Medical College.