

## Doctor still knows best

by *The Milwaukee Journal Sentinel*

The class of drugs known as statins has been remarkably effective at reducing bad cholesterol and fighting heart and coronary disease. A recent long-term study even found that statins can prevent heart attacks up to a decade after people stop taking them.

But despite those well-documented benefits, an advisory panel of the Food and Drug Administration took the correct action last month when it rejected a request by Merck & Co. to make its cholesterol-lowering drug Mevacor available over the counter.

It was the third time Merck had sought such approval. The FDA usually follows the panel's recommendations.

Merck had argued that allowing Mevacor to be sold without a doctor's prescription would help people with moderately high cholesterol control their condition and help prevent heart attacks in high-risk patients, some of whom were not seeking medical care.

In recent years, the FDA has properly allowed a number of prescription medications to be sold over the counter, thus broadening the number of people who can benefit from the medications while also controlling health care costs. As a side note, consumers and health care insurers already are saving money because of generic statins.

Merck officials were understandably disappointed by the panel's decision. So were many consumers who, after hearing for years about the wonders of statins, were naturally excited by the possibility that they could now buy Mevacor off the shelf.

But the ultimate and clearly appropriate responsibility for the FDA in these cases is determining whether the medications are safe and suitable for people to use on their own without the benefit of a physician's oversight.

The panel was justifiably concerned by a study that found about one-quarter of 1,500 people surveyed would take the drug even though they were not at high enough risk to require it, which the panel felt would needlessly expose them to possible side effects in all statins, some of which can be life-threatening. The study also found that about 30 percent of high-risk patients who should be monitored by a physician also wanted Mevacor.

Physicians who testified to the panel made another valid point - that patients with high cholesterol need to undergo blood tests to monitor their levels. Statins already have proved their worth. But not every medication, even something with the terrific track record of statins that have been around for years, should be simply placed on a store shelf for self-medicating consumers.

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