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OTC Mevacor Goes Down for the Third Time

But it's the FDA that deserves a thumbs down

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Last month, the Food and Drug Administration rejected Merck's anti–cholesterol drug Mevacor (lovastatin) as an over–the–counter (OTC) medicine. This latest rejection—the third—was widely expected after the FDA's hand–picked advisory panel recommended rejection in December.

The FDA's rejection of an OTC option stems from its unwillingness to place Mevacor's risks in context. Instead of focusing on the hundreds of thousands of heart attacks and strokes OTC Mevacor could prevent each year, the agency was more worried about hundreds of serious side effects potentially caused by inappropriate use of the drug. That's bad decision making on the part of this government agency.

Although over 13 million Americans take statins, according to the government's National Cholesterol Education Program guidelines, three times as many people should be taking them. Why is usage so low? One reason is that some are leery of Western medicine and pharmaceuticals. Also, many of us see no need for medicine when we feel fine and have no symptoms. Add in the expense and hassle of continually going to a doctor for a prescription, on top of the copay, and the cost of a generic lovastatin prescription is high. The higher the cost of something, the less it will be bought.

If statins were sold OTC, you would learn from a blood test whether you have high cholesterol. If you have high cholesterol, your doctor would probably recommend a statin drug. Instead of needing to visit your doctor every four months to get a new prescription, you would go straight to the pharmacy to buy your medicine over the counter. At your annual physical, you can get your lipid levels checked and reconvene with your doctor. The net result is one visit per year instead of three.

Is it any wonder that not even one out of four patients is still on statin treatment after one year?

The result is that 27 million Americans who would benefit from one of modern medicine's greatest inventions are doing without it. The University of California at Berkeley's *Wellness Letter* (November 2007) estimates that 1,500 heart attacks and strokes are prevented within each group of 100,000 statin users per year. That means that the 13 million statin users are being spared 195,000 heart attacks and strokes each year and that 405,000 equivalent events befall those who should be taking statins, but aren't.

The side effects of statins, moreover, are rare and seldom serious. According to the Wellness Letter, "[t]hese proven lifesavers are considered very safe by all expert organizations, including the American College of Cardiology, American Heart Association, and National Heart, Lung, and Blood Institute." The FDA has, for years, agreed that the 20 mg dose of Mevacor is safe and effective.

The FDA hasn't been convinced that consumers could make informed decisions about how to use OTC Mevacor. Of course, it takes time for people to learn how to best use a medicine. Consumers, with the help of doctors, are still learning how best to use products like acetaminophen (Tylenol) and aspirin. And aspirin has been on the market for over 100 years.

Merck's SELECT trial among 1,497 potential lovastatin OTC customers indicated that some patients would use it in a way that the FDA wouldn't consider ideal. Within this set of "non–ideal" users are two main groups. Patients in the first group should be on something stronger than OTC lovastatin. But many of them would have taken nothing; therefore, it's hard to argue that OTC lovastatin would make them worse off. The second group is at low cardiovascular risk, and probably doesn't need to be on statins. But even for this group, the drugs are safe and have some benefit.

Assume that five million appropriate patients would take an OTC statin each year. Assume, too, that a whopping five million "inappropriate" (by the FDA's standards) patients would also take an OTC statin. Among the appropriate patients, 75,000 heart attacks and strokes would be prevented. Of

the inappropriate patients, almost all of whom would derive some cardiovascular benefit, 10,000 would experience mild muscle pain due to the statin, 250 would experience muscle pain (myopathy) serious enough to stop taking the drug, and about 75 would suffer potentially fatal rhabdomyolysis.

Clearly, the OTC statin alternative isn't perfect (what is?), but is far superior to the status quo. With the benefits and risks being so lop–sided, the OTC statin alternative is better even if 99 percent of all OTC statin customers are inappropriate. Yet the FDA seems to see two classes in America: uninformed consumers who matter and informed consumers who don't. How else can the negative experience of hundreds overrule the dire outcome of 75,000?

OTC statins, moreover, are safer than some other OTC products. Consider aspirin and other drugs in the NSAID class. These products are already available OTC, but they are far from "safe." One researcher reported that at least 6,000 U.S. deaths per year result from NSAID–induced gastrointestinal bleeding.

The FDA considered one alternative in isolation—allowing lovastatin to be sold over the counter—found it less than perfect, and then rejected it. By doing this, the FDA has chosen the status quo under which Americans are suffering 405,000 unnecessary heart attacks and strokes each year. This is bad decision making.

The FDA would do much less harm if it cared as much about those who go without drugs as it does about those who take them.

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