

BRIEF ANALYSIS

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Patient Power: Access to Drugs

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Consumers recently lost a money-saving opportunity when a Food and Drug Administration (FDA) advisory panel voted against over-the-counter (OTC) access to the cholesterol-reducer Mevacor. This is the third time the FDA has turned down a request to make cholesterol lowering drugs available without a prescription, thus denying consumers the power to control an important aspect of their medical care.

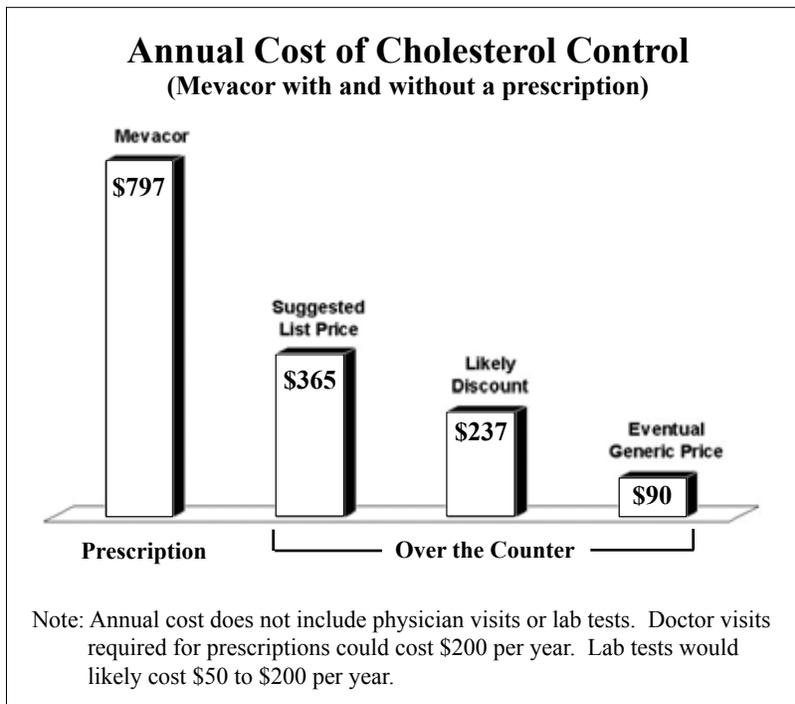
Why should consumers be concerned? Cholesterol control medicine is the most widely used type of prescription drug from the powerful class of medications known as “statins.” For instance, Lipitor, a popular prescription cholesterol reducer, has been the best selling drug in the United States for the past several years. Several other cholesterol medications round out the top 50 drugs most widely used by seniors. Americans spend about \$14 billion per year on cholesterol reducers. Add the cost of diagnostic tests and doctor visits to obtain prescriptions — and this figure probably approaches \$20 billion per year.

Depending on the guidelines used, an estimated 40 million to more than 100 million Americans have high cholesterol. Many of them could benefit from a cholesterol-reducing drug — but aren’t currently taking one. Most don’t seek treatment because it is inconvenient and expensive to visit a doctor and pay for prescription medication.

Potent Pills. Statins can reduce the risk of cardiac events, such as heart attacks, by nearly one-third. These drugs are so beneficial some health experts compare them

to fluoride. A recent BBC news feature whimsically asked, “Is the threat of cardiovascular disease so great that statins may as well be added to the water supply?” Another recent article appearing in the prestigious *British Medical Journal* declared, “Statins are the new aspirin...” On balance, the benefit of statins far outweighs their risks, spurring the British government to approve an OTC version of the cholesterol-control drug Zocor in 2004.

Cost of Prescription Cholesterol Control. Consumers save money when medicines are sold over the counter.



For evidence, we need look no further than the allergy drug Claritin, formerly available only by prescription. Consider this:

■ In 2001, a year’s supply of Claritin cost about \$1,066. Two doctor visits a year to obtain prescriptions would likely push the yearly total to over \$1,200.

■ In late 2002 Claritin was approved for OTC sale, and the price soon dropped to \$365 per year, about \$1 per tablet — no doctor visits required.

■ Currently consumers can buy an entire

year’s supply of OTC Loradatine, the generic version of Claritin, for as little as \$31 at a Costco or local dollar stores.

Thus competition has driven the price of the generic version of Claritin down to 10 to 25 cents. Consumers can save almost 98 percent compared to the combined cost (in 2001) of doctor visits and purchases of prescription Claritin.

Cash-trapped seniors currently pay as much as \$1,500 annually on cholesterol control. Mevacor costs about \$800 per year exclusive of lab tests and doctor’s visits. Lovastatin, the generic version of Mevacor, sells for about half that amount. This suggests that competing drugs, discounted prices and generic over-the-counter

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versions of prescription drugs could drive the cost of cholesterol treatment down by as much as 90 percent. For example:

- Merck's proposed selling price of \$1 per daily dose for OTC Mevacor (\$365 per year) is the same as the initial suggested retail price of OTC Claritin.
- Had Mevacor become available without a prescription, within three years a generic version could have driven its cost down to 25 cents per daily dose, possibly lower. [See the figure.]

Seniors would likely have saved an average of about \$1,000 per year compared to what they currently pay.

Missed Opportunities. Experts had hoped that up to three cholesterol-lowering drugs would become available over the counter during the next few years. The FDA panel's denial of Mevacor will certainly discourage pharmaceutical companies like Merck (whose patent on Zocor expires this year) or Bristol-Myers Squibb (whose request to switch Pravachol was turned down in 2000) from further attempts to move their popular statin drugs to OTC status. The FDA panel reasoned that elevated cholesterol is a medical condition without symptoms, making it difficult to self-diagnose. Thus, people seeking treatment should be monitored by a physician. Another concern was that people with over-the-counter access might not visit their doctor and thus miss out on the expertise gained from professional physician care.

There is little evidence to support these assertions. For instance, the same logic could be used to deny access to over-the-counter pain relievers, cold remedies or antacids. These remedies have not caused people to avoid seeking professional advice for arthritis, colds, allergies and stomach problems. Indeed, access to these medications allows patients to seek advice for conditions that are more critical or to consolidate office visits rather than being forced to schedule a separate (and costly) appointment every time a prescription runs out.

Likewise, selling cholesterol-reducing drugs over the counter would not lead Americans to forgo physician

care. But it would allow them the leeway to discuss treatment with their doctor when it is more convenient. Consumers could obtain lab tests in more convenient, lower-cost settings, allowing them to save money while reducing their cholesterol.

The advent of the Internet has given consumers many new resources to help them understand and manage their cholesterol. For instance, some Web sites discuss cholesterol treatments, and many online health forums allow patients to compare their experiences with others. An Internet-based laboratory service called Direct Laboratory Services, Inc. offers a \$59 battery of tests, called Cardio-Plus, that measures liver and kidney function in addition to several metrics on cholesterol. The company works with about 5,000 labs across the United States, so virtually anyone can access their services. With expanded access to cholesterol medications, results from a direct access laboratory could be shared with one's physician when setting up a regular appointment. Or a consultation could be conducted over the phone with an Internet-based physician specializing in the interpretation of lab results for cholesterol treatment.

Conclusion. Millions of Americans suffer from high cholesterol. Unfortunately, they can't do much about it on their own. This means that people who could have benefited by starting drug therapy earlier in their lives will often wait until they have heart disease. They will then be placed on expensive drugs too late. Many will suffer heart attacks and die prematurely. And millions of Americans already taking a prescription statin drug will pay much more per year than necessary. If the market were allowed to develop with several competing over-the-counter statin drugs, Americans would save plenty. Including the annual cost of lab tests for cholesterol and liver function, generic statin therapy could fall to less than \$100 per year. Compare that to the estimated \$1,000 total annual cost of therapy with prescription Mevacor.

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