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Grassley to the FDA: Are Statins Really Safe?

Patient reports and research noting serious side effects from the wildly profitable cholesterol-lowering drugs prompt Senator Chuck Grassley to ask the FDA for a review

By [John Carey](#)

Cholesterol-lowering drugs have been the most successful medicines in history. Last year, [they racked up \\$33 billion in sales](#) around the world. Just one drug, Pfizer's (PFE) Lipitor, earned \$13.6 billion. But there are [serious questions](#) about whether these drugs are being overused and [whether they are as safe](#) as most people—and doctors—believe. And now Congress is starting to ask those questions, too.

BusinessWeek has learned that Senator Chuck Grassley (R-Iowa), the ranking member of the Senate Finance Committee, has sent a letter to the Food & Drug Administration asking whether the agency has sufficiently considered potential problems caused by cholesterol-lowering drugs (most commonly the class of drugs called statins).

Grassley's investigators were struck by the number of people who have come to them with tales of serious side effects and long-lasting injuries after taking the drugs. The most common side effect of statins is muscle pain. The aches usually go away if people stop taking the drugs, but there's growing evidence that pain—and worse—can continue for years afterward. Georgirene D. Vladutiu, a professor at the State University of New York at Buffalo, for instance, describes patients who are wheelchair-bound from muscle weakness and pain five years after they've stopped taking statins. "It's a myth that patients always get better if they stop the drug," she observes.

DOCTORS DISMISS AND UNDER-REPORT SIDE EFFECTS

There's also evidence that side effects are under-reported. Patients say—and studies confirm—that doctors often don't take their reports of pain, cognitive declines, and other side effects seriously and that most cases of injury don't get reported to the FDA. Patients and researchers also have noted that some side effects listed in other countries, such as muscle cramps, are missing from the drugs' labels in the U.S.

In addition, the worries are getting a boost from research on the biological effects of statins. In addition to lowering cholesterol, the drugs activate a gene that targets proteins in muscle for destruction.

Given the increasing concern over these drugs, Grassley's investigators decided it was time to ask the FDA some questions. They include: Is the agency seeing a lot of adverse events? Are the problems being adequately spotted and reported? Why are side effects listed in other countries missing from U.S. labels? And are there problems with these drugs that aren't being addressed?

The FDA's response? Agency spokesperson Karen Riley confirms that the agency has received the letter. "We will review it and respond to the senator," she says.

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