STATIN SIDE EFFECTS: DO DOCTORS TAKE PATIENTS' COMPLAINTS SERIOUSLY?

by Jay S. Cohen, M.D.

A New Study Reveals What Happens When Patients Complain of Statin Side Effects to Their Doctors.

Patients frequently complain that doctors ignore their complaints of side effects with statin, cholesterol-lowering drugs. Joe and Teresa Graedon, the authors of the People's Pharmacy newspaper column, have published myriad letters on this topic. Here are three examples.

I have taken Lipitor for several years. I now notice numbness in my feet and sporadic memory loss, difficulty balancing my checkbook and using the computer. I have a Ph.D., so this is alarming. My doctor says Lipitor is not to blame. My cholesterol is great and not to stop. Is there any evidence that Lipitor could be connected to these symptoms?1

I have been on cholesterol-lowering medication for some time. I had been telling my doctor that my medication was doing something to my muscles and he would not believe me. I changed doctors and the new one discovered that my muscles enzymes were 800 (normal is 200). He took me off the medication and my enzymes came down. When I went on a different statin, they climbed back up again.2

My doctor insists I must take statins to lower my cholesterol even though I experience pain with all of them. Sometimes the pain gets so bad that I struggle not to cry when I walk down the hall of my child's school. My doctor says I should accept "a little discomfort." He says this pain is rare but I know a lot of people who have had the same muscle pain.3

It has been proven that statins can cause numbness in the limbs, cognitive and memory problems, muscle pain and severe muscle injury. Nevertheless, many doctors still insist that statins do not cause side effects.

A research team at my university, the University of California, San Diego, undertook an investigation of doctors' behavior when dealing with patients who complaints of statin side effects. When patients provided good descriptions of their symptoms, did doctors acknowledge the possibility of statin side effects and assist the patients accordingly? Did doctors submit reports to the FDA? Led by Dr. Beatrice Golomb, the researchers published their results in August 2007.4
The researchers focused on three types of side effects commonly caused by statins. The first type involved muscle pain, tightness, cramping, or weakness. In private consultations, patients described their symptoms to 138 doctors. According to the patients, fifty-three doctors (38%) acknowledged the possibility of statin side effect. Eighty-five doctors (62%) dismissed the possibility.

Patients presented symptoms of cognitive disorders, including impaired memory or thinking, to 56 doctors. Sixteen doctors (29%) acknowledged the possibility of a statin side effect. Forty doctors (71%) dismissed the possibility.

Patients presented symptoms of nerve injuries (neuropathies) including pain, weakness, or loss of function to 49 doctors. Seventeen doctors (35%) acknowledged the possibility of a statin side effect. Thirty-two doctors (65%) dismissed the possibility.

One might ask whether the doctors received enough information to make a connection between the statins and the side effects. In preparation for their consultations with the doctors, patients received materials to help them provide ample descriptions to the doctors. Indeed, separate analysis of patients' symptoms determined that nearly 80% of the cases met the scientific criteria for a definite or probable drug reaction.5

After the interviews with the doctors, patients described their doctors' attitudes about their symptoms (Table 1 below). Many doctors attributed patients' symptoms to age or imagination. Some flatly denied that statins caused any side effects or that statins caused these specific side effects. Yet practicing cardiologists know that muscle symptoms occur in about 35% of statin users, even though the drug companies' claim an incidence is only 5%.

Some doctors in the study denied that statins caused nerve injuries, yet it has been shown unequivocally that patients taking statins are 16 times more likely to develop nerve injuries than similar persons receiving no medications.

Overall, these results demonstrate that according to patients' reports, nearly two-thirds of the doctors in this study failed to diagnose obvious statin-related adverse effects. These findings are disturbing because they indicate a very poor level of medical care among doctors prescribing statin medications. The implications for patients are alarming.

On a broader scale, doctors' refusal to make an obvious diagnosis of
stain side effects suggests that these same doctors would not submit a report to the FDA. The FDA Medwatch system is our primary means of identifying dangerous drugs and taking proper remedial steps. Medwatch relies mainly on reports submitted by doctors to indicate whether a drug is safe or harmful. This study provides strong evidence that with stain side effects, the number of reports received by Medwatch represents a gross underestimate of the scope of the problem.

Now that the FDA has this knowledge, what should be done? The FDA needs to initiate independent studies that actively define the true incidence of stain adverse effects in everyday medicine. The FDA must determine the percentage of doctors who fail to make obvious diagnoses of stain side effects and who fail to submit Medwatch reports. The FDA must pressure stain manufacturers to underwrite intensive training for doctors in diagnosing and reporting stain side effects. The FDA must also launch an initiative to encourage patients to submit their own reports to Medwatch.

Will the FDA act? Unlikely. The FDA has come under intense criticism in recent years for failing to ensure the safety of our medications. FDA officials have announced new initiatives to improve safety monitoring. Experts, however, are not impressed. The FDA continues to underfund Medwatch, and it does not provide adequate personal for Medwatch to function effectively.

We have to remember that the FDA is a highly politicized agency. The drug industry has demonstrated considerable sway over the FDA. Not surprisingly, the FDA demonstrates far more concern about the needs of the drug industry than about our needs for safe medications.

If you are taking a stain drug and you encounter symptoms that might be a side effect, research it yourself before you go to your doctor. If the doctor is more concerned about defending the drug than helping you, find another doctor.

TABLE 1. DOCTORS' COMMENTS

Below are some of the comments by doctors, as reported by patients in this study.

Adverse effect attributed to age (11 doctors).

Just normal aging process.

Can expect some problems at your age.
Well, you're no youngster.

No way, you're just getting old.

Dismissed importance of symptoms (69 doctors).

Doctor said would have to live with side effects and did not seem to care.

Ignored complaints about side effects.

Doctor shrugged and said some people just live with it, then laughed.

Did not seem to be concerned with side effects.

Didn't take seriously.

Made me feel I was alone in my inability to take statins because of 'minor discomfort.'

Said I must continue [statins], protecting the heart was most important.

Dismissed existence of symptom (16 doctors).

Acted as if it was imagination.

Doctor suggested it was imagination.

Don't think doctor believed me.

Told me I just didn't like taking pills.

Nothing wrong with me, it's all in my head.

She 'pooh-poohed' me and said keep taking Lipitor.

Dismissed relation to statins (55 doctors).

Almost impossible.

Cannot be statins.

Not possible.
Denied possibility.

Can't be.

Statins are not cause of problems.

Said problems couldn't be due to Lipitor.

Said: "This has nothing to do with the Pravachol."

Said: "That's not a side effect of this drug."

They [doctors] were very skeptical even though I presented Pfizer's own report on side effects.

Statins could not be cause of symptoms.

Neither doctor [internist, neurologist] believed me -- my pharmacist suggested Lipitor as a cause.

My chiropractor suggested it may be the Lipitor, my M.D. didn't think so.

Dismissed relation of muscle symptoms with statins (43 doctors).

Didn't think Lipitor caused muscle weakness because their was no pain.

CPK didn't indicate statin-related adverse effect.

Wouldn't consider Lipitor the cause of body aches.

Specific muscle pain would not indicate medication, only general muscle pain.

Doctor didn't think cramps were caused by statins.

Dr. Philip that there was no connection between pain and the statin drugs.

Dismissed relation of cognitive symptoms with statins (18 doctors).

Statins do not cause memory loss and may, in fact, help it.

No research linking statins to memory problems.

Doctor said statins would improve (not worsen) memory.
Memory and peripheral neuropathy are not acknowledged side effects of statins.

Hopefully discussion of Lipitor, focused elsewhere.

I was the first to tell him [doctor] about this side effect (memory problems, fragmented thinking) and since then he has had other patients with similar problems.

Disbelief that statins could cause adverse effects in general (12 doctors).

Doctor said there were no side effects.

Doctor had heard of no difficulties.

Said Lipitor has minimum to no ADRs.

Literature did not support ADRs.

Can't be the statins, thinks it is a miracle drug.

Said that only 1% of patients have side effects.

REFERENCES


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