

Cholesterol-Reducing Statin Drug Safety

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Doctors are overwhelmingly inclined to dismiss patients' complaints about potential sideeffects from cholesterol-reducing statins and rarely report those complaints to the FDA, according to a survey conducted by researchers from the University of California at San

Diego and published in the peer-reviewed journal Drug Safety.

The study suggests that doctors have a tendency to attribute patients' complaints to age or other factors unrelated to prescription drugs, and that this problem may extend to drugs other than <u>statins</u>.

"Person after person spontaneously [told] us that their <u>doctors</u> told them that symptoms like muscle pain couldn't have come from the drug," said lead researcher Beatrice Golomb. "We were surprised at how prevalent that experience was."

The researchers solicited survey respondents through advertisements and over the Internet, including on web sites where patients had complained about <u>side effects</u> from the drugs. Most of the respondents lived in the United States, and the average age was in the early 60s. The majority of respondents reported having complained to their doctors about problems that arose after they began the drugs, particularly memory and attention problems or tingling and numbness in the extremities. But few doctors made a connection between these complaints and the drugs, even when the symptoms were documented side effects.

"Overwhelmingly, it was the patient that initiated that conversation," Golomb said. Doctors instead tended to blame the symptoms on aging or even to dismiss them as insignificant or imaginary.

As much as 30 percent of patients taking statins may experience muscle pain or other side effects. But these numbers may be on the low end if doctors are not reporting side effects when they occur.

The FDA relies primarily on doctors to fill out "adverse event reports" to help monitor drugs after they have hit the market. Patients can also file reports at http://www.FDA.gov/medwatch but few people are aware of this program. In contrast, other countries such as New Zealand rely heavily on data from patients to continue monitoring drugs.

According to Golomb, one-fifth of all FDA-approved drugs will eventually be withdrawn from the market or given black-box warnings due to severe side effects.