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## Statins: A Risky Step? (Ivanhoe Exclusive)

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ORLANDO, Fla. (Ivanhoe Newswire) -- Those "miracle" pills that lower your cholesterol may, in fact, be doing more harm than good. At least one researcher is out to determine if statins pose more risks than benefits.

Beatrice Golomb, M.D., Ph.D., from the University of California, San Diego, is involved in an NIH-funded study of 1,000 subjects who have been randomized to receive statins or placebo. The study will look at the effect these drugs have on cognitive function. Another study she's involved in will examine all adverse events caused by the drugs. The research comes during a time when statins are now being questioned by doctors and patients alike. Dr. Golomb says, "From the reports that come into us, people are experiencing severe muscle weakness, which is also linked to cognitive problems." Those cognitive problems include everything from the inability to recall names or balance a checkbook to forgetting whole episodes. The concern, says Dr. Golomb, is that statins haven't been adequately studied for their harmful effects. She tells Ivanhoe: "We're really interested in the balance of risks and benefits of these drugs. There are lots and lots of people looking at the benefit side. There are so few people evaluating the [risk] side. You can bet that the \$20 billion a year in statin drug company revenue is going to make sure that any promising lead looking at potential benefits will be followed."

Statins are not the only drugs that have been questioned. In fact, Dr. Golomb says one-fifth of drugs released to the market will ultimately be withdrawn or have major black box warnings. She says, "A full one-half of the problems that lead to those endpoints won't be identified for over seven years after the drug is released." A recent example of this is the drug Phen-Fen. Dr. Golomb says: "That was a drug given to huge numbers of people for a number of years before a problem was identified. And it wasn't even identified by any of the mechanisms that are in place to try to identify the adverse effects. It was identified by the keen perception of one physician -- a radiologist who happened to notice a lot of the patients that she was seeing heart abnormalities in had listed these medications on their medication list."

Dr. Golomb says statins need further study to fully uncover the true risks in all subgroups of people. She says: "[Statins] clearly benefit middle-aged men with heart disease or [middle-aged men] at risk of heart disease. But they've never been shown to benefit women or the elderly." She says an average 55-year-old woman on statins with no family history of heart disease will not live any longer as a result of taking a statin.

This article was reported by Ivanhoe.com, who offers Medical Alerts by e-mail every day of the week. To subscribe, go to: http://www.ivanhoe.com/newsalert/.

SOURCE: Ivanhoe interview with Beatrice Golomb, M.D., Ph.D., University of California, San Diego, October 19, 2004