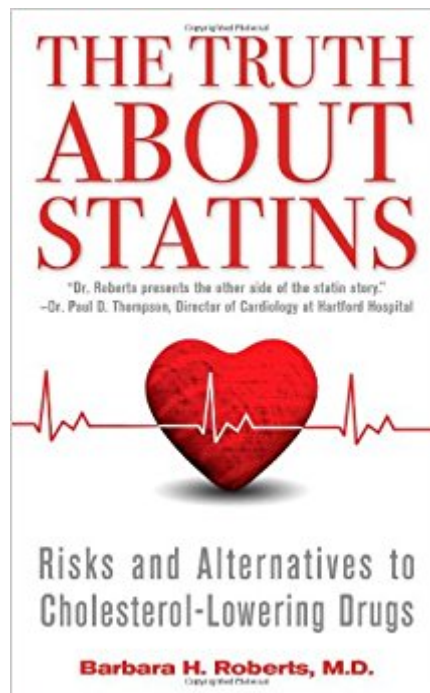




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# The Truth About Statins: Risks And Alternatives To Cholesterol-Lowering Drugs



## Synopsis

From an award-winning cardiologist comes the most up-to-date, definitive reference book about statins—cholesterol-lowering drugs—providing a thorough examination of the uses and safety claims of this high-profile class of drugs. **COULD STATIN DRUGS ACTUALLY HARM YOU?** Despite the rosy picture painted in the ads of a miracle cure for high cholesterol and its attendant heart disease, the reality of taking statins may be far less pretty. Dr. Barbara H. Roberts, director of the Women's Cardiac Center at the Miriam Hospital in Rhode Island, discusses both the benefits and health risks of these popular drugs in this comprehensive guide that finally reveals the questionable science behind the research studies. This honest, patient-friendly appraisal of the most widely used medications in the world may shock you, but it may also save your life. Offering clear-cut, easy-to-understand information in an easily accessible fashion, Dr. Roberts explains how to take the best possible care of your heart, including:

- \* The keys to maintaining cardiovascular well-being
- \* How to interpret your cholesterol numbers
- \* The frightening adverse effects of popular drugs

It is time to take charge of your heart health. Learn the facts behind the hype so that you can make informed decisions on a subject vital to your continued health. If you or someone you love either takes a statin or is considering doing so, you need to read this book.

Includes recipes for a delicious and heart-healthy diet, including Wasabi-Roasted Salmon, Pasta with Avocado Sauce, and Lemon-Pineapple Breakfast Muffins.

## Book Information

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## Customer Reviews

>, is Director of The Women's Cardiac Center at the Miriam Hospital in Providence, Rhode Island. She is also an Associate Clinical Professor of Medicine at the Alpert Medical School of Brown University. She spent two years at the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) where she was involved in the first clinical trial that demonstrated a beneficial effect of lowering cholesterol on the incidence of heart disease. She is currently a principal investigator in another NIH-sponsored trial of cholesterol-lowering therapy.

The Truth About Statins 2> Statin medicines to lower cholesterol were approved in the United States in 1987. Over the last few decades, I have been prescribing statins for my patients when it was indicated, and, initially, these medicines seemed safe and reasonably well tolerated. But the more I have learned about statins, both from the experiences of my own patients and in the medical literature, the more concerned I have become. As more and more people have taken statins, there have been more and more reports of serious and sometimes fatal side effects. Now that statin use has accelerated, I feel compelled to share the results of my research into this powerful class of medicines. By educating readers about the facts behind the supposed miracle cure, I hope to encourage you to speak freely with your medical practitioners and to make informed decisions about preserving your heart's health. Every day, in my practice as director of the Women's Cardiac Center at the Miriam Hospital in Providence, Rhode Island, I see patients who cannot tolerate statins. Some of them complain about muscle aches and weakness, or tendonitis, while others struggle with frightening memory loss and difficulty concentrating. These side effects may not be as rare as we've been led to believe. In fact, my husband developed severe muscle pain from every statin on the market. He was started on statins after a trip we took to Italy in 1995, when he more or less overdosed on prosciutto di Parma. He came home to a total cholesterol count of over 300. His primary care doctor prescribed various statins over the years, but his muscle aches interfered with his ability to run and lift weights, which he loves to do. Finally, he went on the seafood-vegetarian Mediterranean diet that I describe in this book. His cholesterol levels, from this diet and a nonstatin medicine that blocks the absorption of cholesterol, are now satisfactory. Some people can take statins and not develop side effects. But how necessary are statins in the first place? Do they really help prevent strokes and heart attacks? Nowadays, doctors are advised to knock down their patients' cholesterol to very low levels with high doses of statins. But cholesterol, far from being the villain it's said to be, is a vital part of every cell in our bodies. This waxy fat, produced primarily by the liver, is absolutely crucial for the normal functioning of muscles, nerve cells, and the brain—and it's also the

building block that our bodies use to manufacture many hormones, including the reproductive hormones estrogen and testosterone. How will our muscles, brain cells, and nerves react if they are chronically starved of a chemical that is so necessary for their proper functioning? These and other important questions about statins need unbiased, scientifically valid answers. Why do women seem to derive less benefit from statins than men do? Why do women report more side effects from statins? What questions should you ask your doctor if he/she wants you to take a statin? How solid is the science that is used to justify treating people with statins? What is now at stake for the pharmaceutical industry (Big Pharma), the US Food and Drug Administration (FDA), the medical profession, and, most important, the people who take statins? In researching these issues, I pored over the studies that were used to justify treating people with statins. I spoke to my own patients who'd experienced side effects from the drugs, and to other people who'd heard of my interest in statin side effects and contacted me. I educated myself on the interactions among Big Pharma, the FDA, and the medical profession. The FDA is responsible for reviewing and approving any new prescription drugs that pharmaceutical companies want to sell to the American public. When this approval process is complete, the government agency spells out the specific reasons (indications) why doctors may prescribe the drug. The drug label must describe the approved reasons to use the medicine, along with the conditions under which the medicine should not be used (contraindications). For example, taking statins is contraindicated in pregnancy because these drugs can cause defects in a developing fetus. The FDA not only certifies all new prescription drugs but also must approve any new use of existing drugs. However, once the FDA approves a drug, physicians can prescribe it for anything they choose. Unapproved indications are called off-label uses of a drug. Doctors can prescribe, but pharmaceutical companies cannot advertise, off-label uses of a drug. Statins are approved to treat high levels of low-density lipoprotein (LDL) cholesterol (so-called bad cholesterol). In most cases, they are prescribed for people with high levels of cholesterol or with built-up fatty deposits called plaque in their arteries: those who either have or are at risk for atherosclerotic cardiovascular disease (ASCVD). Several scientific studies found that statins lowered the risk of cardiac events in people with established atherosclerosis. (Events is the neutral term we doctors use for really bad outcomes like heart attacks and death.) However, the benefit was modest and was less in women than in men. Furthermore, despite statin therapy, people with ASCVD still had a high residual risk—that is, they had an increased risk of heart attack and stroke even when their LDL cholesterol was brought to very low levels. There were also studies that showed benefits of statin therapy in people without cardiovascular disease but with elevated levels of LDL cholesterol. This benefit was found only in

men, however, not women. In February 2010, based on a study called the JUPITER trial, the FDA expanded the indication for statin use. It now included healthy men ages fifty and older and healthy women ages sixty and older—•even those with normal levels of LDL cholesterol—•if they have evidence of inflammation in the body (indicated by elevated levels of a substance called high-sensitivity C-reactive protein, or hsCRP, in the bloodstream), plus one other risk factor for developing heart disease, such as smoking or high blood pressure. JUPITER is an acronym for Justification for the Use of Statin in Prevention: An Intervention Trial Evaluating Rosuvastatin. This new indication for rosuvastatin (Crestor), the statin used in the trial, could add six and a half million healthy people—•who exhibit no evidence of ASCVD and have normal cholesterol levels—•to the number taking statins. The trial recruited close to eighteen thousand people who were free of diagnosed heart disease. Half were treated with rosuvastatin and half received a placebo, or inactive —•“dummy—• pill. The people enrolled in the study were then followed for the occurrence of cardiovascular events such as nonfatal heart attacks, stroke, or death due to cardiac disease, or the need for coronary artery bypass surgery or other procedures to improve blood flow to the heart. The trial was scheduled to last five years but was stopped prematurely —•“for benefit—• after an average follow-up of just under two years. This means that the investigators felt that the benefit of the statin in lowering the risk of cardiovascular events was sufficient to end the trial before it was scheduled to end. So based on the results of this study, the FDA approved wider use of rosuvastatin. The JUPITER trial was paid for by AstraZeneca, the pharmaceutical company that makes Crestor. The principle investigator, Dr. Paul Ridker, developed the blood test that measures hsCRP, and he receives royalties from its use. Both AstraZeneca and Dr. Ridker stand to make a fortune as this new indication for statin use is implemented. But are the results of this study all they are cracked up to be? Might the findings have been different if the JUPITER trial lasted five years, as originally specified? Was the FDA correct in approving this new indication for rosuvastatin? Were there differences in the results for women compared to men? The answers to these questions may shock you and make you question your physician if he or she wants to put you on a statin. In exposing the shoddy science that underlies many of the —•“guidelines—• that doctors are told they must follow in treating their patients, and in exposing the rampant conflicts of interest among the FDA, Big Pharma, medical scientists, medical centers, and professional medical organizations, I risk being declared a pariah in the medical community. But this story must be told. If you or someone you love takes a statin, please read this book. It might just save your life.

Excellent book. Very good. Bravissimo. Dr. Roberts is a brave woman. I love the unbridled honesty. Made me more convinced that I am surrounded by people that are full of crap. Reps, other docs, administrators, and people in the medical field all seem to have a hidden agenda. This book debunks the myths perpetuated by the pursuit of shareholder profits. You know what? I've been doing ALL of that for years so your book only cemented it in my head. I've picked it up from my own research although the drug trial analyses were new info and sobering. I appreciate the way they are unbiasedly interpreted in this book. I have avoided egg yolks, but I have been reading more that they are ok. Pretty much the only thing I miss is prociutto! I not only do this for heart health (obviously worked since I recently had a normal cath, despite a horrible family history, almost no HDL, long history of heavy smoking in my youth, and NO STATIN). But I truly believe the very same rules hold for Alzheimer's, which being Apo B 4/4 and a Mom with it, I purportedly have a 90-95% chance of getting. I think statins actually can precipitate it in those that are at risk. Aren't brains made of cholesterol anyway? I am neither a cardiologist, nor a cholesterol researcher, so I can't nitpick every little detail or perceived inaccuracy, but I am a vegetarian gastroenterologist with a major interest in nutrition, so I agree completely with the dietary focus that Dr. Roberts promotes. The drug companies are well-aware of our need for a pill to make us feel better about our total lack of self-discipline, when it comes to our health. What we need are more docs/authors, who have the interest (and the guts) to lay the truth on the line.

I just wrote a review on another book which helped me convince my doctor that I did not need statin drugs to lower my cholesterol level. That book was "Fat and Cholesterol Don't Cause Heart Attacks," and is a great source of information regarding the number of ongoing medical studies regarding cholesterol, disproving that fat and cholesterol don't cause heart attacks; sugar and processed foods do! Also look up books by Dr. Robert Lustig for more on that topic. As I mentioned in my other book review, my blood pressure was high and for a number of years has been increasing to the point where my readings were 180-110, so you can see why doctors wanted to prescribe statin drugs to artificially lower my blood pressure. I did a change in lifestyle [diet and exercise] and within a few months, my med test results all came back normal or below the midpoint on each, except for cholesterol. [Read the book I reference above]. Researching my problem with high blood pressure, I came across a number of studies, several books, and this particular book as this particular doctor was involved in several of the studies that in effect debunked cholesterol as a danger to you as well as what statin drugs do and don't do for you. Yes, statin drugs will lower your cholesterol, taking 24 biological stopping processes to get to that point, but along the way, will

create a host of other medical problems for you! The book describes in detail what these illnesses are that can be caused by taking statin drugs. The reduction in my blood pressure did not result from a change in my diet; it was the fact that I was now exercising regularly and not lightly, mind you. Twice a week I did and still do high intensity interval training, which only took 16 minutes per session, and this is what caused my blood pressure to decline dramatically. High intensity interval training [HIIT] allows the body to produce nitric oxide, which the body manufactures but only at extreme levels of physical intensity. The purpose of nitric oxide is to relax the arteries in order for the blood to flow easier as your physical exercise demands high levels of oxygen before going anaerobic, that is, without oxygen. Your body normally produces nitric oxide, however as we age, our physical activity declines or stops, and all of a sudden, we start aging. HIIT assists in the body producing nitric oxide, and thus, reduce high blood pressure! You can also look up books on HIIT to help you, and no, you are never too old to start, as I am evidence of that. My conclusion is that the medical profession is enslaved to the pharmaceutical industry, aided by the FDA which do nothing to help the people, except to enrich the food, drug, and medical industries. We need to do our own research to protect ourselves against selfish industries who look at us as cash cows.

I was looking for a book on statins written by someone with the credentials and wherewithal to provide an unbiased treatment of the subject - one that I could trust. I believe the author, Barbara Roberts, M.D., is such a candidate. She is director of the Women's Cardiac Center at the Miriam Hospital in Providence R.I. In her book, she provides us with the information we need to know to make an informed decision about the use of these drugs. If you are taking statin drugs or plan to, I would highly recommend you read this book. It has an absolute wealth of very important information. She begins by introducing us to the lingo of the world of cholesterol reduction - metabolic syndrome, LDL, HDL, triglycerides, ASCVD, hard and soft end points, and so on. Tables are provided to list the major risk factors and the risks that determine LDL cholesterol goals. Using these tables and something called the Framingham risk score (she provides a web address for the calculator), one can determine if the established guidelines recommend treatment. What I found interesting was that doctors are basically under obligation to prescribe drugs to a patient if the guidelines indicate - lest they be sued should something happen if nothing were prescribed. Also some doctors may prescribe statins even if the guidelines don't indicate such. Know the guidelines. Another interesting thing was the results of six secondary prevention trials (where patients have cardiovascular disease - CVD) and three primary prevention trials (where patients have no signs of CVD). You will find that what is called "absolute risk reduction" was only 7 percent

in the secondary trials and only 1 to 2 percent in the primary trials. Compare this to the "relative risk reduction," which is usually quoted in the literature, of 30 percent and 37 to 44 percent respectively. Basically this is saying, in absolute terms, that your risk of a hard end point (think heart attack, stroke) is not all that much improved by taking cholesterol drugs according to these trials. Caution: never stop taking medication without consulting your doctor first, no matter what you read. On the positive side, Roberts shows that statins do lower LDL, combat inflammation, improve the function of the inner lining of arteries, and reduce blood clot tendency. Some people need these drugs for sure. But there are serious side effects to consider. Roberts devotes an entire chapter to the common side effects. Some that she discusses are: unmasking of previously undiagnosed conditions, rhabdomyolysis, tendon damage, joint problems, effects on liver, effects on nervous system, nerve damage, risk of cancer, risk of diabetes, and more. Her research has showed that "the authors of statin studies and their sponsors in Big Pharma tend to hype the benefits and downplay the harm." The waters are further muddied by the billions of dollars of profit at stake. With so much money on the line, it is hard not to believe that the information we receive will be biased. In the chapter on gender differences and statin use, Roberts reveals the results of various large studies that studied statin use in men and women. One major trial was the JUPITER trial; it was touted as the first primary prevention trial to show statin benefit in women - or did it really? Dr. Roberts shows us some of the major deficits or anomalies in this trial. If I had the space here, I would describe them because what I read is absolutely incredible. This is a must read. Her final opinion: "The results of the JUPITER trial support concerns that commercially sponsored clinical trials are at risk of poor quality and bias." Looking at the studies carried out, it appears that for women, statins may reduce the risk of future recurrence of cardiovascular events, but for women under sixty-five with no established cardiovascular issues, there is zero evidence. In chapter 9, Roberts discusses the clinical research and "science" used to support statin use. She sums up the results of eleven primary prevention trials and three secondary trials. The results are very enlightening. It appears that the absolute risk reduction is puny in the primary prevention trials, but there appears to be a statistically significant reduction in absolute risk in those with existing cardiovascular disease. Even then we are talking only a few percent. What was interesting was that Big Pharma publishes the relative risk reduction when discussing the benefits of the drugs, such as heart attack prevention (this produces more impressive numbers), but chooses to use absolute risk reduction values when reporting the adverse effects of the drugs (this produces the appearance of less risk). Should you be on statin drugs? I believe this is a decision between you and your doctor, but I would recommend including the knowledge contained in this book. It can be a lifesaver.



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