

We win exceptional verdicts and settlements for our clients in cases of brain injury, medical malpractice, wrongful death and other severe injuries.

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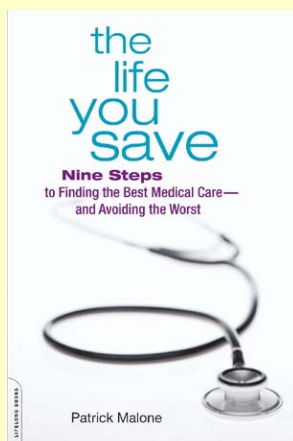
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[Our firm's website](#)

[Read an excerpt](#)

from Patrick  
Malone's book:

***The Life You Save:  
Nine Steps to  
Finding the Best  
Medical Care -- and  
Avoiding the Worst***



## Spotlight on Statins: The Controversy Over New Drug Guidelines

Last month, in an effort to lower the rate of heart attacks and strokes in the U.S., the American Heart Association (AHA) and the American College of Cardiology (ACC) revised the guidelines for prescribing statins, drugs that impair the body's ability to create cholesterol.

The revision focused on preventing a cardiac event among people who have never had one. The panel that composed the guidelines moved away from trying to reach a certain level of blood cholesterol and toward lowering one's overall risk of heart disease and stroke. Defined by risk factors established by the panel, moving the goal from a number to a behavior includes substantially increasing how many people would take statins.

The new guidelines ignited a firestorm in the medical community. Many people found the science wanting and the justification for greater statin use misguided.

This month, we discuss the new recommendations in the hope that individuals -- and their doctors -- better understand their risk of a cholesterol-related heart event, and whether taking the drugs makes sense.

### Who Takes Statins and Why

Last year, about 255 million prescriptions were written for cholesterol-lowering drugs, whose brand names include Crestor, Lipitor and Zocor. As a class of drugs, statins are among U.S. best-sellers, with more than \$14 billion in annual sales.

As explained by the [AHA](#), when too much LDL (low-density lipoprotein) cholesterol circulates in the blood with other substances, plaque can form, narrow the arteries and make them stiffer

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Read our [Patient Safety Blog](#), which has news and practical advice from the frontlines of medicine for how to become a smarter, healthier patient.



(atherosclerosis). If a clot forms and blocks a narrowed artery, heart attack or stroke can result.

One-quarter to one-third of blood cholesterol is carried by HDL (high-density lipoprotein). Known as "good" cholesterol, high levels of HDL seems to protect against heart attack. Statins address LDL.

Cholesterol levels are measured in milligrams (mg) of cholesterol per deciliter (dL) of blood. Before the new guidelines, the AHA and ACC recommended that certain patients be given statins to lower their LDL cholesterol to below 100 milligrams per deciliter if they were otherwise healthy, and to below 70 mg/dl if they already suffered from heart disease.

The new guidelines do not rely on those numbers. Instead, they recommend statins for people deemed by their calculator to be at a lower risk of heart disease -- 7.5% risk within 10 years, versus the 10% to 20% risk of the older guidelines. The drugs also are recommended for people with a risk of stroke.

They no longer recommend statins for the small group of patients who took them solely to lower their LDL. It's interesting that the panel acknowledged that cholesterol lowered by drugs may not have the same effect as cholesterol lowered by nondrug methods, such as diet and exercise, and by having drawn the long genetic straw.

## What's the Problem?

If wider use of statins would result in fewer people having a heart attack or stroke, what's the issue?

A response to the new guidelines published in the [New York Times](#) explained why more is not necessarily better. The article, "Don't Give More Patients Statins," was written by John D. Abramson, a lecturer at Harvard Medical School and author of "Overdosed America: The Broken Promise of American Medicine," and Rita F. Redberg, a cardiologist at the University of California, San Francisco Medical Center and the editor of JAMA Internal Medicine. They wrote:

"This announcement is not a result of a sudden epidemic of heart disease, nor is it based on new data showing the benefits of lower cholesterol. Instead, it is a consequence of simply expanding the definition of who should take the drugs -- a decision that will benefit the pharmaceutical industry more than anyone else."

The revised guidelines would result in more healthy people taking statins, maybe by 70%, or 33 million people.

That would be fine, the writers said, if the drugs demonstrably protected against heart disease; if they helped people live longer or better; if they had minimal adverse side effects. But none of those things is true.

## Evidence Tells the Truth

The [NNT.com](#) is a website whose initials signify "number needed to treat." That refers to how many people need to take a therapy for one

person to benefit.

TheNNT was created by physicians who evaluate therapies through evidence-based studies, and confirms that statins lower cholesterol in most people who have known heart disease or a history of stroke. After five years of daily statin therapy, study subjects achieved a 1.2% lower chance of death, a 2.6% lower chance of heart attack and a 0.8% lower chance of stroke.

Although the chances of any one individual being affected are small (19 out of 20 people who took the drugs for five years saw no effect), when 1 million people take them, roughly 45,000 people see some benefit; 6,000 may experience harm.

But according to a recent story on [The Huffington Post](#) by David H. Newman, M.D., 3 in 4 people having a first heart attack have normal cholesterol levels.

Newman invoked the renowned Framingham Heart Study, in which researchers suggested that cholesterol might be a weak risk factor for heart disease. When 30 years of data were analyzed, high cholesterol wasn't associated with more deaths among most age groups. And for older people, deaths were more common with low cholesterol.

Newman, who contributes to TheNNT.com, said the new guidelines change things most dramatically for people who would derive the least benefit - those without known heart disease. For them, he writes, "the chance of contracting diabetes due to the statin is roughly the same as the chance of avoiding a non-fatal heart attack. ... Worse yet the pills don't save lives, or else they save so few that topic is still hotly debated."

In my newsletter "[One Medical Statistic You Need to Know](#)," I explained "number needed to treat." Basically, it's the answer to: How many people need to take this drug/treatment in order for one person to benefit? The lower the number, the better the treatment.

In terms of statins, among people who don't have high cholesterol but do have high levels of an inflammatory blood marker called C-reactive protein, drug makers like to tout a 50% reduction in heart attacks in the research group that took the statins. The reduction in heart attacks was from 4 in 1,000 patients to 2 in 1,000. Yes, that's a relative 50% drop, but only a real drop of 2 people in 1,000 total, or a NNT of 500.

If it takes 500 patients getting the drug every day for years to save one life, how does that look in comparison to, for example, 10 patients? Not impressive.

As the New York Times writers pointed out, statins are OK for people with known heart disease, but for those with less than a 20% risk in the next 10 years, they fail to reduce the risk of death and the risk of serious illness, as demonstrated by a study showing that 140 people in that risk group would need to be treated with statins in order to prevent a single heart attack or stroke, without any overall reduction in death or serious illness.

## Swallowing Statins versus Eating Nuts

Here's another way of looking at the risks/benefits of statins versus

other things we can do for heart health. As I wrote in a [recent blog](#), [the statistical benefits of putting nuts into your daily diet](#) are pretty interesting, and a graphical display of the apparent benefits shows that nut-eating compares favorably to taking statins. Check out the "forest plot" of the nut-consumption data compared to -- you have to scroll all the way to the bottom of the blog for this -- the statin data. You'll see that even when statin studies are all crunched together by "meta-analysis," the overall benefits are pretty modest.

## The Risk Calculator

The AHA/ACC recommendations assess risk with a calculator they devised. It's supposed to refine who has the most potential for a cardiac event, but many experts claim that it greatly overestimates the risk of heart attack and stroke by anywhere from 75% to 150%, thereby encouraging people who don't need statins to take them.

A story in the [New York Times](#) explained the kerfuffle over the calculator, and quoted a past president of the ACC calling for a halt to the implementation of the new guidelines.

The calculator uses 10-year-old data, but more people smoked then, and had strokes and heart attacks earlier in life. Also, the gap between women's and men's risk isn't as wide as when the data were collected.

It's good that the calculator considers many factors, but that's a double-edged sword -- if your risk factors, including age, smoking and high blood pressure, render a 7.5% chance of a heart event within 10 years, you're in a suggested statin treatment group that used to be 10% to 20%. And what if your risk factor is above the threshold, but your LDL number is low? Why should you take a drug intended to lower cholesterol if that isn't your problem?

## Statins and a Side of Effects

If medical leaders are recommending that millions more people take statins than currently do, they must be sure that potential benefit outweighs potential harm, especially for people without heart problems.

That's not the case with statins. Their side effects, experienced by almost 1 in 5 users, include muscle pain or weakness, decreased cognitive function, increased risk of diabetes, cataracts and sexual dysfunction. Newman said that 1 in 50 people who take statins will get diabetes from the drug. (See our blog, "[Diabetes Warning Issued for Statin Drugs](#).")

"Perhaps more dangerous," said Abramson and Redberg, "statins provide false reassurances that may discourage patients from taking the steps that actually reduce cardiovascular disease. According to the World Health Organization, 80% of cardiovascular disease is caused by smoking, lack of exercise, an unhealthy diet and other lifestyle factors. Statins give the illusion of protection to many people, who would be much better served, for example, by simply walking an extra 10 minutes per day."

## Conflict of Interest

Another red flag hoisted by skeptics of the new guidelines is that many of the experts that developed them have recent or current financial ties to drug makers. And the AHA/ ACC receive significant financial support from Big Pharma.

For more information about conflicted panelists, and an amusing cartoon take on the topic, see a recent edition of [HealthNewsReview.org](http://HealthNewsReview.org).

According to Newman, and others, statin studies were performed mostly by drug companies with a history of fraud in how they report results. Their results are likely to reflect the rosiest version of reality, because that's what sells. Truth is useful only when it moves product. If you're recommending that millions more people take statins than currently do, you must be sure that potential benefit outweighs potential harm, especially for people without heart problems.

## What Should You Do?

The new guidelines are to be applauded for addressing the whole patient, not just his or her lab numbers. But that's pretty much where the accolades should stop. As David Newman noted, 1 in 4 adults older than 45 takes statins, and most don't have heart disease and are unaware of the numbers that should factor into a decision to use this medicine. We take them, he said, because they seem simple, and they're available.

The new guidelines enable this habit.

To determine if you are the best candidate for statins, you must know your risk of heart disease and stroke as defined by blood work, family history, weight, age and lifestyle habits. You must understand that, except for extremely high numbers, blood cholesterol levels might not indicate risk.

The drugs should be taken only by people with the most to gain - those with the highest risk. You, in conjunction with your doctor, can decide what risk is high enough to overcome the potentially harmful side effects.

With statins, as with all drugs, always ask your doctor what are the most common and the most serious side effects before you decide to take them. Ask if there are other ways to manage the condition. Research benefits and potential risks of any marketed drug on [DailyMed](http://DailyMed), the objective resource of the National Institutes of Health.

We agree with Newman: "No doctor should be prescribing a statin and no person should be taking one, unless they have seen [the numbers]. If more people without heart disease take statins it will be a victory of misinformation."

## Recent Health Care Blog Posts

Here are some recent posts on our patient safety blog that might interest you.

- Our occasional series on how to understand [medical statistics has another entry -- this one on how to read "forest plots"](#) which show in a graphical chart how statistically potent the

numbers are in any study or any combination of studies. This one concerns the apparent benefits (apparent, because it's a statistical association and not necessarily cause-and-effect) of daily nut consumption for living a longer life, and we compare the data to the same kind of statistical chart for statins.

- If you're a man of a certain age, you might be suffering from "[Low T.](#)" [low testosterone -- or maybe you're just the target of yet another pharmaceutical profit fantasy](#) -- the medicalization of aging and how spending money might let you sip from the fountain of youth. Along the same line, check out our blog on [heart risks from testosterone therapy](#).
- [When a new doctor comes into your life, he or she may well conclude that your care hasn't been up to snuff](#). How the new doctor talks about that with you, or at all, is the subject of some new important discussions in the medical press. Honesty isn't all that easy but is necessary, especially if the patient has been hurt by another doctor's care.

### Past issues of this newsletter:

Here is a quick [index of past issues of our newsletter](#), most recent first.

Here's to a healthy end of 2013 and new beginnings for 2014!

Sincerely,

A handwritten signature in black ink that reads "Patrick Malone". The signature is written in a cursive, flowing style.

Patrick Malone  
Patrick Malone & Associates