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Don’t Give More Patients Statins

By JOHN D. ABRAMSON and RITA F. REDBERG

ON Tuesday, the American Heart Association and the American College of Cardiology issued new cholesterol guidelines that essentially declared, in one fell swoop, that millions of healthy Americans should immediately start taking pills — namely statins — for undefined health “benefits.”

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 new guidelines, among other things, now recommend statins for people with a lower risk of heart disease (a 7.5 percent risk over the next 10 years, compared with the previous guidelines’ 10 to 20 percent risk), and for people with a risk of stroke. In addition, they eliminate the earlier criteria that a patient’s “bad cholesterol,” or LDL, be at or above a certain level. Although statins are no longer recommended for the small group of patients who were on the drugs only to lower their bad cholesterol, eliminating the LDL criteria will mean a vast increase in prescriptions over all. According to our calculations, it will increase the number of healthy people for whom statins are recommended by nearly 70 percent.

This may sound like good news for patients, and it would be — if statins actually offered meaningful protection from our No. 1 killer, heart disease; if they helped people live longer or better; and if they had minimal adverse side effects. However, none of these are the case.

Statins are effective for people with known heart disease. But for people who have less than a 20 percent risk of getting heart disease in the next 10 years, statins not only fail to reduce the risk of death, but also fail even to reduce the risk of serious illness — as shown in a recent BMJ article co-written by one of us. That article shows that, based on the same data the new guidelines rely on, 140 people in this 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.

At the same time, 18 percent or more of this group would experience side effects, including muscle pain or weakness, decreased cognitive function, increased risk of diabetes (especially for women), cataracts or sexual dysfunction.

Perhaps more dangerous, statins provide false reassurances that may discourage patients from taking the steps that actually reduce cardiovascular disease. According to the World Health Organization, 80 percent 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.

Aside from these concerns, we have more reasons to be wary about the data behind this expansion of drug therapy.

When the last guidelines were issued by the National Heart, Lung, and Blood Institute in 2001, they nearly tripled the number of Americans for whom cholesterol-lowering drug therapy was recommended — from 13 million to 36 million. These guidelines were reportedly based strictly on results from clinical trials. But this was contradicted by the data described in the document itself.

For example, even though the guidelines recommended that women between the ages of 45 and 75 at increased risk of heart disease and with relatively high LDL levels take statins, the fine print in the 284-page document admitted, “Clinical trials of LDL lowering generally are lacking for this risk category.” The general lack of evidence for LDL level targets is why they have been dropped from the current guidelines. In fact, committee members noted that cholesterol lowered by drugs may not have the same effect as cholesterol lowered by nondrug methods, such as diet, exercise and being lucky enough to have good genes.

The process by which these latest guidelines were developed gives rise to further skepticism. The group that wrote the recommendations was not sufficiently free of conflicts of interest; several of the experts on the panel have recent or current financial ties to drug makers. In addition, both the American Heart Association and the American College of Cardiology, while nonprofit entities, are heavily supported by drug companies.

The American people deserve to have important medical guidelines developed by doctors and scientists on whom they can confidently rely to make judgments free from influence, conscious or unconscious, by the industries that stand to gain or lose.

We believe that the new guidelines are not adequately supported by objective data, and that statins should not be recommended for this vastly expanded class of healthy Americans. Instead of converting millions of people into statin customers, we should be focusing on the real factors that undeniably reduce the risk of heart disease: healthy diets, exercise and avoiding smoking. Patients should be skeptical about the guidelines, and have a meaningful dialogue with their doctors about statins, including what the evidence does and does not show, before deciding what is best for them.

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