The Science NOT Opinion e-Newsletter

Cholesterol-Lowering Drugs "Called into Question," Again...

Once again, cholesterol-lowering drugs are being "called into question." While these multi billion dollar drugs are able to lower cholesterol, they are incapable of helping you achieve good health. If you already follow my work you already know this and most importantly; you know what the solution really is.

After reading the following, you'll understand how drug companies manipulate both physicians and their patients with apparently no conscience.

I thank cardiologist David Sim, M.D. for sending me the following information on January 18, 2008, from the news section within the American College of Cardiology publication. These articles are from a wide variety of news organizations.

Clinical News

"Benefits of cholesterol drugs may be overstated.

Business Week (1/17, Carey) reported that "Americans are bombarded with the message from doctors, companies, and the media that high levels of bad cholesterol are" to blame for potentially life-threatening cardiovascular events. **Consumers are told that statins "are the most potent weapons in the "struggle" to reduce LDL cholesterol. However, a number of "researchers harbor doubts about the need to drive down cholesterol levels in the first place**." The article discusses one Lipitor (atorvastatin) ad which claims that the drug "reduces the risk of heart attack by 36 percent...in patients with multiple risk factors for heart disease." The 36 percent figure however, has an asterisk. The ad's small print points out, "That means in a large clinical study, three percent of patients taking a sugar pill or placebo had a heart attack compared to two percent of patients taking Lipitor." Therefore, the "number needed to treat (or NNT) for one person to benefit is 100." Business Week continues, "**That NNT was determined in an industry-sponsored trial using carefully selected patients with multiple risk factors." However, "the only large clinical trial funded by the government...found no statistically significant benefit**."

Life-Systems Engineering Science analysis: We aren't told that medical researchers question the use of statins. And we certainly aren't told, nor are physicians that AT BEST only 1 person in 100 benefits from statin use (an insignificant 1%). Furthermore, these results are from the drug company. When an impartial experiment was done stains were shown to be WORTHLESS, and in many cases harmful when you consider the side affects.

"**Schering-Plough CEO says more data needed to make decisions regarding Vytorin**. Bloomberg (1/18, Pettypiece) reports that according to Fred Hassan, Chief Executive Officer of Schering-

Plough Corp, "the company stands by the effectiveness of its cholesterol drug Vytorin (ezetimibe and simvastatin) after a study showed it may work no better than an older, cheaper medicine." Hassan said that it is still "very early to make too many judgments and decisions because the data isn't all out yet." He added, 'You really have to look at the totality of the data, not just an individual trial.'

Life-Systems Engineering Science Analysis: This article was prompted because a cholesterol–lowering drug combination called Vytorin, was found completely ineffective in reducing coronary artery disease (CAD) progression or death. The researchers were mystified how the drug could lower cholesterol but be worthless for anything else.

For followers of my work it is obvious why the drug fails. Cholesterol numbers, in and of themselves, are meaningless. That's why the body has no cholesterol sensor since keeping cholesterol within a controlled margin is not necessary. This is in contrast to sensors your body does have for truly critical factors like blood sugar levels, calcium and sodium levels.

The article points out that to get the "36% reduction of heart attacks" the drug companies are allowed to use *creative statistics* with something called "endpoints," whereby sample size is not considered. This throws the entire field of statistics out the window because sample size means everything. The actual number of heart attacks was **1%** (3%-2%), not 36%. This means only 1 person in 100 people benefited from taking the drug. A 1% difference is NOT significant in the least and if the drug worked as stated then 85-95% of those taking this expensive drug should benefit from it. The drug company paid for the study AND had the statistics done. When other studies were done the drug didn't work. What a surprise.

The article points out that often older, cheaper drugs work just as well, if not better, than the newer, more expensive ones.

The cardiology newsletter continues…

Health Policy News

Results of clinical trials not required to be released to public.

ABC World News (1/17, story 6, 2:50, Gibson) reported that "[w]hile millions of Americans may be questioning their doctors about Vytorin (ezetimibe and simvastatin), many doctors are asking questions of their own," particularly regarding the apparent delay in the release of the Enhance trial results. According to Merck, the "rigorous study design and analytical process was time consuming and took longer than we originally anticipated." However, Dr. Brian Strom, of the University of Pennsylvania Medical School, said, "**That explanation doesn't make any sense to me. If there was a problem early on, it should have been caught early on." ABC added that drug makers are required to release trial results, "but only to the Food and Drug Administration**." Dr. Jerry Avorn, of Brigham & Women's Hospital, said, "The results of a clinical trial that a company has essentially bought and paid for belong to the company. And the FDA is not at liberty to make those results public." ABC noted that a newly-released review... found that **94 percent of all positive studies are published." However, just one-third "of negative studies ever make it into print," according to the review**.

Life-Systems Engineering Science analysis: This is about the failure of the cholesterol-lowering drug Vytorin. The drug company suppressed the data of the drug's failure for close to 2 years. The laws don't require the drug companies to publish failure so physicians and their patients continue to use a worthless drug.

The cardiology newsletter continues….

Research News

"Surrogate goals" used in clinical trials sometimes misleading.

USA Today (1/17, Rubin) reported that the recently-released results of the Enhance trial "provide another example of how **drug trials' widely used 'surrogate goals' -- easier-to-study intermediate steps, such as lower cholesterol, that stand in for what patients really care about, such as fewer heart attacks -- could be misleading**." The Enhance trial found that Vytorin (ezetimibe and simvastatin) "cut LDL" cholesterol more "than simvastatin alone." However, the "measurements of patients' carotid arteries -- like LDL, another indicator for future heart attacks and strokes -- showed they were of comparable thickness in Vytorin and simvastatin patients." **It had been expected that the arteries of patients taking Vytorin "would not be as thick as the simvastatin patients' since their LDL was lower**." According to Curt Furberg, professor of public health sciences at Wake Forest University, "**Using surrogate goals 'is a shortcut**.'" Furberg added, "You don't have to study thousands of patients for five years. You get an answer in a small number of people in two years." Regarding the Enhance results, Furberg said that using surrogate goals "backfired."

Life-Systems Engineering Science analysis: Drug company studies often measure the wrong thing as this article makes clear. You MUST measure the effect that you are looking for, in this case the incidence of heart attacks, not cholesterol levels because it didn't do anything to prevent heart attacks as this article clearly states. We all get misled, physicians included.

Thanks to Dr. Armando Camara for telling me about the pre-publication feature article (on newsstands January 28th!) from *BusinessWeek* you will be amazed at:

Do Cholesterol Drugs Do Any Good?

By John Carey

January 28, 2008

Lipitor

"**For one thing, many researchers harbor doubts about the need to drive down cholesterol levels in the first place**. Those doubts were strengthened on Jan. 14, when Merck and Schering-Plough (SGP) revealed results of a trial in which one popular cholesterol-lowering drug, a statin, was fortified by another, Zetia, which operates by a different mechanism. The combination did succeed in forcing down patients' cholesterol further than with just the statin alone. But even with two years of treatment, the further reductions brought no health benefit.

Life-Systems Engineering Science analysis: We aren't told about the physician doubts of lowering cholesterol. We are given the impression that all physicians agree with this "treatment."

"Or to put it in terms of a little-known but useful statistic, the **number needed to treat (or NNT) for one person to benefit is 100**.

Compare that with, say, today's standard antibiotic therapy to eradicate ulcer-causing H. pylori stomach bacteria. The NNT is 1.1. **Give the drugs to 11 people, and 10 will be cured**.

Plus, there are reasons to believe the overall benefit for many patients is even less than what the NNT score of 100 suggests. That NNT was determined in an industry-sponsored trial using carefully selected patients with multiple risk factors, which include high blood pressure or smoking. In contrast, the only large clinical trial funded by the government, rather than companies, found no statistically significant benefit at all. And because clinical trials themselves suffer from potential biases…

Life-Systems Engineering Science analysis: this means that there is only 1 chance in 100 that the drug will help you. This is a miniscule 1% chance. If you take statins for heart disease prevention that is exactly what you are doing. NNT means how many people must be given the drug to see just 1 person benefit.

Anything over an NNT of 50 is worse than a lottery ticket.

Several recent scientific papers peg the NNT for statins at 250 and up for lower-risk patients, even if they take it for five years or more. "**What if you put 250 people in a room and told them they would each pay $1,000 a year for a drug they would have to take every day, that many would get diarrhea and muscle pain, and that 249 would have no benefit?** And that they could do just as well by exercising? How many would take that?" asks drug industry critic Dr. Jerome R. Hoffman, professor of clinical medicine at the University of California at Los Angeles.

Life-Systems Engineering Science analysis: Doc Hoffman thinks that 1 in 100 chance is much too optimistic and the real chance of the drug doing anything positive is an even worse 0.4%!

Most important, the statin trials of people without existing heart disease showed no reduction in deaths or serious health events, despite the small drop in heart attacks. "We should tell patients that the reduced cardiovascular risk will be replaced by other serious illnesses," says Dr. John Abramson, clinical instructor at Harvard Medical School and author of *Overdosed America*.

Life-Systems Engineering Science analysis: Many patients are told that the statins will prevent future heart disease in patients that don't have existing heart disease. This is a lie – they prevent nothing. But it gets worse because of the side-effects!

Difficult risk-benefit questions surround most drugs, not just statins. **One dirty little secret of modern medicine is that many drugs work only in a minority of people**. "There's a tendency to assume drugs work really well, but people would be surprised by the actual lack of effectiveness," says Dr. Steven Woloshin, associate professor of medicine at Dartmouth Medical School.

Life-Systems Engineering Science analysis: Doc Woloshin tells us the truth, most drugs won't work for you – if they do you are LUCKY!

If we knew for sure that a medicine was completely safe and inexpensive, then its widespread use would be a no-brainer, even with a high NNT of 100. **But an estimated 10% to 15% of statin users suffer side effects, including muscle pain, cognitive impairments, and sexual dysfunction. And the widespread use of statins comes at the cost of billions of dollars a year**, not just for the drugs but also for doctors' visits, cholesterol screening, and other tests. Since health-care dollars are finite, "resources are not going to interventions that might be of benefit," says Dr. Beatrice A. Golomb, associate professor of medicine at the University of California at San Diego School of Medicine.

Life-Systems Engineering Science analysis: Here's the greater issue. The drugs work for 1 in 100 people BUT 10-15 people taking the drug have very serious side effects. We have been told by urologists many statin patients suffer sexual dysfunction, feel awful, and can't think clearly – all for a 1% chance the drug will work. It's amazing…. Statin's effectiveness is a mere 1% and the amount of side-effects are at least 10% … ten times higher negative side-effects than a potential miniscule success of the drug!

For many other drugs, the NNTs are large. Take Avandia, GlaxoSmithKline's (GSK) drug for preventing the deadly progression of diabetes. The blockbuster, with **$2.6 billion in U.S. sales in 2006, made headlines in 2007 when an analysis of clinical trial data showed it increased the risk of heart attacks. The largely untold story: There's little evidence the drug actually helps patients**. Yes, Avandia is very good at lowering blood sugar, just as statins lower cholesterol levels. **But that doesn't translate into preventing the dire consequences of diabetes, including heart disease, strokes, and kidney failure. Clinical trials "failed to find a significant reduction in cardiovascular events even with excellent glucose control**," wrote Dr. Clifford J. Rosen, chair of the Food & Drug Administration committee that evaluated Avandia, in a recent commentary in *The New England Journal of Medicine*. "**Avandia is almost the poster child for everything wrong with our system," says UCLA's Hoffman. "Its NNT is close to infinite**."

Life-Systems Engineering Science analysis: Drug companies are great at measuring something the drug does, but what the drug can do is very different from solving the problem for which the drug is presumably prescribed.

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When other medications **widely believed to be effective** were tested in a clinical trial, **they flunked**. Hormone replacement therapy didn't protect against heart disease. Anti-psychotic drugs were actually less effective than a placebo in reducing aggression in patients with intellectual disability.

Drug makers, however, do make sure that the researchers and doctors who extol the benefits of medications are well compensated. "**It's almost impossible to .nd someone who believes strongly in statins who does not get a lot of money from industry," says Dr. Rodney A. Hayward, professor of internal medicine at the University of Michigan Medical School**. The NCEP's 2004 guideline update garnered headlines by recommending lower targets for bad cholesterol, which would put more Americans on the drugs. But there was also a heated controversy in the medical community over the fact that **8 of the 9 experts on the panel had financial ties to industry**. "The guideline process went awry," says Michigan State's Barry. He and 34 other experts sent a petition of protest to the National Institutes of Health, saying the **evidence was weak and the panel members were biased by their ties to companies**.

Life-Systems Engineering Science analysis: Objectivity is inversely related to compensation.

But something else has to happen before people get heart disease. For example Spaniards have LDL levels similar to Americans', but less than half the rate of heart disease. The Swiss have even higher cholesterol levels, but their rates of heart disease are also lower. Australian aborigines have low cholesterol but high rates of heart disease.

Life-Systems Engineering Science analysis: Another example whereby the drug companies market drugs that they have, regardless of whether these new expensive drugs actually solve the problems they were intended to address.

When you look at patients with heart disease, their cholesterol levels are not that [much] higher than those without heart disease," he says.

Life-Systems Engineering Science analysis: Again, it's not the cholesterol number, it is cholesterol's STRUCTURE!

In an eagerly awaited trial completed in 2006, the companies compared Zetia plus a statin with a statin alone in patients with genetically high cholesterol. **But the drug makers delayed announcing the results, prompting scientific outrage and the threat of a congressional investigation**. The results, finally revealed on Jan. 14, showed the combination of Zetia and a statin reduced LDL levels more than the statin alone. **But that didn't bring added benefits. In fact, the patients' arteries thickened more when taking the combination than with the statin alone**. Skip Irvine, a spokesman for the joint venture, says the study was small and insists there's a "strong relationship between lowering LDL cholesterol and reducing cardiovascular death."

IRRELEVANT LDL?

If cholesterol lowering in and of itself isn't a panacea, why is it that statins do work for people with existing heart disease? In his laboratory at the Vascular Medicine unit of Brigham & Women's Hospital

in Cambridge, Mass., Dr. James K. Liao began pondering this question more than a decade ago. The answer, he suspected, was that statins have other biological effects.

"Cholesterol lowering is not the reason for the benefit of statins," he concludes.

Life-Systems Engineering Science analysis: By jove I think he's got it! He is saying lowering cholesterol is worthless.

Add it together, and "current evidence supports ignoring LDL cholesterol altogether," says the University of Michigan's Hayward.

In a country where cholesterol lowering is usually seen as a matter of life and death, these are fighting words. A prominent heart disease physician and statin booster fumed at a recent meeting that "Hayward should be held accountable in a court of law for doing things to kill people," Hayward recounts. NECP's Cleeman adds that, in his view, the evidence against Hayward is overwhelming. Not until the country changes the incentives in health care, says UCLA's Hoffman. "The way our health-care system runs, it is not based on data, it is based on what makes money."

Life-Systems Engineering Science analysis: Our current health care system is not about improving a patients health, instead it's about making money (when examined from the pharmaceutical industries perspective). Pathetic!

If you haven't read *The Hidden Story of Cancer* or *The 24-Hour Diet*, I hope this startling newsletter will motivate you to take an active role in your own and your family's health.

If you have any questions of comments about this month's newsletter please e-mail the professor at:

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DO YOU HAVE A GREAT LOW-CARB RECIPE YOU'D LIKE TO SHARE?
Submit your recipe to contact@pinnacle-press.com for consideration to be included in the NEW Cook it Cool cookbook (coming soon). If your recipe gets chosen for inclusion in Cook it Cook, you will receive a FREE copy of the book when it's released.

This Month's Low-Carb Recipe: Pork Fu Yung

INGREDIENTS
1 cup chicken broth
1/2 tsp dark sesame oil, divided
2 teaspoons peanut or coconut oil
1 Tbl cornstarch
1/2 lb boneless pork tenderloin, minced
1 cup sliced mushrooms

5 green onions, sliced thinly, divided
1 cup bean sprouts
1/4 tsp white pepper
2 eggs, beaten well
2 egg whites

PREPARATION
1. Combine broth, 1/4 tsp sesame oil, and cornstarch in a small pan. Stir occasionally as you cook over medium heat until the sauce thickens. Usually takes 5-6 min. Set aside.
2. Heat peanut or coconut oil in a 12-in pan over high heat. Add pork and stir-fry until it's no longer pink. Usually takes about 4 min. Add remaining sesame oil, mushrooms, all but 2 Tbl green onions, salt and pepper. Cook until lightly brown, usually about 4-5 min.
3. Add sprouts and stir-fry a little under a minute. Flatten pork mixture with spatula.
4. Mix eggs and egg whites, pour over pork mixture. Lower heat and cover pan. Cook until eggs are set, about 3 min.
5. Cut into 4 pieces to serve. Top each with sauce and remaining green onion.

Makes 4 servings.

Enjoy!