The Science NOT Opinion e-Newsletter

Jupiter Falling - Scientific proof that the pharmaceutical companies are once again misleading us softly with their statins

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Pharmaceutical companies, doctors, the mass media are all touting the amazing success of a new "cholesterol lowering" statin, Crestor® (Rosuvastatin), when in fact, the test results **as published by the pharmaceutical companies and parroted by The American Heart Association and the media CLEARLY INDICATE THAT ONCE AGAIN STATIN DRUGS FAIL MISERABLY TO CONTROL CHOLESTEROL IN ANY MEANINGFUL WAY!**

That's right, FAILURE; TOTAL and COMPLETE FAILURE! The JUPITER study as reported in *The New England Journal of Medicine* (Ridker PM, et al, 2008;359:2195-207, published November 20) clearly showed another statin failure when the study is analyzed using science instead of emotion.

My review flies in the face of reactions from the American Heart Association and every news organization that has recently reported on this very carefully conceived and constructed study. **There is an enormous difference between "carefully constructed" and first-rate science**. Let us take a look at why the truth is quite the opposite of what has been published. *(Note that the following explanation is lengthy and quite detailed. I have omitted a good majority of details from this Newsletter in an attempt to reach a greater audience. If you wish to see a summary of the end results, please jump to the end of this Newsletter.)*

First, this study applies to a sample population that is virtually nonexistent — meaning that even if the drug did work (which it doesn't), it wouldn't likely help you. In fact, the researchers had to conduct the trial at 1315 different locations to find "special" people meeting the study "requirements." That's right. On average, 4 out of every 5 potential subjects were rejected, too, so that each location only contributed on average 13 patients to the grand total of 17,802 patients—a ridiculously small number, making the process extremely costly and raising the question of why these scientists would go to such extreme lengths.

Desperate times breed desperate errors

If the JUPITER trial was such a failure then why are so many physicians raving about JUPITER's success? The short answer is that when you are desperate to find anything that might work, you make

mistakes — big mistakes. Rosuvastatin clearly doesn't work according to the pharmaceutical company's own measure for success of a drug, which is called the NNT (number needed to treat). The NNT for the Jupiter trial (prevention of a major cardiovascular event) was 95, meaning that for every 95 patients given the drug, **it was a failure for 94 patients or a *failure* rate of 99%!** *(Note that this failure rate does not include additional patients who suffered harmful side effects.).* Contrast this with an antibiotic or insulin reducing blood sugars that have NNTs of 1, meaning that for every 100 patients treated, 99 patients are cured for a success rate of 99%. The higher the NNT, the worse the drug's performance is.

In this trial, LDL cholesterol was lowered an average of 50% and C-reactive protein (CRP - see below for explanation) was decreased 37%. These changes, however, are not significant enough in preventing heart disease because they do not focus on or impact the metabolic pathways that are truly causal and predictive for prevention of cardiovascular disease.

Physicians are grasping at straws, desperate to have something to give patients, even if it works poorly. Desperate people do desperate things, such as failing to ask critical questions and taking pharmaceutically-paid studies at face value without looking too deeply, asking insightful questions, or even using common sense. Add this to the pharmaceutical companies' enormous physician advertising budget dedicated to statins and it is no wonder that most physicians are on the statin bandwagon.

This is not an indictment of physicians; it is an attack on pharmaceutical companies. Understand that most drugs do not make it successfully into human trials. After a pharmaceutical company spends hundreds of millions of dollars and close to a decade in time, most new drug trials are disallowed. Whenever the pharmaceutical company finds a drug that doesn't kill too many people or cause too many immediate serious side effects (there are very few drugs that meet those criteria) they have to put all of their hopes of staying in business on that drug.

The fabrication of a new (profitable) health concern

Because pharmaceutical companies already understood that statins did not alleviate heart disease and caused horrific side effects in too many people, they needed to create a problem that statins actually helped.

It is most important to understand that the gross failure of the Vytorin study in the ENHANCE trial a few years back was withheld by the pharmaceutical company for about 2 years while another study was "developed." They knew they would have to address the fact that despite a 50% reduction in LDL cholesterol, arterial clogging in patients' lumen (vessel interior) was not reduced, intima-media thickness was not reduced, and atherosclerosis was not lessened. This was a major embarrassment and the pharmaceutical company said nothing about the ENHANCE trial for close to 2 years. Their admission

of the ENHANCE debacle coincided with their "discovery" that statins aided a new, more important health concern. What good fortune for the pharmaceutical industry!

Here's what you need to know:

• The JUPITER study enrolled only men OVER 50 and women OVER 60, with average ages of 66. No results should be automatically allowed to be generalized to other untested populations.
• Patients were "pre-screened" on the drug for a month and if there were negative side-effects, it didn't count, and those patients were eliminated from the study, and patients with any history of inflammatory disorders like any history or evidence of heart disease, high blood pressure, diabetes, and arthritis, were eliminated or excluded. You simply can't do this and expect to generalize the results to most physicians' practices.
• These selected people had elevated C-reactive protein levels. C-reactive protein is MERELY a GENERALIZED, nonspecific marker of inflammation that can be caused by a common cold, emotional stress, or even a sprained ankle.
• The patient population was decidedly atypical, with "normal" LDL cholesterol AND elevated C-reactive protein. Patients had no history of any inflammatory disorders. The study authors were trying to claim that the inflammation came from cardiovascular inflammation exclusively. I applaud their effort. Nice try, but wrong.

Critical impact
Here are two critical issues you need to understand regarding the extremely poor "science" desperate pharmaceutical drug companies resort to, in order to get their drugs on the market so that they can start to make back some of the billions of dollars they put into research:

Critical Issue #1: The pharmaceutical companies use the "double-edged" method of misleading both physicians and their patients. When the drug side effect is harmful, they tell physicians that it only occurred in a "small" group. In the example above, the pharmaceutical companies reported great success in the drug's effectiveness with that same "small group." However, in reporting harmful side effects, they then call the exact same results "minor." This is exactly what they did to minimize the increased cases of diabetes in the Crestor patients. *Medical News Today* (Nov. 10, 2008) reported "[B]ut there was a slight increase in diabetes incidence in the statin group, [although the magnitude of that increase was the same as those supposedly helped by the drug] which is usual in most statin trials."

Critical Issue #2: Medical journals and the pharmaceutical companies repeatedly report inflated drug effectiveness when there isn't any. Both physicians and patients are misled with such inflated reports of drug effectiveness. Furthermore, harmful side effects are often under-reported. This is done by

allowing very large probability values (allowing errors often in excess of 20%) instead of the more reasonable 5% error value. Everyone therefore is misled with a double-whammy: a drug that doesn't work, and which also delivers horrific side effects (like a rise in diabetes)—and neither shortcoming is revealed.

Newsflash 2008: A New Focus—LDL-Cholesterol NOW called Meaningless!

Dr. James Stein (University of Wisconsin Medical School, Madison) and Dr. Steven Nissen (Cleveland Clinic) praised the JUPITER investigators and the study sponsor for EXPOSING the current LDL-cholesterol thresholds for lipid lowering therapy as arbitrary… "Many patients with heart attacks have normal LDL cholesterol values…." *[Medscape Medical News: AHA 2008: JUPITER Hits New Orleans: Landmark Study Shows Statins Benefit Healthy Individuals With High CRP Levels. (CME/CE release date: Nov. 10, 2008)]*

Dr. Steven Nissen pointed out that **there has been a lot of recent pushback against the cholesterol hypothesis**, with many speculating that lowering **LDL-cholesterol levels had no impact on the reduction of cardiovascular risk**…. (*Emphasis added*)

Life-Systems Engineering Science commentary

Things can get complex and convoluted at this point, and many readers may not be particularly interested in seeing exactly HOW, on a scientific level this study fails. Therefore instead of continuing with details (you can read them in my full publication if you wish - see end of Newsletter for details), I will provide a *Life-Systems* Engineering Science Commentary as summary.

Here's why the reporting of the JUPITER Study in the medical press is misleading.

1. Taking results of a study applied to an aging population and automatically applying it to everyone, is irresponsible and hazardous. Next, are the pharmaceutical companies going to try to apply these results to children, too?
2. A 30-day "trial" was given in which patients with adverse reactions to medication were immediately thrown out and not included in the study. This is unprecedented in a clinical study and COMPLETELY invalidates any generalization of findings whatsoever they claim in #1 above (only 1 out of every 5 patients screened were enrolled — an 80% study rejection rate). You can't then go back and say this same excluded group, which most physicians will see in their practices, will benefit—because they had bad reactions to the drug and quickly stopped taking it.
3. This study has no independent verification.
4. This study's result shows the **same kind of unremarkable results as other statin studies**. They clearly showed once again that statins don't work as demonstrated by the same level of extremely high NNTs (100+). *[Note: The NNT is fundamental in measuring any drug's effectiveness. It is the sole measure of the drugs significance and effectiveness. The higher the NTT, the lower the effective rate of*

the drug.]

5. This study still had an NNT of over 100 - **99% failure**. In sharp contrast, both antibiotics and insulin have NNTs close to or equal to 1—100% SUCCESS.

6. The results of this study are counter to numerous C-reactive protein studies (see above).

7. Your risk of contracting diabetes increases with the drug.

8. The horrific side-effects of all statins, including Crestor, will often include, in addition to raised likelihood of diabetes: muscle pain, erectile dysfunction, and cognitive problems. With the drug, you will lower your cholesterol and also become weak, stupid, and impotent as the excellent book, *Statin Drug Side Effects* by Duane Graveline, M.D. so aptly details. You must give the pharmaceutical companies some credit for making these horrific side effects seem acceptable.

9. The entire "cholesterol hypothesis," while unsupported by medical physiology, was propagated by the pharmaceutical companies (who manufacture statins) in order to convince physicians to lower LDL cholesterol levels in all Americans. This wrong hypothesis was instigated by the pharmaceutical companies only because they had a drug to lower cholesterol. Although their method failed miserably and continues to fail, physicians were getting upset and their patients frustrated, so something new had to be "cooked up." The new "answer" was C-reactive protein, even though this is not the cause of heart disease as proven by Dr. Borge Nordestgaard, MD, et al. in the Oct. 30, 2008 issue of the *New England Journal of Medicine*, in a study authored by Borge Nordestgaard, MD, et al. and reported in *Scientific American* on October 29, 2008.

It's all in the PEOs

If physicians and cardiologists are forced to laud these horrific statin-prescribed results as spectacular, America and those nations around the world following us are to be pitied. The correct answer is all in the PEOs (parental essential oils) because aside from giving each of your body's 100 trillion cells the unadulterated parent omega-6 it requires, your body's most potent anti-inflammatory PGE1 is made from the parent omega-6 derivative GLA. Your body's natural thrombosis inhibitor and anti-aggretory PGI2 (prostacyclin) is made from the parent omega-6 derivative arachadonic acid. A cellular parent omega-3 component is required but it must be noted that this is significantly less important than the unadulterated parent omega-6. The omega-3 derivatives predominate in fish oil, are even less important. When you connect the dots, the world's leading medical textbooks confirm the heart-health power of the correct PEO formulation.

For complete details, please see my publication, "FAILURE of Statin Crestor® (Rosuvastatin) in the "Justification for the Use of Statins In Prevention and Intervention Trial Evaluating Rosuvastatin" (JUPITER) Study", published in the Cambridge International Institute for Medical Science, and found in PDF format at www.brianpeskin.com.

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

This Month's Low-Carb Recipe: Chicken & Garlic Caesar Salad

INGREDIENTS

Dressing:

½ cup chicken broth
1 can (apx 10 oz) condensed cream of chicken soup
¼ cup balsamic vinegar
¼ cup shredded Parmesan cheese
3 cloves minced garlic
¼ teaspoon black pepper
1 tablespoon Worcestershire sauce

Salad:

4 grilled, boneless chicken breast halves or thighs, cut into 2-inch strips
2 heads romaine lettuce torn into 2-inch strips

PREPARATION

1. Combine the broth, soup, vinegar, 2 tablespoons of Parmesan cheese, garlic, Worcestershire sauce and pepper in a blender or food processor until smooth.
2. Combine lettuce and 1 cup of dressing in bowl, toss well
3. Top with chicken strips.
4. Sprinkle with leftover shredded cheese.
5. You can add croutons if desired, but it will raise carb count.

Serves 8

Enjoy!