

The Peskin Primer

Understanding Professor Peskin's Approach*

The Perfect Ten — Ten Years in Ten Pages

A decade of work by Prof. Brian Peskin

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Relative Risk — Absolute Deception

Why "Studies" are Misleading—Studies Aren't Science

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* Brian Peskin received an appointment as an Adjunct Professor at Texas Southern University in the Department of Pharmacy and Health Sciences (1998-1999).

The Perfect Ten — 10 Years in 10 Pages:

A decade of work by Prof. Brian Peskin

The world's leading physiologic EFA expert — Prof. Brian Peskin



Prof. Brian Peskin is a world-leading scientist specializing in parent EFAs — termed *PEOs* — and their direct relationship to both cancer and cardiovascular disease. While advancing the scientific understanding of the role of essential fatty acids in the body's metabolic pathways, he has concurrently developed a means for alleviating cancer's *prime* cause, as postulated by Nobel Prize-winner Otto Warburg, M.D., Ph.D., by increasing cellular oxygenation (*The Hidden Story of Cancer*, www.pinnacle-press.com). Amazingly, there is a fundamental cancer / heart disease connection, whereby the same physiologic solution solves both conditions. This information will lead to a new understanding of how to treat and prevent both cancer and heart disease. The basis for Peskin's current work, grounded strictly in state-of-the-art science — in particular, physiology — can be found in his seminal work and peer-reviewed medical journal articles. Clinical physicians throughout the world have validated Prof. Peskin's EFA recommendations. In the most exciting development to date, Brian's theoretical conclusions were recently and completely validated in a physiological experiment by precise instrumentation capable of measuring arterial compliance. This experiment (IOWA experiment) provided the first conclusive clinical proof and validation of Prof. Peskin's theory. Peskin Pharmaceuticals has a patent pending on the medicament that embodies this development.

What is a Parent Essential Oil (PEO)?

There are only two (2) essential fatty acids, LA (parent omega-6) and ALA (parent omega-3). They **MUST** come from food. To work properly, **they MUST be NOT heated, chemically *unprocessed*, organically raised and processed to guarantee full physiologic functionality.** Fast foods use *adulterated, non-functional* EFAs that can no longer be termed a fully functional parent essential oils. All other EFAs excluding ALA and LA are correctly termed EFA "derivatives." This includes the most common derivatives such as AA, DHA, EPA, etc. What is not understood by most physicians is that derivatives are made in the body, from the parent EFAs,

on an “as needed” basis in extremely limited quantities. Consumption of derivatives from food is therefore not necessary, yet fish oil consists entirely of DHA and EPA in supra-pharmacological OVERDOSES, thereby overdosing the patient and causing damage instead of health. Few, if any, physicians ask to see the “normal standard” values of physiologic DHA/EPA amounts in tissue and plasma compared to the parent PEO amounts in tissue and plasma. When they discover the truth of how little DHA and EPA there should be in relation to how much they’ve been administering, physicians are shocked and dismayed that they have been (unknowingly) harming their patients, and wish to correct their recommendation to Peskin Protocol PEOs (as per the above physician testimonials). **Peskin Protocol PEOs are a (patent-pending) plant-based proprietary formulation unlike any in the world and can be obtained organically from precise mixtures of sunflower, safflower, pumpkin, and evening primrose seed oils and coconut oil.**

IOWA (Investigating Oils With respect to Arterial blockage) Experiment

This is the first experiment using photoplethysmography to detail the differences in arterial flexibility between subjects taking PEOs and those taking fish oil. The results were staggering and shocking for those unfamiliar with Peskin’s work. IOWA is the first experiment conclusively proving the INFERIORITY of fish oil to PEOs as regards cardiovascular protection.

The IOWA experiment (whose testing center is in Des Moines, Iowa) is run under the direction of Prof. Peskin (of Houston, Texas) in conjunction with renowned interventional cardiologist David Sim, M.D. (of Boise, Idaho).

Long-term PEO supplementation in patients presenting with a broad spectrum of maladies resulted in: 35 subjects, 13 male and 22 female, aged 35-75. **The median age was 62 years old.** These volunteers were supplemented with plant-based essential fatty acids of the Peskin Protocol formulation for a period of 3 months to 48 months.

The median duration of use was 24 months. Half of the subjects used the PEO formulation for less than 24 months and half used it for more than 24 months. Twenty-five of the subjects improved their arterial flexibility. **That’s a stunning 73% effectiveness (absolute – not relative). The average improvement was a 9 year decrease in biological arterial age, making their effective age younger than their physical age.**

What is outstanding is the NNT (number needed to treat to see an effect in just one person) was 1.4. Pharma considers an NNT of less than 50 a good result for the effectiveness of their drugs. For example, for statins, the

NNT to “prevent” one cardiovascular event is >80. That means more than 80 people would need to take a statin to see a single positive outcome. In contrast, just 1.4 people taking parent essential oils are required to see a positive outcome in 1 person. The statistical significance of the experiment, according to Alex Kiss, PhD, a statistician who has worked as consultant to the National Institute of Health (NIH) and is co-author of numerous peer-reviewed medical journal papers, including *New England Journal of Medicine* and *Cancer*, is extremely high (99.85%), compared to most studies, which come in at only 95%. This experiment is 30 times more accurate than the average clinical study. That means the results can’t be due to chance or error. **The mean (average) arterial (biological) age of the subjects dropped over 8.8 years – making each of them in effect a younger patient!**

Predictable failure of fish oil

In a completely different group of subjects, fifteen (15) subjects (7 males and 8 females aged 46-74, average age was 60 years old) were consuming fish oil supplements for at least 6 months prior to switching to PEOs. Baseline analysis was performed prior to switching to PEOs. After *an average time duration of PEO use of only 3.5 months*, another scan was performed. Thirteen (13) of the 15 patients improved. That’s an **87% effectiveness rate**, a **NNT of only 1.2**, and a **reduction in biological arterial age of 11.1 years**, measured by standard population samples. One subject remained unchanged, and one subject worsened (by a mere 1 year, which is statistically irrelevant). **The statistical significance was 99.99%**. CONCLUSION: you can take this result “to the bank.”

It gets even more exciting. In subjects with high cholesterol, simply replacing their fish oil with PEOs improved 6 of the patients. Here the **NNT to improve the vascular system in those with high cholesterol was an incredible 1.2**. One subject with both diabetes and high cholesterol improved. Again, statins would need more than 80 people treated to effect one less cardiovascular event, an NNT of 80 (at best, as some studies show statins have an NNT of 300+). **In two patients on statins, both improved their arterial flexibility by 20 years with the PEO formulation.** Here, we have a group of people across all walks of life – no special groups were used and no particular groups were excluded. Using **fish oil**, the biological mean (arithmetic average) arterial biological age was **49**. After using **PEO**, it fell to **38 – 11 years YOUNGER**. CONCLUSION: compared to PEOs, fish oil worsens the cardiovascular system.

Fish oil (and krill oil) don't work in clinical practice (despite most everyone saying they do)

Sometimes, ingrained beliefs, even those without scientific foundation, are hard to change. As has occurred with many other nutritional supplements once in the limelight, there is little, if any, scientific validity to fish oil and krill oil's miraculous claims. It is simply another case of "**finance masquerading as science**" – in this case, developing new markets for fish – and of medicine's long history of mistakes and wrong recommendations. Making money is fine when you truly help people, but not when you harm them, even unknowingly. Results consisting of **mere "associations," and "studies" conducted without valid experiments in which only one variable is changed at a time are meaningless.** That's why the recommendations from most "studies" are later reversed and withdrawn, which leaves the lay public confused.

In sharp contrast, the IOWA experiment is definitive and remarkable in proving PEOs increase arterial compliance (flexibility). When physicians hear of IOWA, they realize this information is irrefutable because these results, unlike those of other "studies," are not open to interpretation; the machine output of photoplethysmography is akin to measuring one's weight with a scale. **IOWA's landmark results afford a unique and significant opportunity.** Melatonin was hailed decades ago as a "wonder supplement," then faded into obscurity because its benefits were never based on science. IOWA's results are based solely on science and the positive results are predicted theoretically. These results, like gravity, are here to stay.

Fish oil supplements were an initial attempt at correcting EFA deficiencies due to the widespread consumption of processed foods, but its constituents are far from being correct physiologically for most tissue. **In fact, contrary to helping patients, fish oil is harmful for most patients.** With today's state-of-the-art science spearheaded by Prof. Peskin, we can move far beyond fish oil and significantly improve patient outcomes. **PEOs' significant positive effects in increasing cardiovascular compliance (increased arterial flexibility) compared to fish oil – IOWA experiment – resulted in an 11.1-year biological age improvement (a younger patient).** The following is a representative sampling of international physicians using Peskin Protocol PEOs instead of fish oil:

"Having implemented EFA supplementation for over 25 years, clinical results were mediocre until I began using the Peskin

Protocol. Dr. Rudin's work with flax oil was important but lacked clinical effectiveness; likewise with Horrobin regarding GLA from Borage, Black Currant, and Evening Primrose oils. Unlike the studies suggested, **fish oil, too, was disappointing.** Finally, I read *The Hidden Story of Cancer*, which introduces the Peskin Protocol. Once implemented, I experienced clinical success. Although Brian's book deals extensively, but not exclusively, with cancer prevention, **utilizing his protocol I have seen positive results (dermatological, cardiovascular, pediatric, and neurological) in over 100 of my patients."**

*Abram Ber, M.D., Homeopathy
(Phoenix Scottsdale, AZ)*

"As a **practicing cardiologist**, I have a strong interest in both the treatment and prevention of cardiovascular disease. As Brian details, the paramount discovery by Otto Warburg regarding oxygenation must also be considered the most important physiologic discovery in the cardiovascular disease arena. **Brian has advanced the basic science principles of Warburg into a practical, cost-effective formula - the Peskin Protocol - for patient care utilizing an increased scientific understanding of Omega-6 and Omega-3 essential fatty acid ratios. For those patients in my practice, and others I am aware of (hundreds) willing to embrace these basic principles, I have seen clinical improvement and success without adverse effects.** Brian Peskin, in my opinion, has diligently and carefully "teased out" from the available, published scientific data base the links necessary to explain, understand, and help combat the most prominent cardiovascular state faced by patients."

David Sim, M.D., Interventional Cardiologist (Boise, ID)

"I have been using the Peskin Protocol EFAs for the last five months. **I have had excellent reports from patients.** Previously, I was recommending fish oil to almost all my patients. Some improved, specifically those with joint pains and heart disease. However, **I did not see any improvement in my diabetic / HTN patients or those w/dermatologic problems. In fact, the latter group actually got worse.** These patients had eczematous type rashes and psoriasis. After reviewing Brian's data regarding the concentration ratios of parent Omega-6 to parent Omega-3 in various tissues, it all made sense - **five out of six (83%) of my worst dermatologic**

cases showed good to very good improvement in as little as three months with Peskin Protocol. Just taking Omega-3 alone (flax or fish oil) without regard to the appropriate balance can adversely affect diabetic patients. This was proven in two of my patients. These patients kept meticulous effect of diet on their glucose levels. Without changing their diets, they noticed significant **elevations in the glucose levels** after Omega-3 fatty acids for three to four months; **one patient had an increase of 40 points. After starting the YES balanced blend of parent Omega-6 and -3, not only did their BS normalize to more normal values, but they felt better overall and both commented that their energy level improved.** Use of the Peskin Protocol in clinical practice has made a strong believer out of me, and I will continue to recommend this product to ALL my patients and refer them to Peskin's research for more information."

*Angelo A. Della Pietra, M.D., D.O., Family and Integrative Medicine
(Poughkeepsie, New York)*

"I had been taking high-dose fish oil for many years in an attempt to prevent C-V disease and retard inflammation. However, I noticed that my **fasting blood sugars were always in the high range (100-115)** and measurements of oxidative stress also reflected high levels. **No one could explain it** since my hemoglobin a1c always stayed low. **Since switching to the parent EFAs (PEOs), as recommended in *The Hidden Story of Cancer*, my FBS came down to 84. My lipids also looked better than ever. I think many of our colleagues do not appreciate the dangers of high dose fish oil.** Derivative EFAs like fish oil easily oxidize, and although some surrogate markers may improve, the final cost is still unknown. Thanks so very much for your book."

*A4M Fellowship physician Ira L Goodman, M.D.
Ophthalmic Surgeon (retired), Holistic Medicine*

"**Impeccable research and novel insights of sheer genius.** Brian's accomplishment is singular - no groups, no public money, only elegant science showing how proper use of EFAs is the missing link for practical application of Otto Warburg's discovery. **This knowledge is priceless for your future health.**"

*Brian N. Vonk, M.D., Board certified: Internist, Cardiologist
and Radiologist (Norfolk, Nebraska)*

“This information could prove to be one of the **most significant health discoveries of the 21st century**. It is extraordinary. Finally, an effective and practical program of cancer prevention. **Brian Peskin has put together a program that must be called ‘brilliant.’** It is a must... for all.”

*Stephen Cavallino, M.D., Emergency Physician, Prototherapy Specialist,
(Reggio Emilia, Italy)*

How and why PEOs work when omega-3 derivative fish oil doesn't work?

Physiology is the prime science utilized to determine the correct tissue amounts of parent omega-6, parent omega-3, and their derivatives. Once these values are known, biochemistry may then be utilized. Fortunately, these physiologic values have already been determined, making it immediately obvious why fish oil can't possibly work as claimed because, aside from the brain and nervous system, the body has little use for DHA/EPA. The prime issue that everyone overlooks is that the body can easily supply the brain and nervous system with adequate parent PEOs without the risk of overdosing on EPA/DHA. **There is a maximum of <2% natural conversion of ALA to DHA and less than a mere 0.3% into EPA.** Even babies adequately convert PEOs into derivatives. These physiologic facts have been obscured. Parent PEOs are much more significant as compared to derivatives, and no one until now has focused on them. The tables below exemplify key tissue physiology.

Ratio of Tissue Composition			
Tissue	Percentage of Total Body Weight	Omega-6 PEO	Omega-3 PEO
Brain/Nervous System	3	100	1
Skin*	4	1000	1
Organs and Other Tissues	9	4	1
Adipose Tissue (bodyfat)	15-35	22	1
Muscles	50	6.5	1

* There is virtually NO omega-3 in skin tissue.

With all the focus on omega-3 fatty acids today, it is significant to note that the free fatty acids in human plasma ordinarily are composed of about 15% LA (linoleic acid, parent omega-6) and just 1% of ALA (alpha linolenic acid, parent omega-3), a 15:1 ratio with just 2% DHA (docosahexaenoic acid). Cholesterol esters and plasma phospholipids have ratios of 100:1 in favor of parent omega-6. Physicians need to know these important and critical facts.

Percentages of Linoleic Acid (LA) and Alpha Linolenic Acid (ALA) in Plasma and Classes of Lipids				
Fatty Acid	Plasma % Unesterified	Plasma % Triglycerides	Plasma % Phospholipids	Plasma % Cholesterol Esters
LA (Parent Omega 6)	17	19.5	23	50
ALA (Parent Omega 3)	2	1.1	0.2	0.5
LA : ALA ratio	8.5:1	17.5:1	115:1	100:1

References: Sinclair HM. Essential fatty acids in perspective. Hum Nutrit 1984;38C:245-260; and Spector A. Plasma free fatty acid and lipoproteins as sources of polyunsaturated fatty acid for the brain. J Mol Neurosci 2001;16: 159-165.

Amounts of EPA/DHA in fish oil

It is common amongst fish oil capsule manufacturers to have in excess of 300 mg of EPA and over 200 mg of DHA, with insignificant amounts of other omega-3 derivatives. They typically recommend 2 capsules each day for a total of over 600 mg EPA and 400 mg DHA daily. Three grams of PEOs per day is the general prophylactic dosage. Therefore the amount of parent omega-3 (ALA) is approximately 1,000 mg. Given that 2% maximum of this would be converted into the omega-3 derivative DHA, that would mean the body would *naturally convert* only 20 mg to DHA. Contrast this with the fish oil dosage of more than 400 mg, i.e., a **DHA pharmacological overdose by a factor of 20!** EPA overdose is even worse, as only 0.26% of ALA is normally converted. Of the 1,000 mg of ALA in Peskin Protocol PEOs, just 2.6 mg is converted, whereas the fish oil supplement provides over 600 mg or a **250-fold** pharmacological overdose of EPA. This is analogous to giving the patient 250 aspirin tablets – you would kill him! Krill oil has less of the overdose amounts (approximately 130 mg EPA and 70 mg DHA per capsule) but it is still quite harmful. Given these facts, is it any wonder that fish oil categorically fails in experimental tests? No, of course not. Recommending these pharmacological overloads without compensating PEOs or omega-6 based derivatives is even worse, because of the gross disparity between the omega-6 and omega-3 series derivatives. Fish oil is harmful to most patients and the **IOWA experiment proves its enormous NEGATIVE effect in the cardiovascular area.**

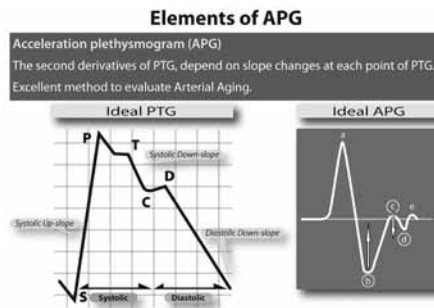
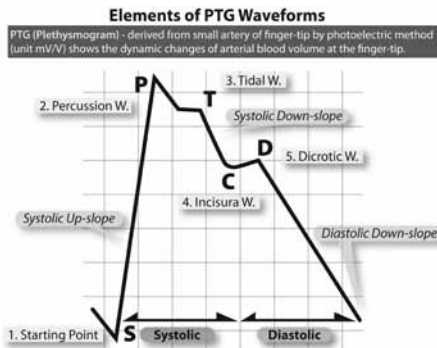
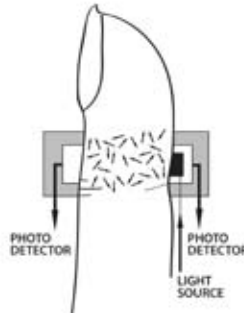
Photoplethysmography (PTG) / Digital Pulse Analysis (DPA) and why I trust it

Photoplethysmography (PTG) is a noninvasive method to measure arterial compliance (flexibility). Processing of this waveform by digital pulse analysis (DPA) affords clinicians a superb diagnostic tool. "Hardening of the arteries" is a prime cause of heart disease. Therefore, reversing or eliminating hardening of the arteries leads to significantly less patient heart disease. A digital pulse analyzer (DPA) can measure arterial flexibility. This device is simple. You put your finger in a plastic clip. It emits a soft laser light into your fingernail, much like an oxygen analysis with the common pulse oximeter. The waveform it reads is an incredibly accurate measure of the elasticity (or stiffness) of both your large (aorta) and small arteries of

the cardiovascular system. Arterial rigidity is a direct reflection of arterial damage and arteriosclerosis. Computer software analysis allows simple and precise computation of the speed and volumes of the blood along with the associated waveforms over time. Mathematically, second derivatives (a tool of calculus) of the PTG waveforms are then taken to produce another waveform termed an accelerated plethysmograph (APG). This output is compared with outputs of known population values so it is easy to provide a “biological age” of the arteries based on already scanned populations. Supplementation with PEOs resulted in substantial improvement in arterial flexibility – i.e., a younger patient.



Simple, easy-to-use, non-invasive finger probe



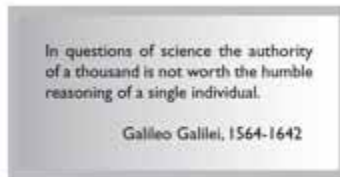
Flax, krill, and coconut oils ...Aren't they good?

Flax oil contains much *more parent omega-3 than omega-6 – a backwards-physiologic ratio*. Krill oil is in the same category as fish oil. Furthermore, no human would ever naturally eat krill, as it is a food for whales, seals, penguins, squid, various fish, and sea birds, not humans – as they are simply

too small to bother with. Most of the krill catch is used for aquaculture and aquarium feeds, as bait in sport fishing, or in the pharmaceutical industry. Coconut oil is not unhealthful, but contains very few PEOs (<10%); it is fine to use for cooking, frying, etc.

Why do so many promote krill/fish oil?

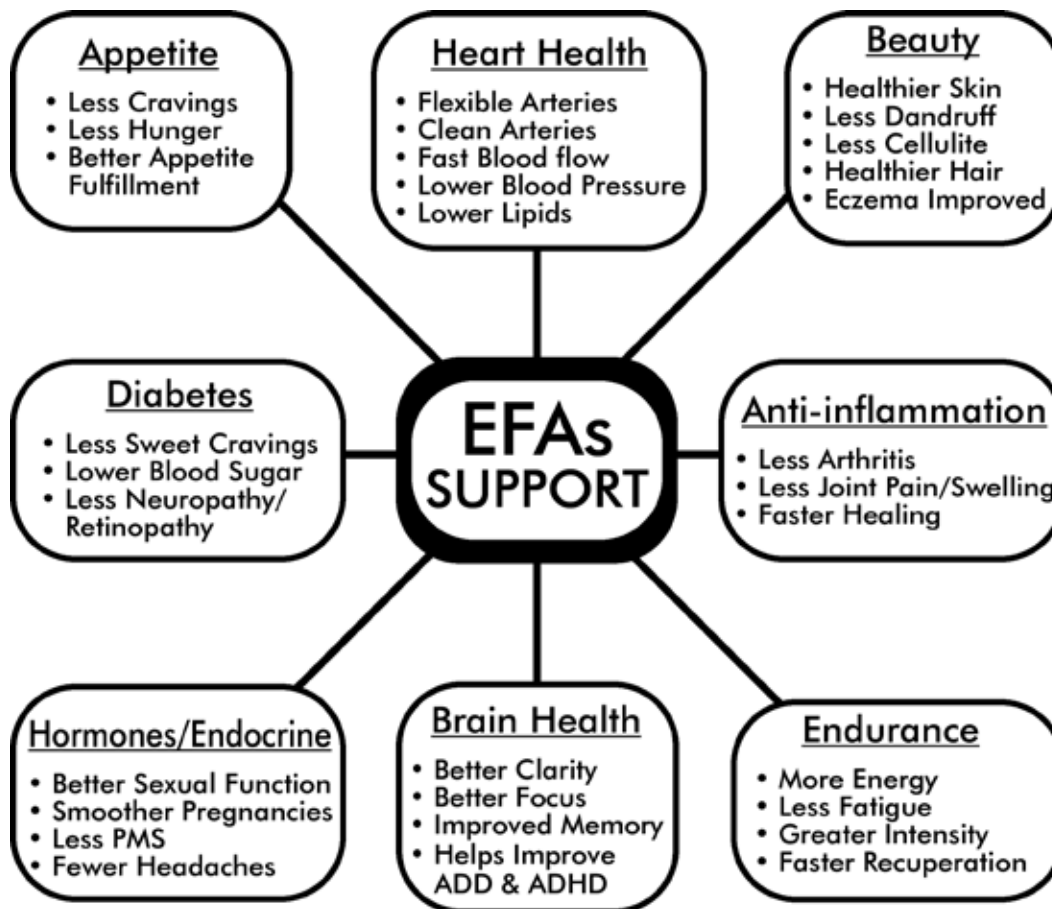
They are simply wrong. Also, significant financial interests may be in play. Krill is cheap. Financial benefit is fine, IF and ONLY IF the science is correct. In this case it is tragically incorrect, and the science supports the direct opposite of fish oil's "opinions and opinionated studies." Widespread mistakes are nothing new in the fields of science and medicine. As the brilliant Galileo stated back in the 1600's: **"In question of science the authority of a thousand is not worth the humble reasoning of a single individual."**



Also, as Nobel Prize-winning physicist Richard Feynman brilliantly stated, "It does not make any difference how smart you are, who made the guess, or what his name is – *if it disagrees with real-life results, it is wrong. That is all there is to it.*" The IOWA experiment proves how wrong everyone is concerning fish oil and cardiovascular protection. **State-of-the-art physiologic science will prevail.**

How long to see results and what objective results can I expect to see in my patients?

Positive results of PEO supplementation often occur very quickly in patients, sometimes within a few days. However, for significant results to manifest, allow patients 3-4 months daily use, as this is the time frame that tissues require to incorporate a significant amount of PEOs. Fully solving PEO deficiency can take 12-18 months. If a patient has been taking fish oil, allow them sufficient time to see and feel improvements of at least 3 months. Examples of physiologic areas of improvement are included below, and also included in the "MacPhail and Sommerfield" testimonials.



Relative Risk — Absolute Deception

Why “Studies” Are Misleading—Studies Aren’t Science

This report was developed to assist physicians and health care professionals in their evaluation of treatment protocols. It also serves as a response to the following question:

How Can Professor Peskin Be Right and Everyone Else Wrong?

I am frequently asked, “How can you be right, and everyone else wrong?” This is a valid question. First, everyone else is not “wrong.” There are others who understand and report on the pharmaceutical companies’ statistical misrepresentations, but they are typically overlooked by the media. I am not alone in exposing the fallacies behind many pharmaceutical and nutraceutical “successes.” In particular, world-renowned physician, mathematician and statistician John P.A. Ioannidis, MD, DSc, is a prominent colleague who has been questioning the “massaged” pharmaceutical statistics for many years.

I am right in my scientific conclusions because, like Dr. Ioannidis, I follow the science and only use studies to confirm where the sciences of human physiology and biochemistry lead. I also understand the science of statistics and am not easily fooled by its often-improper use by those more interested in finance than accuracy. But physicians and health researchers are overworked and have precious little time to do their own research and analysis of the latest “breakthrough” study. They need to be able to rely upon studies published in the professional journals.

Sharon Begley’s insightful *Newsweek* article, “**Why Almost Everything You Hear About Medicine is Wrong**,” which cites Dr. Ioannidis’ findings, was published in the January 31, 2011 edition on pages 8-9. Prepared to be shocked:

- “**But what if wrong answers aren’t the exception but the rule**? More and more scholars who scrutinize health research are now making that claim.
- “...[T]he very **framework of medical investigation may be off-kilter**, leading time and again to **findings that are at best unproved and at worst dangerously wrong**.
- “The result is a system that **leads patients and physicians astray**—spurring often costly regimens that won’t help and may even **harm you**.

- “As the new chief of *Stanford University’s Prevention Research Center*, Ioannidis is cementing his role as one of *medicine’s top mythbusters*. **‘People are being hurt and even dying’ because of false medical claims**, he says: not quackery, but **errors in medical research**.

- “But if Ioannidis is right, *most biomedical studies are wrong*. [Note: Dr. Ioannidis is very right!]¹

- “*In just the last two months, two pillars of preventive medicine fell*.
- “A major study concluded there’s no good evidence that statins (drugs like Lipitor and Crestor) help people with no history of heart disease. The study, by the Cochrane Collaboration, a global consortium of biomedical experts, was based on an evaluation of 14 individual trials with 34,272 patients. **Cost of statins: more than \$20 billion per year, of which half may be unnecessary**. [Note: This evaluation did not even consider the negative side-effects unnecessarily experienced by the unsuspecting patients.]
- “**‘Negative results sit in a file drawer, or the trial keeps going in hopes the results turn positive.’ With billions of dollars on the line, companies are loath to declare a new drug ineffective**. As a result of the lag in publishing negative studies, **patients receive a treatment that is actually ineffective**. That made Ioannidis wonder, how many biomedical studies are wrong?
- “His answer, in a 2005 paper: ‘the majority.’ From clinical trials of new drugs to cutting-edge genetics, biomedical **research is riddled with incorrect findings**, he argued. Ioannidis deployed an abstruse mathematical argument to prove this, which some critics have questioned. [Note: I found his proof unquestionably correct.]
- “Stanford, the epitome of the establishment, hired him [Dr. Ioannidis] in August to run the preventive-medicine center. ‘The core of medicine is getting evidence that guides decision making for patients and doctors,’ says Ralph Horwitz, chairman of the department of medicine at Stanford. ‘John has been the foremost innovative thinker about biomedical evidence, so he was a natural for us.’

1. When I was working on my undergraduate thesis at M.I.T., I derived a different result than one reported in a top science journal. Naturally I thought I was wrong, but I wasn’t wrong. To my surprise, my thesis adviser told me that 95% of the published journal articles are WRONG. As a young student, I was shocked and appalled! When it comes to the next “miracle” product, you should approach the journals with a healthy dose of skepticism

“Ioannidis’s first targets were **shoddy statistics used in early genome studies**. [Note: See the report, “Good News: It’s Not Genetic” at www.brianpeskin.com.]

- “When you do thousands of tests, statistics says you’ll have some *false winners*,” says Ioannidis.

• “Drug companies *make a mint on such dicey statistics*. By testing an approved drug for other uses, they get *hits by chance*...”

• “Even when a **claim is disproved, it hangs around** like a deadbeat renter you can’t evict.”

(Emphasis added.)

I warned you in advance that you’d be shocked to discover this deception. Now, I will give you the tools so that you will never be fooled again.

Deceptive Statistics Mislead Patients...

- Recently, a physician colleague told me that there were over fifteen thousand — that’s correct, 15,000 — studies showing fish oil’s effectiveness. My first response was laughter.
- The next day, a close friend of my wife told her she needed to take calcium because it decreased risk of colon cancer by 40%. She went on to explain that because she was taking it, and my wife was not, that she had a 40% lower risk of contracting colon cancer. Again, I started laughing...
- Later in the week, another physician colleague told me statins decrease the chance of a heart attack by over 30%. You’ve likely guessed it... more uncontrollable laughter. We shall soon discover why, but first let’s explore the reasons for the absurd number of repetitive studies.

Startling Revelation: The number of studies is inversely proportional to the effectiveness of what is being studied.

There should not be a need to keep repeating studies unless the substance being studied doesn’t work; if you do this, you are **trying to get random chance**

to back up your study, rather than science confirming its effectiveness. This is precisely the reason why there may be 1,000 studies showing a positive result and 950 showing a negative result, yet the “positives” are considered to prevail. Physicians will actually say this slight preponderance “proves it works.” This is dreadfully WRONG and shows an enormous lack of scientific reasoning by the health and medical professions, because they have no idea of where the science is leading them. Experimental results MUST CONFIRM science’s prediction, not be counter to it. How we become misled is described below.

Is Gravity Confirmed on a Weekly Basis?

How many experiments have been recently done confirming gravity? None. It was proven hundreds of years ago, and a small number of scientists confirmed its mathematical effects, resulting in proven theorems such as that showing the relation between how much distance is traveled versus the length of time an object drops when released from the top of a tall structure. Case closed. Contrast this to fish oil’s reported 15,000 studies. Consider why so many studies need to be done IF it really works. When you hear terms like “1,000 studies show...” simply ask, “why so many?” You are being deceived.

When a study or, better yet, an experiment (which has just one highly controlled variable), is conducted, the result is either significant in EFFECTIVENESS – working very well on the vast majority of patients – or it isn’t. Then, if you want to double check, another group performs the same experiment ONCE more, to confirm it. That’s it. (As an example of both high effectiveness and high significance see www.brianpeskin.com for the IOWA Experiment.)

Before any experiment is conducted, one should have a good idea of what the result will be based on established physiology and biochemistry. This was conveyed to me while a student at Massachusetts Institute of Technology (MIT). The experiment should merely CONFIRM the SCIENCE.

As a prime example, take fish oil. The simple reason for so many “studies” is that it simply doesn’t work as we are led to believe. Fish oil doesn’t work because it can’t work. It can’t work because there are no significant metabolic pathways that omega-3 EFA derivatives influence that could possibly give

those supposed “extraordinary” results (see www.brianpeskin.com for “Fish Oil Fallacies” report). A quick review of physiology (see “Fish Oil Fallacies” at www.brianpeskin.com) tells us why it can’t work – humans don’t live in frigid cold waters like most fish do. EPA/DHA oxidize (turn rancid and spoil) automatically at room temperature and oxidize even more rapidly at body temperature.

Physicians are in an Unfortunate Situation

Physicians want to help their patients. As a result, they are often quick to dismiss failure or harmful side effects in order to give something to a suffering patient. As a recent example, physicians often told patients that side effects such as muscle weakness, cognitive impairment, decreased sexual desire, etc., did not occur from statin use. After 10 years of steadfastly denying that these harmful side effects existed, physicians recently had no choice but to acknowledge them.

Clear thinking is required of today’s medical researchers; unfortunately, it doesn’t often occur.

“The scientists of today think deeply instead of clearly. One must be sane to think clearly, but one can think deeply and be quite insane.”

Nicola Tesla

Finance Masquerades as Science....The Ultimate Tragedy

To compound the problem, finance often masquerades as science. Nutritional companies and pharmaceutical companies often mislead both physicians and their patients while chasing profits. Instead of measuring the outcome directly, such as fewer heart attacks or less cancer, “surrogates” are used. A surrogate is a substitute measure *assumed* to be associated with the desired outcome. This consistent mistake often leads to the tragedy of more failure. For example, doctors and researchers concentrate on lowering cholesterol rather than studying the ultimate objective of decreased heart attacks. There is an assumed relationship. However, this is not backed up by the science: while drug companies have done a wonderful job of discovering cholesterol-lowering drugs, this has unfortunately not translated into fewer heart

attacks. Yet this practice is so prevalent that it has become “conventional wisdom” that you are supposed to reduce your (LDL) cholesterol!

Without being overly cynical, this is done because the latest “wonder” drug likely has an effect on the surrogate, without regard to its DIRECT impact on the problem at hand. Consequently, the drug-company-led studies focus on their drug’s ability to alter the surrogate.

“Effectiveness” is Interpreted Quite Differently Than Any True Scientist Would

If I were told that taking a drug affords me 40% less risk, then I would *assume* that taking that drug would reduce my risk of contracting said disease by 40% compared to someone not taking the drug. WRONG. You can’t tell the size of the effect unless you know the subject population size. **This “40% reduction” that you *think* you have achieved would be what is called an “absolute” risk, but all the pharmaceutical studies use “relative” risk when reporting statistics. The difference is staggering**, and it is virtually guaranteed that the real difference, the ONLY one that matters, is FAR LESS than the reported percentage. This is illustrated in the example below.

Absolute Risk vs Relative (“Endpoint”) Risk — A Case Study in Tortured Logic

Question: What is the difference between 2 successes in 1,000,000 (drug) vs. 1 success in 1,000,000 (placebo)?

<u>Drug</u>	vs	<u>Placebo</u>
2 patient successes out of 1,000,000 patients treated		1 patient success out of 1,000,000 patients treated

Answer: The absolute result is 0.0002% vs. 0.0001%, or effectively 0% success in both cases—ABSOLUTE FAILURE...

That is, unless you are part of the pharmaceutical or nutraceutical industry, whereby 0% success MAGICALLY BECOMES 50% success.

Here’s how they deceive you: The calculation they will use is this: Ignoring the total number of patients tested, they will say that there is a 50% difference in effectiveness of the results (2 to 1). They have deleted the sample size of 1,000,000 patients. This calculation of 50% is termed “relative” risk because the sample size was deleted and only the “endpoints” – the *successes* in each group – are used. There is only one “small” problem with this method of reporting the drug’s supposed success – it’s absurd!

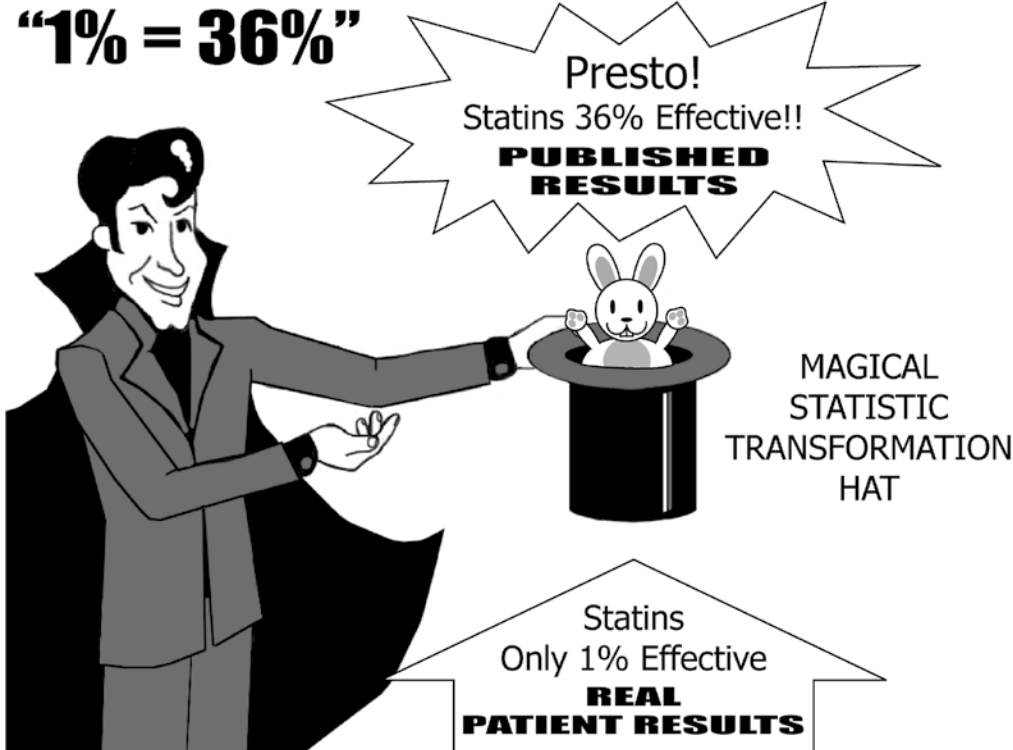
Absolute Risk MUST Include Sample Size

No honest scientist or physician would claim a 50% improvement with this drug, because the **SAMPLE SIZE is not included.**

In the following statin example, 1% “magically becomes 36%,” misleading you as to the true, accurate measure of difference in heart attack risk. The TRUE EFFECTIVENESS is the difference in results in ABSOLUTE MEASURES that INCLUDE SAMPLE SIZE: 3% effectiveness of the statin minus 2% effectiveness of a placebo equals 1% effectiveness in absolute terms. That’s right, a shockingly low 1% is reported as a much more significant 36%!

Pharmaceutical Sleight of Hand

“1% = 36%”



Presto!
Statins 36% Effective!!
PUBLISHED RESULTS

MAGICAL
STATISTIC
TRANSFORMATION
HAT

Statins
Only 1% Effective
REAL PATIENT RESULTS

*“That means in a large clinical study, 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.”

Shockingly, there is a one percent (1%) difference in effectiveness between the results with Lipitor and the results with a placebo. If you were given this information, would you take this drug? Of course not. That is, IF you knew and understood the TRUTH.

This miniscule 1% difference is termed *absolute risk* and correctly takes into account the sample size. This leads to NNT (number needed to treat) and shows why it is critical when evaluating the effectiveness of a protocol.

NNT (Number Needed to Treat) is Paramount – Not Misleading “Endpoint” Statistics

Many physicians are misled because they have no idea the pharmaceutical companies are allowed to manipulate statistics. Pharmaceutical companies shockingly, yet legally, get to remove the sample size. Again, when is one patient event *in a million* (drug) compared to two patient events *in a million* (placebo) equal to 50% improvement instead of the statistically correct 1 in 1,000,000 or 0.0001%? Answer: with the fanciful “*pharmaceutical endpoint method*,” also termed “relative risk,” as Professor of Medicine Stanton Glantz so aptly put in his book. (Glantz SA. Primer of Biostatistics. 5th ed. New York, NY: McGraw-Hill, 2002, 149-156.)

You will often see the statement, “Lipitor reduces the risk of heart attack by 36% ... in patients with multiple risk factors for heart disease,” quoted in drug ads, such as the one on television a few years back featuring Dr. Robert Jarvik, inventor of the Jarvik artificial heart. In newspaper ads, the 36% comes with an asterisk (*) saying, “That means in a large clinical study, 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.” The difference between the treated and non-treated groups is a miniscule 1%, hardly worth getting excited about UNLESS you are a pharmaceutical or nutraceutical company that has already invested hundreds of millions of dollars in this drug and must ultimately sell this FAILURE to the desperate masses.

In the case of statins, the NNT is 100 (the reciprocal of the absolute risk, i.e. $1/1\% = 1/.01 = \text{NNT of } 100$). No, this “100” isn’t a perfect score you aspire to on a college exam; quite the contrary, it is an awful score. It means that to see a positive effect in just one patient, one hundred patients have to be

treated, and often treated for many years at that. Therefore, *99 out of 100 patients will see no positive effect* – a **99% FAILURE RATE!** Many medical researchers are convinced that the real NNT for statins in a standard *mixed* population, such as the typical patient a physician treats for CAD, may be closer to 250. Even assuming the lower 100 NNT figure, this is even more problematic for statins' performance because 10% to 15% of statin patients experience negative side effects, including sexual dysfunction, muscle aches – prominently mentioned on Lipitor's label – and significant cognitive problems, including loss of memory. Be aware that neither the NNT nor any of the risk statistics looks at negative side effects. This is an entirely separate issue.

Dr. Nortin M. Hadler, Professor of Medicine at the University of North Carolina at Chapel Hill and a long-time drug industry critic, states, "Anything over an NNT of 50 is worse than a lottery ticket; there may be no winners." (Carey J., "Lipitor: for many people, cholesterol drugs may not do any good," *BusinessWeek*. January 17, 2008:52-59.) Even Las Vegas has games with a chance of winning greater than 1% or 2%. Shouldn't drugs or nutraceuticals have a higher standard?

Grasping the Magnitude of the Problem

Decades old antibiotics commonly have an NNT = 1.1. When 11 people are given antibiotics, ten patients are cured of the problem for which the antibiotics were prescribed. Contrast this with statins, where 100 patients are given the drug and one person is helped; NNT = 100.

The higher the NNT, the LESS effective the drug.

If you remember only one point from this report, it should be that the intelligence of the answer is directly related to the intelligence of the question. Don't let yourself be misled with shoddy statistics that don't include the critical sample size.

One Last Critically Important Thought

When you receive news of the next "miracle" supplement, aside from requiring SPECIFIC METABOLIC PATHWAYS and state-of-the-art physiologic science supporting these claims, ask yourself:

1. Why is this needed TODAY when it wasn't needed years ago?

Take fish oil supplements. People living in 1950 certainly *consumed significantly less fish oil supplements than we do today*; there was only a very small market for it. The supposed benefits of fish were not publicized in 1950, and fish oil supplementation (being highly susceptible to spoilage) was simply not as common as it is today. Therefore, we should have seen gross pathological disorders due to the deficiency of DHA/EPA found in those supplements, which of course we did not.

- Were there tremendous neurological impairments in the brain, eyes, and central nervous system due to low DHA levels? **No**, and there should have been if the supposition were true.
2. Will taking the supplement stop or reverse conditions it is supposed to prevent?

Regarding fish oil and its huge (supra-physiologic) amount of DHA/EPA, it should both prevent Alzheimer's AND stop the progression of Alzheimer's in patients with low DHA levels. Does it?

No, in 2010, fish oil FAILED miserably to prevent Alzheimer's (see www.brianpeskin.com, "Fish Oil Fallacy" Special Medical Report). Fish oil FAILED to either prevent or to slow the progression of Alzheimer's. Since the same metabolic pathways are used to both *prevent* and to *slow progression* of any disease, you CANNOT make the absurd claim, as was made in front of hundreds of physicians, that fish oil prevents Alzheimer's, but once you have it, fish oil won't slow its progression. Logic maintains that it is more difficult for a substance to prevent a disease (the ultimate "cure") than for a substance to slow progression of that disease. It is illogical to state that it will prevent but NOT slow progression. Scientific logic must prevail.

1. Look at the dosage the supplement provides vs. the amount of food that would need to be eaten to provide it. While we are discussing fish, do you realize that suggested amounts from the manufacturers themselves provide DHA up to 120 times what your body would *naturally produce* on its own, and up to 500 times the amount of EPA that your body would *naturally produce* on its own. Ask what are the effects of this tremendous overdosing?
2. Never rely on mere "associations" from "studies" masquerading as experiments (where one controlled variable only is changed). This is why one medical and nutritional recommendation after another gets REVERSED, like women taking *synthetic* HRT for its supposed heart protection and cancer protection, when in fact the opposite was true. (Often you never see the retraction.)

Advanced information for health care professionals (not required for the lay public, but included for a more complete understanding of this subject)

What is a “p”-value?”

Statistics is mathematics and therefore extremely detailed. However, the essential concepts you need to know so that you aren't misled again are relatively simple:

1. The first value looked at by physicians and others (and mistakenly too often assumed to be the only important value) is the “p value” or $1 - (\text{p-value})$, meaning this experimental result occurred by chance alone, i.e., the drug doesn't really work. When the study or experiment is repeated many times using the same general group of people, this same “successful result” recurs that is entirely due to chance alone. *The item of interest (drug or nutraceutical) really didn't work at all, but we think it did work.*
2. Typically, the p-value is set to 0.95 (at a 95% confidence level you get an inherent 5% allowed possible error rate) for the result to be considered “statistically significant.” If $p = 0.95$ then the study would be termed a 95% confidence level study (although a bit more information is required). A 0.99 (1% error rate) or 0.995 p-value (0.5% error rate) would be even better because there would be much less of a random chance effect behaving as though the drug worked when it really didn't, thereby fooling both the physician and patient. With $p=95\%$, even if the drug didn't work, there is a 5% chance that you would get these pseudo-positive results 5% of the time, making it *appear like the drug did work*. This 5% means 1 out of 20 times you are FOOLED into thinking FAILURE is SUCCESS.

Once again, a 95% p-value means that if this experiment were carried out in the same population sample 100 separate times, then this same result would be included at least 95% of the time; this pseudo-positive result would occur entirely randomly 5 times, although the drug was a complete FAILURE.

It's Easy to Mislead Everyone...

All a company has to do is to conduct many studies and then purposely select only those that randomly show a “positive” result. Don’t mention the failures, and presto, you have a “successful” drug! All you need is lots and lots of money.

- The p-value is NOT a measure of the size or magnitude of the effect of the drug. That is a completely different issue and has to do with the means (difference of the averages between both groups). Many physicians and patients don’t understand this critical fact and mistakenly think that a p-value alone is all that is needed. Wrong.
 - It is true that the MINIMUM p-value should be at least 95%; however, even IF the study has a “significant” effect, then one must ask this next critical question:
-

How Strong is the Effect? A Little or A Lot?

You need to ask “*What is the magnitude of the positive effect?*” A positive effect can range from a very small negligible effect to a tremendous effect.

What is considered a significant amount or a significant effect?

If more than 51% (the majority) of a group doesn’t respond IN ABSOLUTE NUMBERS (NOT relative measures) to the drug, then I am not impressed, and you shouldn’t be, either. Typically today, if just 20% of the treated group obtains any positive effect (regardless of how little), it is considered a huge success. But **this really means 80% FAILURE**.

I am disgusted when substantial failure is transformed, by statistical sleight-of-hand, into a so-called success. To put this into a real-world perspective, an 80% FAILURE rate, whereby buildings collapsed or televisions blew up in your face when turned on, would be unacceptable. I hope you would concur.

Before I personally would trumpet a drug's success, at least 80% of the subjects IN ABSOLUTE NUMBERS must benefit. Recall that there *are* examples of such high levels of success with drugs: insulin lowers everyone's blood sugars; thyroid hormone decreases everyone's TSH level; the proper antibiotics stop every infection.

Is the Item Measured Significant, or a Worthless "Surrogate"?

Low NNT is a necessary, but not an entirely sufficient condition to be able to claim victory. Is there a DIRECT cause/effect relationship? This is absolutely required or once more, you are being misled.

To Reiterate: Worthless Surrogates — NOT the Desired Result Itself — Are Often Used... The Deception Continues...

Even though statins lower LDL-cholesterol, heart disease is not significantly reduced. The tragic truth was only recently accepted. This still hasn't stopped the pharmaceutical companies and physicians from saying that lowered LDL-cholesterol is all that counts. They are WRONG, and patients are paying with their lives.

Therefore, one CANNOT blindly assume that the "disease" is solved when a worthless "SURROGATE" is used INSTEAD of measuring the result itself, such as *how many heart attacks occur with and without statins* (the answer is the same amount, or even more, occur WITH STATINS). This means that statins are ineffective at stopping heart disease.

A recent example: The JUPITER FAILURE Hailed as A Success

Of course, from the above, it goes without saying that there must first be a direct cause/effect relationship to the disease. If you treat 100 patients with a drug and all 100 improve, the drug's number needed to treat (NNT) is 1 (100 patients/100 successes). If you treat 100 patients and only 1 patient responds positively the NNT would be 100 (100 patients treated/1 positive response). This is an awful result and equivalent to a 99% failure rate. Dr. Nortin M. Hadler, Professor of Medicine at the University of North Carolina at Chapel Hill states: "Anything over an NNT of 50 is worse than a lottery ticket..."

Of significant importance is the fact that the 2008 JUPITER study was used to try and gloss over the fact that numerous attempts to prove the "cholesterol theory" (the lower the patient's low density cholesterol [LDL-C], the greater the prevention of CVD), by attempting to make the case that the real mode

of action of statin drugs was C-reactive protein (CRP) reduction, have failed. However, there is one tragic flaw: CRP is not a reliable prognostic indicator of cardiovascular events; there are better markers. An article entitled *Largest-Ever Meta-Analysis Finds CRP Is Unlikely to Be Causal for CVD*, reports that scientists of the Cambridge-based Emerging Risk Factors Collaboration (ERFC) found:

“[A]lthough CRP concentration was linearly associated with CHD (coronary heart disease), stroke, and vascular mortality, as well as nonvascular mortality, statistical adjustment for conventional cardiovascular risk factors resulted in considerable weakening of associations.”

An Example of How They Fool You

In the Jupiter Study, the NNT of 240 for statins, in preventing any stroke (99.58% failure disguised as a hazard ratio of 0.52; p = 0.002), was not stated.

This means that the JUPITER Study had an **undisclosed** NNT of 240 (**99.6% FAILURE**) for preventing any stroke – instead, a hazard ratio (an estimate of *relative risk*) of 0.52 (appearing as a 52% success) was published, thus **making the trial appear much more successful than it actually was.**

What *appears* more impressive? A 0.04 success rate / **99.6% FAILURE** rate or a 52% success rate / smaller 48% FAILURE rate? Physicians are deceived and so are their patients.

- **Always ask for the SAMPLE SIZE, since without it you cannot draw any meaningful conclusions.**
- **Always ask for the ABSOLUTE RISK DIFFERENCE BETWEEN BOTH GROUPS, since without it you cannot draw any meaningful conclusions.**