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INTRODUCTION

Dr. Arthur Furst who founded the GNLD Scientific Advisory Board used to say that you could prove almost anything by a "scientific study" if you design the study right. Unfortunately, many studies today are used to promote an agenda.

Abram Hoffer wrote, "In the double-blind study, we have our new naked emperor, clothed by the imagination and misconceptions of research establishments. I consider it expensive, inappropriate, unethical way of testing treatment in people, useful only for obtaining research grants and for making it easier to publish in standard medical journals. I cannot recall a single successful new medical treatment that has emerged over the course of my career that depended upon the double-blind method for its introduction."

This is an amazing statement from a scientist who conducted six doubleblind controlled, randomized trials demonstrating that niacin improved the two-year recovery rate from schizophrenia from 35% to 75%.

Hoffer had a reason to resent the manner in which the scientific method was applied. Morris Lipton, Associate Editor of the *American Journal of Psychiatry*, told Hoffer "he would never publish any paper of mine no mater how good it was." Much of the work Hoffer did was discredited by others who repeated his work using different kinds of patients and different preparations in backward mental hospital settings. He wote, "I am still amazed at the facility with which physicians feel no compunction to repeat original work as it was done originally."

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ATTACK ON MULTIVITAMINS

In 2002 the *Journal of the American Medical Association* published an an editorial in which they recommended the use of vitamin supplements for all adults. They wrote, "Most people do not consume an optimal amount of all vitamins by diet alone. Pending strong evidence of effectiveness from randomized trials, it appears prudent for all adults to take vitamin supplements." This conclusion was based on two scientific reviews based on 30 years worth of scientific papers relat-



ing nutrition to chronic diseases.

It came as a surprise to many, therefore, when the Annals of Internal Medicine published an editorial attacking the use of supplements and suggesting they should be avoided. The editorial stated, "Evidence is sufficient to advise against routine supplementation, and we should translate null and negative findings into action. The message is simple: Most supplements do not prevent chronic disease or death, their use is not justified, and they should be avoided. This message is especially true for the general population with no clear evidence of micronutrient deficiencies..."

The first report was largely ignored by the media, while the second received prominent nationwide publicity. The editorial in the second report was based upon three studies which will be discussed here.

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THE FIRST STUDY

Multivitamins and Cognition

The first study involved the supplementation of 5,947 affluent physicians 65 and older with an inexpensive multivitamin (Centrum Silver) or a placebo between 1997 and 2011.

The authors of the study noted that



this study was limited by the low potency of the supplement and the fact that the study population was possibly too well-nourished to benefit from this small amount of supplementation. The supplement contained only 60 mg. of vitamin C, 25 mcg. of B12 and 20 mcg of selenium.

Assessment of the use of the vitamins was made by 4 telephone interviews over 12 years. Subjects only had to use the supplements 2/3 of the time to be compliant and they were not asked to return any unused product to verify their use of the product.

After 2.5 years the group using the multivitamin did show benefit, but it never reached statistical significance. The editorial writers ignored this and the possibility that increasing the potency of the supplement or addition of nutrients such as omega-3 fatty acids might have allowed the results to demonstrate statistical significance.

John Michael Gaziano co-author of cognitive study said, "It drives me crazy that they say 'enough is enough,' when there's only been one large study of (standard) multivitamins and it's ours."

One commentator on this study wrote, "While this study did not find benefit in cognitive function of male physicians aged 65 years or older, two other recently released arms of the Physicians' Health Study II did find benefit in the specific study population in reducing the risk of cancer and cataracts." Lead researcher Howard Sesso said, "because of the possible cancer-related benefits tied to multivitamins, they are still worth considering."

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http://www.blackmoresinstitute.org/login/newsand-insights/Response-to%20Annals-editorial

THE SECOND STUDY

Cancer and Heart Disease

The second study focused on cancer and heart disease. Two independent investigators selected 26 out of 12,760 study abstracts for inclusion in their analysis. To be included in the review doses of supplements had to be lower than the upper tolerable limit set by the U.S. Food and Nutrition Board. This means a maximum of 100 IU of vitamin D. Most of the studies examined were less than 10 years.

This review was conducted in order to update vitamin treatment guidelines for the U.S. Preventive Services Task Force. This is a panel of medical "experts" who recommend the government on treatments.

Two of the included studies found a borderline-significant benefit in reducing cancer in men. This particular study is what is called a meta-analysis. William Parsons, Jr., the man who demonstrated that niacin is much more effective than statin medications in lowering cholesterol, had much to say about these kinds of studies. He wrote, "Today's successor to such armchair studies is a current fad, the 'meta-analysis.' The authors of this type of study don't do any original research themselves; they just pull together the results of a number of studies on the same subject and with similar endpoints, then analyze them as though this was one massive study. The larger numbers of participants give greater statistical force to the results."

"All this sounds good, but it ignores the fact that the studies lumped together in this manner are really not 100% comparable." He also notes, "The authors can omit some reports based on whatever criteria they decide to set up, so the selection of data may not be entirely unlike that of Keys."

Ancel Keys made the front page of Time Magazine for an armchair study in which he demonstrated that fat intake is linearly related to death from heart disease. It was later noted that Keys selected data from seven national reports which supported his theory and omitted data from 15 national reports which disproved his hypothesis. George Mann said, "Such data selection is, of course, cheating."

Many studies of multivitamins have shown benefit in reducing risk of cancer and heart disease. A study by Hercberg and associates found that "after 7.5 years, low-dose antioxidant supplementation lowered total cancer incidence and all-cause mortality in men..."

The Physician's Health Study II found that "daily multivitamin supplementation modestly but significantly reduced the risk of total cancer." Gaziano mentioned earlier with regard to the cognition study was involved with



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this positive research which explains his frustration with the rush to attack multivitamin use because of poor results with the cognition study.

A German study of 23,943 subjects using an antioxidant multivitamin found the subjects were 48% less likely to die from cancer and 42% less likely to die from all causes after 11 years. These researchers also suggested that many people who start using supplements are sick. This factor can skew research results.

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THE THIRD STUDY Multivitamins and Heart Attack

The third study used to bolster the attack on multivitamin use focused on the use of a high potency multivitamin after patients had a heart attack and were put on standard medications. There was not a statistically significant reduction in cardiovascular events. The researchers noted that "There was considerable nonadherence and withdrawal, limiting the ability to draw firm conclusions."

The nonadherence to the program by 46% of test subjects also "reduced statistical power due to a small difference between groups..."

It should be noted that there was a 11% reduction in heart events at the primary endpoint of the study and a 18% reduction in the secondary endpoint among the multivitamin users. The researchers criteria was a 25% reduction in risk as the baseline for cardiovascular benefit "that may have been overly optimistic for the oral vitamins."

In other words, the choice of a baseline of 25% reduced risk was the primary reason this study could be called a failure. This study did show a benefit for the use of high dose multivitamins and minerals. This was in spite of the fact that more subjects in the multivitamin group suffered with diabetes which greatly increases the risk for heart disease.

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COUNCIL FOR RESPONSIBLE NUTRITION

The Council for Responsible Nutrition commented on the *Annals of Internal Medicine* editorial as follows: "The editorial demonstrates a closeminded, one-sided approach that attempts to dismiss even the proven benefits of vitamins and minerals. It's a shame for consumers that the authors refuse to recognize the real-life need for vitamin and mineral supplementation, living in a fairy-tale world that makes the inaccurate assumption that we're all eating healthy diets and getting everything we need from food alone."

"So we agree enough is enough. Stop the reductionist approach to nutritional research. Stop insinuating there is evidence of harm. Stop ignoring the scientific evidence that demonstrates there is value to getting your essential nutrients. There is plenty of scientific evidence that recognizes that vitamin and mineral supplements have a role in good health for all Americans."

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THE CARET TRIAL

The CARET Trial (Beta-Carotene and Retinol Efficacy Trial) was a test of the efficacy of beta-carotene and vitamin A (retinyl palmitate) in the prevention of lung cancer among smokers. The trial was ended 21 months early because the group receiving the supplements had 28% more lung cancers and 17% more deaths than the control group.

These researchers demonstrated that they had no understanding of the synergistic activities of the antioxidant family of nutrients. This study focused on smokers who are frequently deficient in vitamin C because smoking depletes this vital nutrient. Vitamin C is the last step in removing free





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radicals from the body.

This was described in Science News as follows: "The scheme the chemists propose works something like a bucket brigade, with the dangerous chemical property being passed from one molecule to the next. First, vitamin E reacts with the free radicals, restoring them to their less harmful state. This reaction, however, turns vitamin E into a potentially damaging free radical, which the carotenoids then inactivate. Finally, vitamin C repairs the resulting carotenoid radicals, and the water soluble vitamin C radicals eventually wash out of the body."

Another flaw of this study was that it used synthetic nutrients. Synthetic beta-carotene is manufactured from acetylene gas. Melvyn Werbach, a medical researcher, has noted that there are 272 stereoisomers (3-dimensional arrangements) of beta-carotene.

Synthetic beta-carotene consists of totally different stereoisomers than does the natural product. One researcher wrote, "how a particular beta-carotene came to be selected for world-wide testing is neither hard to understand nor easy to forgive." Werbach suggests, "There is now considerable evidence to suggest the advantage of supplementing carotenoids in more natural forms."

Many researchers have moved to use of the more natural forms of carotenoids because they are more effective than synthetic forms of these nutrients. For example, Prasad writes, "The natural form of β -carotene was selected because it has been shown to be more active. For example, natural β -carotene protects against radiation-induced transformation in vitro (in a test tube), whereas synthetic β -carotene was ineffective."

It is important to note that carotenoids in their natural forms as found in fruits and vegetables have repeatedly been shown to reduce the risk of a variety of cancers. One should not consider a study done on a synthetic nutrient as having results that apply to a natural form of the nutrient.

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