



MS Drugs Are Criminally Expensive Failures

Association Between Use of Interferon Beta and Progression of Disability in Patients With Relapsing-Remitting Multiple Scleros is (MS) by Afsaneh Shirani, published in the July 18, 2012 issue of the Journal of the American Medical Association, found that, "Among patients with relapsing-remitting MS, administration of interferon beta was not associated with a reduction in progression of disability." The investigators conclude, "The ultimate goal of treatment for MS is to prevent or delay long-term disability. Our findings bring into question the routine use of interferon beta drugs to achieve this goal in MS."

(80% of MS is the relapsing-remitting variety. The progressive variety (20%) shows even fewer benefits from MS medications.)

Comment: Since January 15, 2009, I have been conducting a study, along with the neurology department of Oregon Health & Science University (the medical school in Portland), of the effects of the McDougall Diet on people with multiple sclerosis (MS). We have finished enrollment as of March 2012. Analysis of the data will continue throughout this year and scientific reports will follow. The study protocol requires participants to remain on their MS medications; the most common class used is called "interferon" (referred to as "interferon beta" and "beta interferon"). I have told study participants that I believe that these medications are unjustified because of their lack of benefits, side effects, and costs. I have also reminded them that study protocol requires that they continue all MS-related medications for the duration of our investigation (one year).

MS lesions occur in the brain and spinal column when the body attacks itself (an autoimmune disease). Interferon is believed to act by suppressing the inflammation that follows the attacks. Interferon beta is sold under the trade names Avonex, Rebif, Betaseron, Betaferon, and Extavia. It is given by intramus cular injection at intervals as frequently as every other day, by the patient. The cost of the medication alone is \$36,000 annually. The most commonly reported side effects are inflammation at injection site, flulike symptoms, damage to the liver and blood, depression, and seizures. If patients were honestly informed, few would agree to take interferon. And if the costs came out of their own pockets, rather than being paid for by insurances companies, no patient would waste their money on MS medications because they don't prevent long-term disability or won't prolong the length of their life.

Pharmace utical companies have funded a lmost all previously published studies on drug treatments. Financial bias considered; results all of this investigation still shows only minimal benefits. However, this current study from the *Journal of the American Medical Association* appears to be free of conflicts of interest and is supported by the Canadian Institutes of Health Research and the National Multiple Scleros is Society. This lack of influence from drug money is important for the honest interpretation of these results. And the authors say it clearly: the drugs don't work.

Other medications commonly used for MS are Copaxone and Tysabri, with costs exceeding \$42,000 annually for the drug alone. The long-term benefits from these two medications have not been established to be any better than those found with interferon. Thus, there are no good alternatives for people with MS, save one: diet.

I believe, based on nearly a half century of work by Roy Swank, MD, former head of the neurology department of Oregon Health & Science University, that the McDougall Diet will stop this devastating disease in the vast majority of patients. Hopefully, our current clinical research will confirm my belief. Regardless, the McDougall Diet costs nothing to implement, has no adverse side effects, causes loss of excess body fat, and solves multiple health problems. Every patient diagnosed with MS should be told by his or her neurologist to follow our healthy diet, but this advice is rarely, if ever, given. As part of their "faith-based medicine," physicians believe only in the benefits of drugs, regardless of the overwhelming evidence to the contrary.

Shirani A, Zhao Y, Karim ME, Evans C, Kingwell E, van der Kop ML, Oger J, Gustafson P, Petkau J, Tremlett H. Association Between Use of Interferon Beta and Progression of Disability in Patients With Relapsing-Remitting Multiple Sclerosis. *JAMA*. 2012 Jul 18;308

## One Simple Colon Exam Will Suffice

Colore ctal-Cancer Incidence and Mortality with Screening Flexible Sigmoid oscopy by Robert E. Schoen, published in the June 21, 2012 issue of the New England Journal of Medicine, found, "Screening with flexible sigmoid oscopy was associated with a significant decrease in colore ctal-cancer incidence (in both the distal and proximal colon) and mortality (distal colon only)." From 1993 through 2001, 154,900 men and women 55 to 74 years of age were assigned to either screening with flexible sigmoid oscopy, with a repeat screening at 3 or 5 years, or to usual care. Half (46%) had only one exam and the other half had a repeat exam in 3 to 5 years. The results were a 21% reduction of colon cancer incidence and a 50% reduction in mortality. These finding are from a large US study known as the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial.

Comments: These results from the PLCO trial are remarkably similar to those of the Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial, published in the May 8, 2010 issue of the Lancet.<sup>2</sup> In this massive undertaking, 170,432 individuals 55 to 64 years of age were assigned to either once-only flexible sigmoidoscopy or no screening. For those who completed the sigmoidoscopy screening, the incidence of colorectal cancer was reduced by 33% and mortality by 43%.

Now there are two major studies published in our two best medical journals (*N Engl J Med* and *Lancet*), involving more than 335,000 people, which establish that screening for colon cancer is effectively accomplished by a sigmoid exam, performed once during a person's life.

Colon cancer is prevented by examinations with a scope when precancerous polyps are removed before they turn into real cancer that spreads throughout the body and can then kill. The colon can be directly examined with two different lengths of instruments. Colon oscopy is performed with a 6-foot flexible tube, rather than the 2-foot equally flexible sigmoidoscope. Colonoscopy requires a thorough bowel preparation (lasting as long as three days), sedation, and at least 30 minutes to perform. The cost is around \$3,000. The risks from the sedation and passage of the tube are considerable. The worst outcome is that a few healthy people suffer from perforation of the colon by the colonoscope and die. In contrast, a much more comfortable sigmoidoscope exam requires at most a day of preparation, costs a bout \$200, and can be completed in 10 minutes. No sedation is required and harm is rarely caused to the patient. Read more about these exams.

I recommend my patients have one sigmoid examination around age 60. If all is found to be normal, no polyps or cancer, then no further examinations to prevent colon cancer need to be performed for the remainder of the patient's life. When a bnormalities are detected future procedures are often required. This onetime recommendation is for people who have eaten the Western diet. Eating animal foods causes both polyps and colon cancers and puts the average Westerner at high risk. People who have eaten healthy for a lifetime will reap few be nefits from a bowel examination, because their risk for colon disease is so much lower. The bottom line is: colon cancer prevention is best achieved by putting healthy foods, rather than a scope, into a person's intestine.

- 1) Robert E. Schoen, M.D., M.P.H., Paul F. Pinsky, Ph.D., Joel L. Weissfeld, M.D., et al; for the PLCO Project Team. Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoid oscopy. *N Engl J Med* 2012; 366:2345-2357June 21, 2012.
- 2) Atkin WS, Edwards R, Kralj-Hans I, Wooldrage K, Hart AR, Northover JM, Parkin DM, Wardle J, Duffy SW, Cuzick J; UK Flexible Sigmoidos copy Trial Investigators. Once-only flexible sigmoidos copy screening in prevention of colorectal cancer: a multicentre randomised controlled trial. *Lancet*. 2010 May 8;375(9726):1624-33.

## Surgery for Prostate Cancer Does Not Save Lives

Radical Prostatectomy versus Observation for Localized Prostate Cancer by Timothy J. Wilt, published in the July 19, 2012 is sue of the *New England Journal of Medicine*, found, "Among men with localized prostate cancer detected during the early era of PSA testing, radical prostate ctomy did not significantly reduce all-cause or prostate-cancer mortality, as compared with observation, through at least 12 years of follow-up." The authors' conclusion is, "Informing men of the favorable long-term effects of observation on mortality, bone metastases, urinary and erectile function, and quality of life, and increasing the use of observation may avert the harms of unnecessary biopsies, and interventions, while maintaining excellent long-term disease-specific survival."

In this study of 731 men, 364 were assigned to radical prostatectomy, and 21 (5.8%) of this group died from prostate cancer or the treatments, as compared with 31 (8.4%) of the second group (367 men) assigned to observation. (This is an absolute risk reduction of only 2.6 percentage points.) The study population was representative of men in the community at large. Their average age at enrollment was 67 years, and as a result of this advanced age, many died of diseases commonly seen in later life, such as heart disease (rather than from their prostate cancer). The average PSA level was 7.8 ng/ml and a bout half of the men were classified as

having higher risk cancer based on a Gleason score of 7 or greater. (The Gleason score is determined by examining the prostate tissues under a microscope.)

**Comments:** Unfortunately, the negative findings of this study will seldom be frankly discussed by the urologist with a man newly diagnosed with prostate cancer. Nor will their doctors explain the results of two large randomized trails involving 182,000 men in Europe and 76,693 men in the US, which showed little or no reduction of death in men with PSA-detected prostate cancer, who were subsequently treated with the best surgical, radiation, and chemotherapy treatments that modern medicine has to offer.

Surgery is painful and risky. After the operation, urinary leakage, which requires diapers, and sometimes indwelling catheters, occurs in about half of the treated patients. Problems of sexual dysfunction can be expected in as many as 80 percent of men. All combined, published scientific research should have long ago put an end to PSA testing and the treatments that follow. Unfortunately, the truth is unlikely to change this <u>multi-billion-dollar business</u>.

My recommendation is first for men to not get PSA blood tests or digital rectal exams to detect prostate cancer. For the estimated 241,740 men who have already been discovered to have prostate cancer in the US in 2012, nothing more should be done to them (unless they have symptoms requiring relief). The strategy of doing nothing is called "watchful waiting," "active surveillance," and "expectant management." These obscure terms fail to focus on the first rule of medicine, a ccording to Hippocrates: "Do no harm." Doing nothing should be referred to as "humane treatment." Read more about prostate cancer.

Wilt TJ, Brawer MK, Jones KM, Barry MJ, Aronson WJ, Fox S, Gingrich JR, Wei JT, Gilhooly P, Grob BM, Nsouli I, Iyer P, Cartagena R, Snider G, Roehrborn C, Sharifi R, Blank W, Pandya P, Andriole GL, Culkin D, Wheeler T; Prostate Cancer Intervention versus Observation Trial (PIVOT) Study Group.

NEngl J Med. 2012 Jul 19;367(3):203-13.

## Fish Oils Fail to Prevent Heart Disease

N-3 fatty acids\* and cardiovascular outcomes in patients with dysglycemia by The ORIGIN Trial Invest igators, published in the June 11, 2012 issue of the New England Journal of Medicine, found, "Daily supplementation with 1 g of n-3 fatty acids did not reduce the rate of cardiovascular events in patients at high risk for cardiovascular events." In this study, triglyceride levels (a risk factor for heart disease) were reduced by 14.5 mg per deciliter (mg/dL). Because of their high risk of developing cardiovascular disease (heart disease and strokes), patients with elevated blood sugars (dysglycemia), characterized by diabetes, would be the ones most likely to show any benefits from a therapy like n-3 fatty acids (fish oils), if benefits existed. The pharmaceutical company, Sanofi, funded this study of 12,536 patients and Pronova BioPharma Norge provided the fish-oil supplement.

\*N-3 fat, also known as omega-3 fat, is most commonly obtained from fish for the production of supplements. Flaxseed oil is another common source of these fats. Only plants synthesize omega-3 fats; fish concentrate these pre-synthesized pharmacologically active oils in their bodies.

Comments: Many physicians and patients believe that fish oil supplements will improve health, and more specifically, reduce the risk of dying of a heart attack. Heart attacks occur when a blood clot suddenly forms in a heart artery as a result of the rupture of a small plaque. O mega-3 fats inhibit blood clotting and in this manner are believed to prevent heart attacks. Although, hy pothetically, these supplements should be beneficial, a recent meta-analysis of only the highest quality studies (blinded, randomized, placebo-controlled trials) showed no effect on cardiovascular outcomes. This means the speculative benefits from the blood-thinning effects of fish oils fail to compensate for the harmful effects of the meat- and dairy-based Western diet.

Eating fish oil has serious downsides. The blood-thinning properties increase the risk of generalized bleeding; these consequences could mean death from a car accident. Fish oil suppresses the immune system. The result might be a reduction of arthritic pains, but this same suppression will accelerate cancer growth. Fish oil is 100% fat, and the fat you eat is the fat you wear. Thus, it causes weight gain. Approximately one billion dollars are spent on this supplement annually, compared to multivitamin sales of \$4.8 billion. You can expect these supplements to remain popular because selling fish fat is big business.

Read more about this subject in "Confessions of a Fish-Killer," a chapter in my new book, The Starch Solution.

1) The ORI GIN Trial Investigators. n-3 Fatty Acids and Cardiovascular Outcomes in Patients with Dysgly cemia. *N Engl J Med.* 2012 Jun 11. [Epub a head of print].

2) Kwak SM, Myung SK, Lee YJ, Seo HG; for the Korean Meta-analysis Study Group.

Efficacy of Omega-3 Fatty Acid Supplements (Eicosapentaenoic Acid and Docosahexaenoic Acid) in the Secondary Prevention of Cardiovascular Disease: A Meta-analysis of Randomized, Double-blind, Placebo-Controlled Trials. *Arch Intern Med.* 2012 Apr 9.

## Folic Acid Fails to Prevent Heart Disease

The effect of folic acid based homocysteine lowering on cardiovascular events in people with kidney disease: systematic review and meta-analysis by Meg J Jardine, published in the June 13, 2012 issue of the *British Medical Journal*, concluded, "Folic acid based regimens should not be used for the prevention of cardiovascular events in people with kidney disease." This review of 11 trials included 4,389 people with chronic kidney disease. Because of their high risk of developing cardiovascular disease (heart disease and strokes), patients with kidney disease would be the most likely subjects to show any benefits from a therapy like folic acid, if they existed.

**Comments:** Folic acid, taken as a supplement, is believed to reduce the risk of dying from heart disease by lowering homocysteine levels found in the blood. Homocysteine is a risk factor for heart attacks, strokes, and other diseases commonly seen in people who eat the Western diet. Unfortunately, lowering this laboratory test number (like lowering triglycerides with fish oil in the study above) does not solve the health problems. The real fix for common diseases is a simple cost-saving, starch-based diet (the antithesis of the Western diet).

Read more about the failures and harms of folic acid supplements in "Just to Be on the Safe Side, Stay Away from Supplements," a chapter in my new book, The Starch Solution.

Jardine MJ, Kang A, Zoungas S, Navane ethan SD, Ninomiya T, Nigwekar SU, Gallagher MP, Cass A, Strippoli G, Perkovic V. The effect of folic acid based homocysteine lowering on cardiovascular events in people with kidney disease: systematic review and meta-analysis. <u>BMJ</u>. 2012 Jun 13;344:e3533. doi: 10.1136/bmj.e3533.

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