

“HERBAL” *and* “ALL NATURAL” *Are They Safe?* *Are They Effective?*



Stanley Brosman M.D.

When I asked a group of men what “Prostate Health” meant to them, most of them didn’t have an answer. They all admitted to receiving mailers and seeing advertisements advocating taking one thing or another to promote the nebulous concept of “Prostate Health” or “Men’s Health”. These terms were created by the advertising industry to promote and sell various products that are largely unregulated and have no scientific support for their claims.

American consumers are being exposed to an overwhelming flood of advertising for dietary supplements and homeopathic products. There appears to be a belief among consumers that some governmental agency such as the FDA has determined that these products are safe and effective. The fact that these ads are broadcast, printed and mailed seems to give assurance to the consumer. What people

don’t realize is that most of these products do not have to pass any examination to evaluate their safety and effectiveness. This widespread misconception has resulted in the spending of billions of dollars for products made by a multibillion dollar industry that does not have to perform research on their products.

One of the biggest sources of revenue involves products that purport to enhance sexual performance. For hundreds — perhaps thousands — of years, men have sought all sorts of herbs, spices, liquids and devices that promised improved sexual performance. The purveyors of these products make preposterous claims and we men believe them and can’t wait to buy the next remedy. As Shakespeare said, “What fools we mortals be”. We can apply this same thinking to most of the dietary supplements that “cure cancer”, prevent aging, and give us instant youth.

In 1906, the Pure Food and Drug Law was passed by Congress to eliminate this unscrupulous practice and for many years Americans had some protection from unproven products. However, in 1994, led by Senator Orrin Hatch of Utah, the Dietary Supplement Health and Education Act was enacted that allowed manufacturers to market products without FDA approval of safety and efficacy. It is no coincidence that at that time, Utah was the home of the dietary supplement industry. Attempts to modify this law have been unsuccessful as other lawmakers have thwarted the use of reason and science because of their own misguided beliefs.

The Federal Trade Commission (FTC) is charged with preventing fraudulent, deceptive and unfair business practices and with helping consumers to avoid them. Because of all of the claims that are being made regarding impotence, the agency has issued a consumer alert entitled “The Truth About Impotence Claims”[1].

The agency has attempted to clarify several issues and draw attention to the misleading nature of some marketing claims on the subject of impotence. This subject is of particular importance for men with prostate cancer since erectile dysfunction — impotence — is a frequent by-product of every therapy used to treat prostate cancer. Men with prostate cancer are a prime target for these manufacturers. Marketers are able to obtain mailing lists and offer a variety of products that are “guaranteed” to cure the problem.

The FTC Alert states that:

Products advertised as effective for treating impotence without a doctor’s prescription should be ignored, as they cannot cure the condition

Products advertised as “breakthroughs” in the treatment of impotence mandate double checking with a physician for legitimacy.

Some manufacturers of impotence cures claim that their product is “scientifically proven” to work. When a consumer sees the phrase “clinical studies prove it works”, caution is in order, as these claims are often false.

Claims providing very high rates of success are often bogus. Some manufacturers create phony “clinics” and fake “institutes” solely to promote bogus impotence cures.

When impotence cures are said to be “herbal” or “all natural”, the product should be ignored.

There is no herb or “all natural” substance proven to cure impotence.

The FDA has also gotten into the campaign regarding claims for treating impotence. In 2006 they published a report giving the results of a study in which 17 “dietary supplements” promoted on the internet were analyzed. Some of these products including: Zimaxx, Libidus, Neophase, Nasutra, Vigor-25, Acta-Rx and 4EVERON were promoted and sold as dietary supplements but were actually illegal drugs containing potentially harmful, undeclared ingredients [2].



The agency concluded that the claims made for these products were actually based on undeclared non-dietary components. What were these added agents? None other than sildenafil (Viagra) and vardenafil (Cialis). The FDA sent warning letters to these marketers explaining the illegal nature of their activities, halted shipment

of some of them into the United States and threatened to take additional actions. Does any of this sound familiar? About ten years ago there was a dietary supplement called PC-SPEs that was used to treat prostate cancer. It was effective but was discovered to contain estrogen, Valium and Coumadin. This too was taken off the market.

In 2007, the FDA announced a final rule establishing regulations for the current good manufacturing practices (cGMP) of dietary supplements. The new rules were designed to ensure that supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled. This sounds good doesn’t it? Various consumer watchdog groups immediately pointed out that supplement manufacturers have never been required to prove that their products are safe and effective. These regulations also failed to require fundamental evidence of quality. One expert stated that “Knowing you have pure and well-made useless crap is little better than having impure useless crap, but not by much.” [3]

Many companies are competing aggressively to capture a share of this lucrative market. The story of one of these products, Enzyte, is illustrative. Enzyte was manufactured by a Cincinnati-based company and become known for its ubiquitous “Smiling Bob” television ads. The marketer capitalized on the premise that a gullible public would readily buy an unproven, natural, herbal supplement that claimed to cure or treat impotence. They were right.

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The ads also promised that Enzyte would add as much as three inches to the length of the penis. Website testimonials claimed benefits such as full and satisfying erections and reversing the normal changes in erectile function associating with aging. What man could refuse to buy this product? Men with prostate cancer were the best customers because of the penile atrophy and erectile dysfunction associated with their disease and its treatment. The ingredients included niacin, zinc, copper, Korean red ginseng root, ginko, pine bark, Tribulus terrestris, arginine, Avena saliva, horny goat weed (I love this one), maca root, muira puama, saw palmetto (of course), and Swedish flower pollen [4].

The FDA got on their case and after receiving more than 3700 consumer complaints sued the company and later settled for a fine of \$2.5 million. It was estimated that the company took in more than \$100 million dollars for this product. The charges included sending supplements that were not ordered, charging

credit cards without authorization and laundering the money. In spite of the indictments and fines, companies such as this are still in business. They change the name of their product and just as P.T. Barnum said: “There’s a sucker born every minute”.

When the initial studies with Viagra, Levitra and Cialis were performed there was an interesting observation. The studies involved randomizing men into a control group receiving a placebo and a group receiving the active agent. The agent that was being tested was statistically superior but the control group reported success with the placebo in 30% of the subjects. Now you can see how a product like Enzyte could earn \$100 million dollars. If you made a product that satisfied 30% of your customers, you too would make a lot of money.

It is important to understand that many of the so-called studies using dietary supplements use flawed methodology. For example, KyoGreen powder (barley, wheat grass, seaweed) claims to improve

sexual function as does ArginMax (herbs, vitamins, minerals). Both products demonstrated effectiveness in their “clinical trials” but neither used a control group, a methodology that casts significant doubts on their claims. This is the case with many of the so-called studies on dietary supplements.

Another example is from a recent report on “Ginko biloba for Preventing Cognitive Decline in Older Adults” by Snitz et al published in the December 23rd issue of the Journal of the American Medical Association. These investigators reported that compared to a placebo, G. biloba, 120 mg taken twice daily, did not result in a decrease in the rate of cognitive decline in older adults or those with mild cognitive impairment. They note that previous studies failed to show any reduction in dementia or Alzheimer’s dementia. Has this stopped the advertising for this supplement? Of course not.

Some supplements can also be harmful. An example is the finding that Chinese herbal products containing Aristolochic acid increases



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the risk of urinary tract cancer. Some supplements have been associated with increased bleeding during surgery and people taking Coumadin have to especially careful.

Let's examine the use of dietary supplements promoted for "Prostate and Men's Health". These use the same advertising strategy to sell agents that claim to prevent prostate cancer, treat prostate cancer and have a healthy prostate (translated as improving sexual function). The meaning of the word supplement is to add something to correct a deficiency. If you are low on vitamin D, which can be measured with a blood test, a vitamin D supplement makes sense. Likewise any nutritional substance that is lacking or deficient can be corrected with an appropriate supplement. The problem is that we are unable to measure most of the elements that we deem helpful and hope that by throwing a lot of one thing or another into our mouths that something good will occur. The SELECT trial that studied the potential benefits of selenium and vitamin E either alone or in combination in 18,000 men, failed to show any benefit.

The fact is that we do not know how to determine the need for dietary supplements let alone which ones and how much to use. The best advice still comes from your mother and grandmother. Eat your fruits and vegetables, stay away from the fatty foods, the fried foods, the processed foods, don't eat too much and exercise.

I don't know about you but I'm clearing out my shelves of all those sexually enhancing dietary supplements. I'm sure my wife will fill the empty space with more vitamins and this week's cancer cure-all.

Resources

1. Accessed February 2010 at <http://www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt048.shtm>
2. Accessed February 2010 at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108690.htm>
3. See ABC News article at <http://abcnews.go.com/Health/story?id=3307441&page=3>
4. Accessed February 2010 at <http://www.enzyte.com/faq.aspx#>