



June 18, 2009

VIA REGULAR MAIL AND FAX TO 973-254-4853

Gary S. Balkema, President
Consumer Care Division
Bayer HealthCare LLC
36 Columbia Rd
Morristown, NJ 07962-1910

Re: Bayer's false and deceptive marketing for its Men's Multis for prevention of cancer

Dear Mr. Balkema:

The Center for Science in the Public Interest ("CSPI") intends to file a lawsuit against Bayer HealthCare LLC ("Bayer") for fraudulent and deceptive practices in the marketing and sale of Bayer's One A Day Men's 50+ Advantage multivitamin and Bayer's One A Day Men's Health Formula multivitamin (jointly, "Men's Multis").

This letter describes Bayer's illegal practices and offers settlement to avoid the necessity of a lawsuit.

If litigation is necessary, CSPI plans to seek an injunction prohibiting Bayer from representing (either expressly or implicitly) that any of its products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease. CSPI also may seek corrective advertising, restitution, damages, disgorgement, and attorneys' fees.

Facts Giving Rise to Bayer's Liability

The details of Bayer's wrongdoing are set out in a complaint CSPI is filing today with the Federal Trade Commission, a copy of which is attached and incorporated herein by this reference. In summary, these are the facts giving rise to Bayer's liability:

Bayer promotes the extra selenium in its Men's Multis for the mitigation, prevention, treatment, or cure of prostate cancer in several ways: on package labels, on its website, and in television and radio advertisements. Bayer has run at least 11 different television ads and at least 9 different radio ads since 2008 linking its men's multivitamins to the prevention of prostate cancer.

For example, the back of the package for One A Day Men's Health Formula bears this claim:

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer?

Similarly, one of the radio ads claims:

Prostate cancer. It's an important subject. Did you know that there are more new cases of prostate cancer each year than any other cancer? And here's something else you should know. Now, there's something that you can do that may help reduce your risk. Along with your regular doctor checkups, switch to One A Day men's. A complete multivitamin plus selenium, which emerging research suggests may reduce the risk of prostate cancer. One A Day Men's. Because staying healthy is serious business.

Bayer's website expands on these claims:

Did you know that 1 in 6 men will face prostate issues? Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer.

The attached FTC complaint discusses the research in detail, but, in summary, the research does not substantiate Bayer's cancer claims—and in fact shows that the amount of selenium in the Men's Multis may be harmful.

The Nutritional Prevention of Cancer (NPC) trial, upon which Bayer presumably relies, shows that the benefit of selenium supplementation for the prevention of prostate cancer was limited to a very small subgroup of men with the lowest levels of blood selenium and low baseline PSA scores.

More importantly, analysis of the NPC data found nearly a three-fold increased risk of diabetes in the men who were assigned to take selenium and who had the highest levels of blood selenium at the start of the trial.

In making its claims, Bayer ignores the findings of the federally funded Selenium and Vitamin E Cancer Prevention Trial (SELECT), the most important and compelling study. It did not find any evidence that selenium reduces the risk of prostate cancer in average, healthy men.

The SELECT trial was designed to last up to 12 years. However, in October 2008, it was abruptly terminated after the study's independent Data and Safety Monitoring Committee reviewed the SELECT data up to that point and concluded that selenium and vitamin E, alone or together, did not prevent prostate cancer in men.

The Data and Safety Monitoring Committee was also concerned that more new cases of diabetes may have occurred in men taking selenium alone, compared to the men taking the placebo.

In January 2009, the details of the SELECT trial were published in the Journal of the American Medical Association for all to read. The authors' conclusion: "Selenium or vitamin E, alone or in combination at the doses and formulations used, did not prevent prostate cancer in this population of relatively healthy men."

In fact, the American College of Physicians recommends against use of selenium supplements:

Selenium supplements appear to increase the risk for diabetes. Although the findings need to be confirmed, long-term selenium supplementation should not be viewed as harmless and a possibly healthy way to prevent illness.

Despite the public announcement of the failure of the SELECT trial to find any effect of selenium on prostate cancer risk, despite the possible increased risk of diabetes, and despite the recommendations of the American College of Physicians, Bayer continues to advertise the selenium in its Men's Multis as a way to prevent prostate cancer.

If Bayer has additional scientific substantiation for its prostate cancer claims for Men's Multis, please provide it to me as soon as possible. In the absence of being provided with such additional substantiation, CSPI will presume that none exists.

Bayer's Multiple Violations of State Consumer Protection Laws

Bayer's claims (1) are illegal claims of disease prevention, (2) do not have prior substantiation, (3) fail to warn of the possible increased risk of diabetes, and (4) are generally false, misleading, and deceptive.

Therefore, the labeling and marketing of these Men's Multis are unfair and deceptive under state consumer protections laws, such as Massachusetts G.L. c. 93A, Texas Business & Professions Code § 17.41 *et seq.*, District of Columbia Code § 28-3905 *et seq.*, New Jersey Statutes Ann. 56:8-1 *et seq.*, California Business & Professions Code Sections 17200 and 17500, and California Civil Code §§ 1770(a)(5) & 1770(a)(14) (jointly, "UDAP" laws).

For the same reasons, these Men's Multis are both "adulterated" and "misbranded" in violation of state food and drug laws, such as the California Food, Drug, and Cosmetic Act, California Health and Safety Code § 110660.

As the manufacturer and distributor of these Men's Multis, Bayer is responsible for the injuries caused by its actions. Consumer injury occurs each time a consumer sees marketing for or purchases one of these products. Each occurrence is a separate injury. *E.g., Aspinall v. Philip Morris Companies, Inc.*, 442 Mass. 381, 813 N.E.2d 476 (Mass. 2004).

Settlement Demand

In light of the foregoing, CSPI demands the following to settle this matter at this time before filing suit:

- Entry of a permanent injunction that prohibits Bayer from representing (either expressly or implicitly) that any of its products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- Entry of a permanent injunction that prohibits Bayer from any representation with respect to any disease for its Men's Multi's.
- Entry of a permanent injunction that mandates a series of corrective advertisements to correct Bayer's prior consumer deception with respect to the cancer-preventative benefits of its Men's Multis.
- Disgorgement of Bayer's profits from the sale of its Men's Multis since 2002, when it began making prostate claims.

This offer of settlement will remain open for 30 days from the date of this letter, pursuant to Cal. Civ. Code Sec. 1782 and other state statutory notice requirements, after which it shall be automatically withdrawn and become null and void.

Please have your own counsel contact me if Bayer is willing to discuss settlement or needs additional information about this lawsuit.

Yours truly,

A handwritten signature in blue ink, appearing to read "Stephen Gardner", with a long horizontal flourish extending to the right.

Stephen Gardner
Litigation Director

cc: Michael F. Jacobson, Ph.D., Executive Director
Katherine Campbell, Staff Attorney

Attachment

Complaint to Federal Trade Commission



June 18, 2009

Ms. Mary K. Engle
Associate Director
Advertising Practices
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Ms. Engle:

The Center for Science in the Public Interest (CSPI)¹ is bringing to the attention of the Federal Trade Commission the misleading and irresponsible claims Bayer Healthcare LLC (“Bayer”) is making in advertisements for its two men’s One A Day multivitamins (“multis”).

Pursuant to Section 4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), and 16 C.F.R. § 2.1, we request that the Federal Trade Commission halt the false and misleading claims made in advertisements by Bayer. Each advertisement constitutes a “false advertisement” as defined by Sections 12 and 15 of the Federal Trade Commission Act (FTCA), 15 U.S.C. §§ 52, 55, and hence is “unfair or deceptive” under Section 5 of the FTCA, 15 U.S.C. § 45. These advertisements also violate the FTC consent decree Bayer signed in January 2007.

The two dietary supplements are Bayer’s One A Day[®] Men’s 50+ Advantage multivitamin and Bayer’s One A Day[®] Men’s Health Formula multivitamin. Both contain 105 micrograms of the trace mineral selenium per daily dose, or about twice the Recommended Dietary Allowance (RDA), which is 55 micrograms a day for adults.²

Bayer’s Dishonest Marketing Campaign

Bayer promotes in several ways the extra selenium in these men’s multis for the prevention of prostate cancer: on package labels, on its website, and in television and radio advertisements. According to VMS, an advertisement monitoring service, Bayer

¹ CSPI, a non-profit consumer organization supported by approximately 900,000 members, has worked since 1971 to improve national health policies. We have been especially concerned about the effect of dietary supplement advertising on consumer health.

² Centrum Silver from Wyeth Consumer Healthcare, on the other hand, contains 55 micrograms per daily dose.

has run at least 11 different television ads and at least 9 different radio ads since 2008 linking the prevention of prostate cancer to their men's multivitamins.³

Here's a transcript of one of the radio ads:

Prostate cancer. It's an important subject. Did you know that there are more new cases of prostate cancer each year than any other cancer? And here's something else you should know. Now, there's something that you can do that may help reduce your risk. Along with your regular doctor checkups, switch to One A Day men's. A complete multivitamin plus selenium, which emerging research suggests may reduce the risk of prostate cancer. One A Day Men's. Because staying healthy is serious business.⁴

From the company website:

Did you know that 1 in 6 men will face prostate issues? Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer.⁵

From the back of the package for One A Day Men's Health Formula:

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer?⁶

In fact, the most important and compelling research by far to emerge on this question, the federally funded Selenium and Vitamin E Cancer Prevention Trial (SELECT), did not find any evidence that selenium reduces the risk of prostate cancer in average, healthy men.⁷

First Trial found Selenium May Have Benefited Only a Very Small Subgroup of Men

The notion that selenium might reduce the risk of prostate cancer was inspired by the Nutritional Prevention of Cancer (NPC) trial, the first results of which were published in 1996.⁸ Although the NPC trial's primary objective was to evaluate whether selenium

³ VMS search conducted for CSPI on March 23, 2009.

⁴ "More new cases of prostate cancer each year than others," VMS ID 080422285

⁵ <http://www.oneaday.com/mens.html> (accessed June 16, 2009)

⁶ See Attachment A.

⁷ The Food and Drug Administration did approve a qualified health claim in 2003 for selenium supplementation and the reduction in risk of "certain forms of cancer," but not for any specific cancer. This qualified claim must be accompanied by the statement: "However, FDA has determined that this evidence is limited and not conclusive." This statement appears on package labels of One A Day[®] Men's 50+ Advantage and One A Day[®] Men's Health Formula, but not on the One A Day websites or in other advertisements. <http://www.cfsan.fda.gov/~dms/ds-ltr35.html>

⁸ [JAMA](#). 1996 Dec 25;276(24):1957-63

supplementation prevents skin cancer (it didn't), an analysis of secondary outcomes found that the men in the study who received 200 micrograms of yeast-based selenium had a significantly lower risk of developing prostate cancer over the six years of the study.

The NPC trial was the first and only randomized controlled trial in men to see such an effect from selenium. Subsequent examinations of the NPC data found that the benefits of selenium supplementation in this study were less than what they first seemed.

A 2003 analysis of the NPC data determined that the benefit of selenium supplementation for the prevention of prostate cancer was limited to a very small subgroup of men with the lowest levels of blood selenium and low baseline PSA scores.⁹

Furthermore, a 2007 analysis of the NPC data found nearly a three-fold increased risk of self-reported diabetes in the men who were assigned to take selenium and who had the highest levels of blood selenium at the start of the trial.¹⁰ In response to that finding, the American College of Physicians issued a summary for patients, stating:

Selenium supplements appear to increase the risk for diabetes. Although the findings need to be confirmed, long-term selenium supplementation should not be viewed as harmless and a possibly healthy way to prevent illness.¹¹

Larger, Second Trial of Selenium Found It Ineffective for Preventing Prostate Cancer

In 2001, the National Institutes of Health began the \$118.5 million Selenium and Vitamin E Cancer Prevention Trial (SELECT), based in large measure on the promising initial evaluation of the NPC study. The largest prostate cancer prevention study ever undertaken, SELECT was designed to see if 200 micrograms of selenium in the form of selenomethionine, or 400 IU of vitamin E, or a combination of the two could lower the risk of developing prostate cancer more than a placebo in 35,000 men in the United States, Puerto Rico, and Canada.

The SELECT trial was designed to last up to twelve years. However, in October 2008, it was abruptly terminated after seven years when the study's independent Data and Safety Monitoring Committee reviewed the SELECT data up to that point and concluded that selenium was not preventing prostate cancer in the men. Neither was vitamin E, or selenium and vitamin E together.

The Safety Monitoring Committee was also concerned that more new cases of diabetes occurred in men taking selenium alone, compared to the men taking the placebo, although this difference was not quite statistically significant (p=.08). (Vitamin E

⁹ BJU International 2003; 91: 608-612.

¹⁰ Ann Intern Med 2007; 147: 217-223.

¹¹ Ann Intern Med. 2007 Aug 21;147(4):114.

appeared to spur prostate cancer, although that, too, did not quite reach statistical significance (p=.09)).

Despite the public announcement last October of the failure of the SELECT trial to find any effect of selenium on prostate cancer risk, and despite the increased risk of diabetes seen in the NPC study and the possible increased risk of diabetes in the SELECT trial, Bayer continues to advertise the selenium in its men's multis as a way to prevent prostate cancer.

In January 2009, the details of the SELECT trial were published in the Journal of the American Medical Association (JAMA) for all to read. The authors' conclusion: "Selenium or vitamin E, alone or in combination at the doses and formulations used, did not prevent prostate cancer in this population of relatively healthy men."¹²

In an editorial accompanying the study's publication, Peter Gann of the University of Illinois at Chicago advised, based on the SELECT trial results, that: "...physicians should not recommend selenium or vitamin E—or any other antioxidant supplements—to their patients for preventing prostate cancer."¹³

Despite the publication in JAMA of the SELECT trial's failure to find any effect of selenium on prostate cancer risk, Bayer continues to promote in television and radio advertising and on its website the selenium in its men's multis as a way to prevent prostate "issues" and prostate cancer.

New Study of Selenium Fails to Prevent Prostate Cancer

In April 2009, Canadian researchers released the results of a new three-year trial of selenium, vitamin E, and soy in men with high-grade prostatic intraepithelial neoplasia (HGPIN). The combination therapy did not halt the progression of the lesions to prostate cancer.

"The results of this study support the findings of the SELECT trial which also demonstrated no benefit using Vitamin E and selenium," said Christopher Amling, MD, a spokesman for the American Urological Association, at whose annual meeting the results of this trial were presented. "These studies highlight the importance of conducting randomized trials of these agents since many of these supplements are promoted falsely to the general public as having beneficial effects on cancer prevention and progression."¹⁴

Violation of Previous Bayer Consent Decree with the FTC

¹² JAMA. 2009 Jan 7;301(1):39-51.

¹³ JAMA. 2009 Jan 7;301(1):102-3.

¹⁴ http://www.auanet.org/content/press/press_releases/article.cfm?articleNo=115

Bayer's false claims about the ability of its selenium-containing One A Day multivitamins to lower the risk of prostate cancer violate the terms of the consent decree the company signed with the Federal Trade Commission in January, 2007.¹⁵

In that case, the FTC charged Bayer with making unsubstantiated claims about another One A Day multivitamin called WeightSmart, and the company paid a \$3.2 million civil penalty. The FTC alleged that these unsubstantiated claims violated a 1991 Commission order against Bayer's predecessor, Miles Inc., that require all claims about the benefits of One A Day brand products to be substantiated by competent and reliable scientific evidence.

In the 2007 agreement, Bayer was once again prohibited from violating the earlier FTC order and in the future from "making unsubstantiated representations regarding the benefits, performance, efficacy, safety, or side effects of any dietary supplement, multivitamin, or weight-control product."

Bayer has clearly violated this agreement again.

Bayer is currently running corrective advertising in the U.S. for its Yaz brand of contraceptive, as part of a settlement with the Food and Drug Administration (FDA) and the attorneys general of 27 states, who accused Bayer of overstating the benefits and downplaying the risks of the drug. Bayer has agreed to spend at least \$20 million on corrective ads in 2009 and to submit for screening by FDA all of its proposed Yaz ads for the next six years.¹⁶

Action Requested

We urge the Federal Trade Commission to take swift and strong action to get these deceptive Bayer ads off television, radio, and the Internet and out of newspapers and magazines or wherever else they may be displayed.

Since these ads have run so often for so long, deeply reinforcing the false notion that selenium is protective against prostate cancer, and because selenium supplementation may actually be harmful by increasing the risk of diabetes, the FTC should require Bayer to run corrective advertising.

And we urge that strong monetary sanctions be imposed on Bayer for repeatedly violating its agreements with the FTC, both to encourage better behavior by that company and as an example to other companies.

¹⁵ <http://www.ftc.gov/os/caselist/bayercorp/070104consentdecree.pdf>

¹⁶ <http://www.nytimes.com/2009/02/11/business/11pill.html>

For the foregoing reasons, we request that the Commission:

- (1) Bring an action pursuant to Section 13 of the FTCA, 15 U.S.C. § 53, to enjoin further distribution of any advertisements by Bayer regarding the impact of selenium supplement consumption and prostate health pending issuance of a complaint under Section 5 of the FTCA, 15 U.S.C. § 45;
- (2) Initiate action under Section 5 of the Act, 15 U.S.C. § 45, to permanently prohibit dissemination of the advertisements;
- (3) Require the payment of a monetary penalty; and
- (4) Require corrective advertising.

Sincerely,



David Schardt, MS
Senior Nutritionist



Katherine Campbell
Staff Attorney

Michael F. Jacobson, Ph.D.
Executive Director

Directions: Adults. One tablet daily, with food.

Supplement Facts

Serving Size: One tablet

Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value
Vitamin A (14% as beta-carotene)	3500 IU 70%	Vitamin B ₆	3 mg 150%	Selenium	105 mcg 150%
Vitamin C	90 mg 150%	Folic Acid	400 mcg 100%	Copper	2 mg 100%
Vitamin D	400 IU 100%	Vitamin B ₁₂	18 mcg 300%	Manganese	2 mg 100%
Vitamin E	45 IU 150%	Biotin	30 mcg 10%	Chromium	120 mcg 100%
Vitamin K	20 mcg 25%	Pantothenic Acid	5 mg 50%	Potassium	100 mg 3%
Thiamin (B ₁)	1.2 mg 80%	Calcium (elemental)	210 mg 21%	Lycopene	600 mcg *
Riboflavin (B ₂)	1.7 mg 100%	Iron	0 mg 0%		
Niacin	16 mg 80%	Magnesium	120 mg 30%		
		Zinc	15 mg 100%		

INGREDIENTS: Calcium Carbonate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid, dl-Alpha-Tocopheryl Acetate, Corn Starch, Croscarmellose Sodium, Acacia, Dicalcium Phosphate, Zinc Oxide, Niacinamide, Gelatin, Stearic Acid, Silicon Dioxide, Dextrin, Magnesium Stearate, D-Calcium Pantothenate, Manganese Sulfate, Pyridoxine Hydrochloride, Hypromellose, Cupric Oxide, Calcium Silicate, Resin, Glucose, Riboflavin, Sucrose, Vitamin A Acetate, Thiamine Mononitrate, Dextrose, Soy Lecithin, Chromium Chloride, Lycopene, Folic Acid, Sodium Carboxymethylcellulose, Beta-Carotene, Sodium Selenate, Sodium Citrate, Tricalcium Phosphate, Sodium Ascorbate, Tocopherols, Biotin, Phylionadione, Cyanocobalamin, Ergocalciferol, Ascorbyl Palmitate.
Contains: Fish (cod, pollock, haddock, hake, cusk, redfish) and Soy.

THE COMPLETE MULTIVITAMIN PLUS MORE[†] FOR MEN

Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer? One A Day[®] Men's Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate.* Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of Selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

[†] Compared to One A Day[®] Essential, and with nearly twice the Selenium in Centrum[®] for prostate health.

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.