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	Harry Shulman (SBN 209908)							
2 II	The Mills Law Firm 880 Las Gallinas Avenue, Suite 2							
- 11	San Rafael, CA 94903							
	(415) 455-1326 (415) 455-1327 (512)							
1	(415) 455-1327 (fax) harry@millslawfirm.com San Francisco Gounty Surveyior Court							
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6	Stephen Gardner CASE MANAGEMENT CONTROL PARK-LI, Cierk							
_ !!	Center for Science in the Public Interest Deputy Clerk							
8	5646 Milton Street, Suite 211 MAR 5 - 2010 - 9 MAM Dallas, Texas 75206							
9	Telephone: (214) 827-2774 DEPARTMENT 212							
10	Facsimile: (214) 827-2787 Pro Hac Vice to be filed							
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12	Attorneys for Plaintiff							
13	SUPERIOR COURT OF THE STATE OF CALIFORNIA							
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16	CENTER FOR SCIENCE IN THE) Case NGC - 09 - 49 3 0 4 0							
17	membership organization, on behalf of)							
18	itself and on behalf of its members, COMPLAINT FOR VIOLATIONS OF							
19	Plaintiff,) THE CONSUMER LEGAL REMEDIES							
20) ACT, THE UNFAIR COMPETITION							
21	vs.) LAW, AND FOR DECLARATORY) AND INJUNCTIVE RELIEF							
22	BAYER CORPORATION, BAYER) HEALTHCARE LLC, and DOES 1-10.)							
	HEALTHCARE LLC, and DOES 1-10.							
23	Defendants.) JURY TRIAL DEMANDED							
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25								
26	INTRODUCTORY STATEMENT							
27	1. The non-profit organization Center for Science in the Public Interest							
28	("CSPI") brings this lawsuit because Defendants Bayer Corporation and Bayer HealthCare LLC							
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	II '							

(collectively "Bayer") have unconscionably deceived its members. CSPI's members have suffered damage and lost money in that they paid for vitamins that were not as represented.

- 2. Since at least 2002,¹ Bayer has labeled and advertised that the selenium in its One A Day Men's Multivitamins will "support prostate health" and "reduce the risk of prostate cancer" ("prostate claims"), on websites, in television and other advertising, and on product labels. In fact, the selenium in the Men's Multis neither support prostate health nor reduce the risk of prostate cancer.
- 3. Instead the selenium in the Men's Multis may actually cause harm to consumers:
 - Men with prostate cancer who have high blood levels of selenium and a common genetic trait may have an *increased risk of aggressive prostate* cancer.
 - Selenium supplements such as Bayer's Men's Multis may *increase the risk* for diabetes.
- 4. Bayer's labels and advertisements of the Men's Multis are unlawful, unfair, fraudulent, and unconscionable and therefore in violation of California's Consumer Legal Remedies Act and the Unfair Competition Law.
- 5. After CSPI sent Bayer a letter notifying it that it was acting in violation of the law, Bayer told CSPI that it would cease making prostate claims for the Men's Multis. However, while there appear to be changes on the Men's Multis' websites that remove the prostate claims, Bayer (1) made no effort to ensure that CSPI's members actually learned of these changes, (2) refused to recall products that made these claims, (3) advised that the claims would remain on some third-party websites, and (4) refused to agree that it would not resume making the prostate claims in the future.

¹ PR Newswire, Prostate Cancer Awareness Month Highlights Importance of Defending Prostate Health; New One-A-Day Multivitamin Offers Men a Game Plan to Support Prostate Health, Aug. 21, 2002.

 6. Indeed, Bayer strenuously denied that its actions were in any way prohibited by law. Thus, there is nothing to prevent Bayer resuming these prostate claims at a future date.

- 7. In fact, the prostate claims remain on the labels of boxes currently for sale.
- 8. The culmination of CSPI's discussions with Bayer was not resolution, but rather a threat by Bayer to sue CSPI for defamation and libel.
- 9. For these and other reasons, this Court should declare that Bayer's prostate claims are actions that are unlawful and unfair within the meaning of the Consumer Legal Remedies Act and the Unfair Competition Law, and enjoin Bayer from making such prostate claims in the future.

THE PARTIES

Plaintiff

organization founded in 1971. CSPI has approximately 756,000 U.S. members, nearly 93,000 of whom are California residents. It has been a strong advocate for nutrition and health, food safety, alcohol policy, and sound science. Its award-winning newsletter, *Nutrition Action Healthletter*, with some 900,000 subscribers in the United States and Canada, is the largest-circulation health newsletter in North America. CSPI has carved out a niche as the organized voice of the American public on nutrition, food safety, health, and other issues. It has long sought to educate the public, advocate government policies that are consistent with scientific evidence on health and environmental issues, and counter industry's powerful influence on public opinion and public policies.

Defendants

- 11. Bayer Corporation is organized and incorporated under the laws of the State of Indiana, with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.
- 12. Bayer HealthCare LLC is a limited liability corporation organized under the laws of the State of Delaware, with its principal place of business at 555 White Plains Road,

Tarrytown, New York 10591. This Complaint jointly refers to both defendants as "Bayer," in the singular, unless the context demands otherwise.

- 13. Defendants Does 1-10 are other persons or entities, whose names are currently unknown to CSPI despite diligent efforts to identify them, who participated in, assisted in and/or committed the torts alleged against Bayer in this action. When the actual names of such individuals or entities become known, CSPI will promptly take steps to name them in this action.
- 14. At all relevant times, both Defendants, and each of them, were acting within the scope and course of their authority and with the permission and consent of the other Defendant. Defendants engaged in the misconduct alleged herein for the purpose of enriching themselves at the expense of CSPI and its members, including those in California.

JURISDICTION AND VENUE

- 15. This Court has jurisdiction of this action under section 410.10 of the Code of Civil Procedure. Jurisdiction is also proper under California Civil Code § 1750 *et seq*.
- 16. Venue is appropriate in the County of San Francisco pursuant to Civ. Code §1780(d) and Code of Civ. Proc. §395 because Plaintiff's members reside in this county, and because Bayer does business in this county. Plaintiff is concurrently filing the Declaration as to Venue required by Civ. Code §1780(d).

GENERAL ALLEGATIONS

- 17. Bayer has promoted 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, in television and radio advertisements, and in other manners. Bayer has run at least eleven different television ads and at least nine different radio ads since 2008 linking its Men's Multis to the prevention of prostate cancer.
- 18. 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?"
- 19. Similarly, the back of the package for One A Day Men's 50+ Advantage claims that it contains "nearly twice the Selenium in Centrum Silver to support prostate health."

 20. One of the radio ads claimed:

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.

- 21. Bayer's website expanded 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."
- 22. Bayer ran a television commercial for One A Day Men's Health Formula that said:

Did you know one in three men will face prostate issues? One in three, really? That's why One A Day Men's is a complete multivitamin with selenium which emerging research suggests can help prostate health. One A Day Men's.

23. Bayer ran a television commercial for One A Day Men's 50+ Advantage that said:

To stay on top of my game after 50, I switched to a complete multivitamin with more. Only One A Day Men's 50+ Advantage has gingko for memory and concentration plus support for prostate and heart health. Safe. That's a great call. One A Day Men's.

- 24. Scientific research does not substantiate Bayer's cancer claims. In fact, the research shows that the amount of selenium in the Men's Multis may be harmful.
- 25. There have been two randomized controlled trials of selenium supplementation for the prevention of prostate cancer the Nutritional Prevention of Cancer ("NPC") trial and the federally funded Selenium and Vitamin E Cancer Prevention Trial ("SELECT").

JAMA 2009; 301: 39-51.

JAMA 2009; 301: 39-51.

8 http://www.cancer.gov/clinicaltrials/digestpage/SELECT

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33.

⁹ JAMA 2009; 301: 39-51 [emphasis added].

¹⁰ JAMA 2009; 301: 102-3 [emphasis added].

formulations) *did not prevent prostate cancer* in the generally healthy, heterogenous population of men in SELECT."⁹

32. An editorial in the Journal of the American Medical Association accompanying publication of the SELECT results concluded that "physicians should not recommend selenium or vitamin E – or any other antioxidant supplements – to their patients for preventing prostate cancer." ¹⁰

In their letter to the Federal Trade Commission of June 18, 2009, nine

[P]roduced strong evidence last October that selenium does not prevent prostate cancer in a generally healthy, heterogenous population of men in the United States and Canada. This Federally-financed study was the largest individually randomized cancer prevention trial ever conducted, and, given its high rates of adherence and its statistical power, it is unlikely to have missed detecting a benefit of even a very modest size. *Bayer Healthcare is doing a disservice to*

men by misleading them about a protective role for selenium in prostate cancer. We ask that you

take whatever steps are necessary to halt these ads as soon as possible. 11

34. These are not the only studies showing the failure of selenium to prevent prostate cancer. June M. Chan of the University of California at San Francisco and her colleagues at the Dana-Farber Cancer Institute, the Harvard Medical School, and the Fred Hutchinson Cancer Research Center found in their study of plasma selenium and manganese superoxide dismutase (SOD2) genotypes in men with prostate cancer that men with high blood levels of selenium who carried the V allele had a more than two-fold increased risk (RR = 2.48) of presenting with aggressive prostate cancer, a finding that was statistically significant. About 75% of men carry the V allele.

¹¹ http://cspinet.org/new/pdf/bayer-ftc-letter-scientists.pdf [emphasis added].

- 35. They concluded that "for the 75% [of] men who carry a V allele, higher selenium levels might increase the likelihood of having worse tumor characteristics." They cautioned "against broad use of selenium for men with prostate cancer." ¹²
- 36. In fact, Philip Kantoff, MD, director of Dana-Farber's Lank Center for Genitourinary Oncology and senior author of the study, said that "if you already have prostate cancer, it may be a bad thing to take selenium . . . There is some precedent to this [since] research has suggested that antioxidants could be protective if you don't have cancer, but once you do, then antioxidants may be a bad thing." ¹³
- 37. This study involved an ongoing cohort of men diagnosed with prostate cancer who donated blood for research before undergoing any type of local therapy and who consented to clinical research follow-up. It was not a randomized controlled trial and could not demonstrate cause and effect. However, the researchers concluded that it provided "strong support for the hypothesis that plasma selenium levels and SOD2 genotype interact to influence risk of presenting with aggressive prostate cancer at diagnosis in men with localized or locally advanced prostate cancer."
- 38. Despite Bayer's attempts to characterize this study as unexpected and unprecedented, the authors stated in their discussion of the results that data from previous studies indicated that higher doses of selenium could have adverse effects. And while they could not exclude the possibility that men with worse clinical features were taking extra selenium, they went on to say that this was unlikely, in part because the blood was donated shortly after diagnosis.
- 39. Yet another recent study showed that selenium failed to prevent the development of prostate problems, announced April 26, 2009, at the annual meeting of the American Urological Association (AUA).
- 40. In a three-year trial funded by the National Cancer Institute and the Ontario Institute of Cancer Research, men with precancerous lesions in the prostate called high-grade prostatic intraepithelial neoplasia who received a daily supplement of 200 micrograms of

¹² J Clin Oncol 2009; 27: 3577-83.

¹³ http://www.dana-farber.org/abo/news/press/2009/selenium-intake-may-worsen-prostate-cancer-in-some-study-reports.html.

¹⁴ Journal of Urology 2009; 181 (4 Suppl): 263.

15 http://www.auanet.org/content/press/press releases/article.cfm?articleNo=115 [emphasis added].

http://www.healthyontario.com/NewsItemDetails.aspx?newsitem_id=1616. Accessed September 28, 2009.

¹⁷ US Fed News: US Fed News: REVIEW OF PROSTATE CANCER PREVENTION STUDY SHOWS NO BENEFIT FOR USE OF SELENIUM, VITAMIN E SUPPLEMENTS. October 27, 2008.

18 http://www.cancer.gov/newscenter/pressreleases/SELECTJAMAresults2008

selenium, 40 grams of soy protein, and 800 IU of vitamin were just as likely to develop invasive prostate cancer as men who received a placebo.¹⁴

- supplement that will reliably prevent prostate cancer," said Christopher Amling, MD, an AUA spokesman. "The results of this study support the findings of the SELECT trial which also demonstrated no benefit using Vitamin E and selenium. 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." ¹⁵
- 42. "There was great hope that this would be a magic bullet that would help prevent prostate cancer," lead researcher Dr. Neil E. Fleshner, a Clinical Studies Resource Centre Member at the Ontario Cancer Institute and Love Chair in Prostate Cancer Prevention at the University of Toronto, said. "Unfortunately, it doesn't appear to be so." ¹⁶
- 43. The cumulative evidence thus shows that, rather than insuring that its marketing claims were substantiated by good science, Bayer has chosen to ignore the everincreasing scientific data on selenium, instead continuing to make its illegal claims.
- 44. The termination of the SELECT trial because it failed to show any benefit from selenium supplementation became public on October 27, 2008. The results of the SELECT trial were published online on December 9, 2008. And the results were published in the Journal of the American Medical Association on January 7, 2009. The results of National Cancer Institute and Ontario Institute of Cancer Research study were announced in April, 2009. Yet, for more than eight months until after CSPI wrote to it Bayer continued to promote the use of selenium supplementation for the prevention of prostate cancer in advertisements, on its website, and on its package labels.

- 45. On June 18, 2009, CSPI sent Bayer a notice of intent to sue for its false and deceptive marketing of its Men's Multis for prevention of cancer.²⁰ In the letter, CSPI referred to the California laws that form the basis of this lawsuit, and stated that it intended to file a lawsuit against Bayer for fraudulent and deceptive practices in the marketing and sale of Bayer's Men's Multis.
- 46. The letter described Bayer's illegal practices and offered settlement to avoid the necessity of a lawsuit. It said that if litigation was necessary, CSPI planned to seek an injunction prohibiting Bayer from representing that its products can diagnosis, cure, mitigate, treat, or prevent disease. The letter added that CSPI also might seek corrective advertising, restitution, damages, disgorgement, and attorneys' fees.
- 47. On June 30, 2009, counsel for Bayer called CSPI stating that he would like to discuss CSPI's notice letter. Bayer's counsel represented that Bayer would engage in discussions aimed at resolution of the prostate claims. CSPI had a conference call with Bayer's counsel on July 10, 2009, in which it learned that Bayer was more interested in speaking to CSPI about general policy initiatives than addressing the claims at the heart of CSPI's June 18 letter.
- 48. Still hopeful for a resolution about Bayer's prostate claims, CSPI met in person with Bayer's counsel on July 16, 2009. During the meeting, it was clear that Bayer did not intend to reach a settlement about the prostate claims. Bayer instead used the time to present its case for a potential collaboration with CSPI to address FDA policies on health claims, which was not a collaboration CSPI had suggested or desired.
- 49. During the July 16 meeting, CSPI offered the following terms of a settlement: (1) An agreed injunction prohibiting Bayer from making any form of prostate claim for its supplements, with monetary sanctions for violation; (2) cy pres payment amounting to 10% of the gross sales of the two Men's Multis; and (3) minimal attorneys' fees, which included necessary compliance monitoring in the future.

¹⁹ JAMA 2009; 301-: 39-51.

²⁰ CSPI Letter to Bayer, June 18, 2009 (attached as Exhibit 1).

- 50. CSPI had two more conference calls with Bayer's counsel on July 23 and 29, 2009. In the July 23 call, Bayer's counsel represented that Bayer would take off all references to "prostate" from Bayer's websites. However, there would continue to be mention of "prostate" and Bayer on television and in other promotions. Bayer's counsel stated that Bayer would revise the labels of the Men's Multis to remove all references to "prostate." However, the Men's Multis labels with the prostate claims remain on the marketplace shelves.
- 51. Despite all these statements, Bayer refused to enter into a settlement with CSPI about the prostate claims and, significantly, refused to agree not to make the claims in the future.
- 52. On July 30, 2009, Bayer's counsel wrote to CSPI²¹ but did not respond to any point in CSPI's settlement proposal. Instead, it went into lengthy discussions as to why Bayer's actions were legal, in the past, and for the future.
 - 53. Bayer has been caught in illegal behavior many times in the past, including:
 - In 2001, Bayer paid \$14 million to U.S. and state governments to settle allegations that the company's actions helped health care providers submit inflated Medicaid claims for drugs.²²
 - In 2003, Bayer pleaded guilty to a criminal charge and paid \$257 million in fines and penalties after a whistleblower exposed a scheme by the company to overcharge for the antibiotic Cipro.²³ Media accounts at the time described it as the biggest recovery for Medicaid fraud.
 - In 2004, Bayer pleaded guilty to a criminal charge and paid a \$66 million fine after a Justice Department investigation into Bayer's role in a price-fixing conspiracy involving a chemical used to make rubber products. Two Bayer executives separately pleaded guilty and were sentenced to prison for their role in the scandal.

²¹ Bayer Letter to CSPI, July 30, 2009 (attached as Exhibit 2).

²² www.nytimes.com/2001/01/24/us/bayer-to-pay-14-million-to-settle-charges-of-causing-inflated-medicaid-claims html

www.nytimes.com/2003/04/17/business/17DRUG.html.

www.usdoj.gov/atr/public/press_releases/2004/204602.htm.

²⁵ www.ksag.org/page/attorney-general-morrison-announces-30-state-settlement-with-bayer-corporation.

²⁶ www.ftc.gov/opa/2007/01/weightloss.shtm

²⁷ http://www.oag.state.md.us/Press/2009/020909.htm.

²⁸ Bayer Letter to CSPI, September 2, 2009 (attached as Exhibit 3).

- In 2007, Bayer paid \$8 million to resolve allegations by <u>state</u> attorneys general that the company failed to warn physicians and consumers about safety issues surrounding its cholesterol-lowering drug Baycol, which is no longer on the market.²⁵
- Bayer has even gotten into hot water with the federal government in the past over its One A Day marketing. In 2007, it paid a \$3.2 million civil fine as part of a consent decree reached with the Federal Trade Commission and the Department of Justice. The case centered on weight loss claims that the FTC said violated an earlier order requiring that all health claims for One A Day be supported by competent and reliable scientific evidence. Bayer's prostate claims for the Men's Multis violate this consent decree.
- This year, Bayer was required to run a \$20-million corrective advertising campaign about its birth control pill Yaz, and to submit its ads for FDA approval, as part of a settlement secured by a number of <u>state</u> attorneys general and the FDA.²⁷
- 54. Given this history and Bayer's unwillingness to agree not to make its prostate claims in the future, CSPI had no reason to believe that Bayer's actions were in fact a permanent change in its behavior.
- 55. Thus, after exhausting attempts to negotiate a settlement with Bayer, CSPI was compelled to bring this lawsuit on behalf of itself, and on behalf of its members.
- 56. However, this was not the last CSPI heard from Bayer. On September 2, 2009, CSPI received a letter of intent to sue from Bayer.²⁸ In its letter, Bayer threatened to file a lawsuit against CSPI, Stephen Gardner (CSPI's Litigation Director), and any other directors responsible for "CSPI's false, misleading, and defamatory mailing regarding [the Men's Multis],

²⁹ Id.

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SECOND CAUSE OF ACTION FOR INJUNCTIVE RELIEF

(Violation of the Unfair Competition Law, California Business and Professions Code §§17200 et seq.)

- 62. CSPI, on behalf of itself and its members, seeks injunctive relief pursuant to the Unfair Competition Law ("UCL"), California Business and Professions Code §§17200 *et seq.*, to enjoin Bayer from making the prostate claims about its Men's Multis. The UCL defines unfair competition to include any "unlawful," "unfair," or "fraudulent" business act or practice. The UCL authorizes injunctive relief for violations. Bayer's advertisements and labels of its Men's Multis are a business act or practice.
- 63. The marketing of Bayer's Men's Multis with the prostate claims is an unlawful business act or practice because it violates the Consumer Legal Remedies Act, as set forth above.
- 64. Bayer has violated and continues to violate California's food and drug law, the Sherman Law.³² The Sherman Law declares that any food or drug is misbranded if "its labeling is false or misleading in any particular."³³ The Sherman Law also provides that it is unlawful for any person to misbrand any food or drug.³⁴ Bayer's Men's Multis are misbranded because the labeling is false and misleading.
- 65. Bayer has marketed its Men's Multis for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. The Sherman Law prohibits such disease claims for a product unless it is an approved drug.³⁵ Bayer's Men's Multis are not approved drugs, and are therefore sold in violation of this provision of the Sherman Law.

³⁰ Cal. Bus. & Prof. Code §17200.

³¹ *Id.* at §17203.

³² Sherman Food, Drug and Cosmetics Law ("Sherman Law"), Cal. Health & Saf. Code, § 109875 et seq.

³³ Cal. Health & Saf. Code, §§ 110660 and 111330.

³⁴ Cal. Health & Saf. Code, §§ 110765 and 111445. The Sherman Law defines a "person" as "any individual, firm, partnership, trust, corporation, limited liability company, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within the state, and any representative, agent, or agency of any of the foregoing." Cal. Health & Saf. Code § 109995. Each Defendant is a corporation and, therefore, a "person" within the meaning of the Sherman Law.

³⁵ Cal. Health & Saf. Code §§ 109925 and 111330.

- 66. Bayer's violation of the Sherman Law violates the UCL.
- 67. Bayer's business practices with respect to Men's Multis are also unfair within the meaning of the UCL, in that the actions were deceptive, sharp, immoral, unethical, oppressive, unscrupulous, substantially injurious, and operate to the competitive disadvantage of other supplement manufacturers that do not engage in such practices. Moreover, the injury to consumers is substantial, it is not outweighed by any countervailing benefits to consumers or competition, and is one that consumers themselves could not reasonably have avoided.
- 68. As a result of Bayer's unfair and deceptive business practices, CSPI's members have suffered damage and lost money in that they paid for Men's Multis that were not as represented.
- 69. CSPI requests that the Court enjoin Bayer from making prostate claims regarding Men's Multis.

THIRD CAUSE OF ACTION FOR DECLARATORY RELIEF

- 70. An actual controversy has arisen and now exists relating to the rights and duties of the parties in that CSPI contends that Bayer's prostate claims are unlawful, unfair, and fraudulent, whereas Bayer disagrees. CSPI maintains that each prostate claim is unlawful, unfair, and fraudulent in that it is unconscionable, deceptive, and misleading in violation of both the Consumer Legal Remedies Act and the Unfair Competition Law.
- 71. CSPI desires a declaration as to whether each of Bayer's following prostate claims is unlawful, unfair, or deceptive. A judicial declaration is necessary and appropriate at this time so that CSPI may ascertain its rights and duties, the rights and duties of its members, and the rights and duties of Bayer.
 - "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?"
 - "[N]early twice the Selenium in Centrum Silver to support prostate health."
 - "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."

- "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."
- "Did you know one in three men will face prostate issues? One in three, really? That's why One A Day Men's is a complete multivitamin with selenium which emerging research suggests can help prostate health. One A Day Men's."
- "To stay on top of my game after 50, I switched to a complete multivitamin with more. Only One A Day Men's 50+ Advantage has gingko for memory and concentration plus support for prostate and heart health. Safe. That's a great call. One A Day Men's."

Exhibit 1 Letter from Center for Science in the Public Interest to Bayer HealthCare LLC Dated June 18, 2009



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.

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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.

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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,

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. Although the NPC trial's primary objective was to evaluate whether selenium

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

^{4 &}quot;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.

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.

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

Kathrein fampbell Michael F. Jacobson

Michael F. Jacobson, Ph.D. Executive Director

Directions: A	dulis Ore i	akkel di	Ny with food							
Supplement Facts Serving Size: One tablet										
	Amount Per Serving	% Daily Value		ant Per Serving	% Daily Value		Amount Per Serving	% Daily Value		
Vitamin A	3500 IU	70%	Vitamin B ₆	3 mg	150%	Selenium	105 mcg	150%		
			Folic Acid	400 mcg	100%	Copper	2 mg	100%		
Vitamin C	90 mg	150%	Vitamin B ₁₂	18 mcg		Manganese	2 mg	100%		
Vitamin D	400 IU	100%	Biotin	30 mcg	10%	Chromium	120 mcg	100%		
Vitamin E	45 IU	150%	Pantothenic Acid	5 mg	50%	Potassium .	100 mg	3%		
Vitamin K	20 mcg	25%	Calcium (elemental)	210 mg	21%		200 mag	*		
Thiamin (B ₁)	1.2 mg		Iron	O mg	0%	Lycopene	600 mcg			
			Magnesium	120 mg	30%	*Daily Value not	t established.			
Nifacin	16 mg	80%	Zinc	15 mg	100%		****			

INGREDIENTS: Calcium Carbonate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid. di Alpha Tocopheryl Acetale, Corn Sterch, Croscarmellose Sodium, Acacia, Dicalcium Priosphale, Zinc Oxide, Niacinamide, Gafatin, Stearic Acid. Silicon Dicvide Dexim, Magnesium Stearare, D-Calcium Partothemae, Manganese Sulfate, Prindoxine Hydrochloride, Hydrochloride, Cupric Oxide Calcium Silicate. Resin Glucose, Ribollavín, Sidrose Vitamin A Acetate, Thiarrine Mononitrate. Dextrose: Soy Lectifin, Chromium Chloride, Lycopene, Folic Acid. Sodium Carborymeinyfoellulose, Beta-Carotene, Sodium Selenate, Sodium Citrate, Tricalcium Priosphale, Sodium Ascorbate. Tocoobroos, Piolin, Phytosphale Oyanocobalerin, Ergocalciferol, Ascorbyl Parmitate. Contains: Fish (cot.) pollock, haddock, hake, cusk, redish) 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 rish of prostate cancer? One A Day

emerging research suggests Selenium may reduce the rish of prostate cancer? One A Daya, Men's Health Formula is a complete multivitamin plus key nutrients including Selenium to support a healthy prostate.* Selenium may reduce the rish of certain cancers, Some scientific evidence suggests that consumption of Selenium may reduce the rish of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

*Compared to One A Daye Essential, and with nearly twice the Selentian in Centrum® for prostate health
*This slatement has not been evaluated by the Food and Grug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Exhibit 2 Letter from Counsel for Bayer HealthCare LLC to Center for Science in the Public Interest Dated July 30, 2009



SIDLEY AUSTIN LLP 1501 K STREET, N.W. WASHINGTON, D.C. 20005 (202) 736 8000 (202) 736 8711 FAX BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
SYDNEY
TOKYO'
WASHINGTON-D.C.

jcohn@sidley.com (202) 736-8110

FOUNDED 1866

July 30, 2009

Stephen Gardner
Director of Litigation
Center for Science
in the Public Interest
1875 Connecticut Avenue, NW
Suite 300
Washington, DC 20009

Re: One A Day® Men's & One A Day® Men's 50+ Multivitamins

Dear Steve:

As per your request during our conference call on July 29, 2009, we write to describe our proposal for addressing the issues and concerns that you have raised regarding One A Day® Men's & One A Day® Men's 50+ Multivitamins. Of course, as you know, Bayer HealthCare LLC ("Bayer") already decided to remove from its labels and advertisements all of the language to which you are objecting. Bayer diligently monitored the emerging science addressing the connection between selenium and prostate health. And, in light of recent studies and the position of the U.S. Food and Drug Administration ("FDA"), Bayer is revising the labels and advertisements.

We have also discussed our willingness to continue working with the Center for Science in the Public Interest ("CSPI") on how to establish best industry standards for qualified health claims. Although we have no doubt that the One A Day® Men's & One A Day® Men's 50+ labels and advertisements are not misleading and are protected by the First Amendment, see, e.g., Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), we are willing to consider alternative standards going forward. To reach agreement on best industry standards, we have offered to have a dialogue with you on how to proceed. One possibility is to file a citizens petition with the FDA, but this is by no means the only way, or necessarily even the best way, to resolve the issue. As previously discussed, we are also willing "to sit down at the table" with you, the FDA, and other members of the industry.

In our view, through such a process, we can reach a satisfactory agreement with you and within the industry on best standards, perhaps with the imprimatur of the agency. And we are confident that this is the most promising path to reaching a resolution that is beneficial to



Stephen Gardner July 30, 2009 Page 2

the industry and consumers alike. In any event, as explained on the call, we are open to negotiating other possibilities for finding a *prospective* solution.

Finally, although there is no need to reiterate our analysis of the merits (or lack thereof) of a possible lawsuit, we did want to continue our conversation on why CSPI should not be setting its sights on One A Day® Men's and Men's 50+. Not only are the products' claims protected under *Pearson* – which rejects the suppression of a manufacturer's claims where, as here, an FDA-drafted disclaimer cures any alleged misleadingness, *see Pearson*, 164 F.3d at 658-59 – but (1) Bayer had evidence supporting the connection between selenium and prostate health, as the FDA itself acknowledge in 2003, (2) Bayer's decision to speak specifically of "prostate cancer" instead of generically of "certain cancers" accords with the science and FDA's current position, (3) Bayer diligently monitored the science and responded to the new studies as reflected in the FDA's current position, ¹ (4) the government was simultaneously examining at length the connection between selenium and prostate cancer, which confirms that the issue was a serious one, and (5) unlike other members of the industry, Bayer did not "split" its claims from the disclaimer in an attempt to hide the disclaimer. Accordingly, we respectfully suggest that, if CSPI concludes that consumers would benefit from a lawsuit, CSPI should identify a different target.

Again, we are willing to chat more about these issues at your convenience.

Very truly yours,

Yonathan F. Cohn

JFC:lea

¹ We further note that, although Bayer has decided to change its labels and advertisements in light of the recent studies and the FDA's current position, others are challenging the FDA's new position on First Amendment grounds. We have learned that a lawsuit will be filed tomorrow, putting before the courts the constitutionality of the FDA's approach to qualified health claims.

Exhibit 3 Letter from Counsel for Bayer HealthCare LLC to Center for Science in the Public Interest to Dated September 2, 2009



SIDLEY AUSTIN LLP 1501 K STREET, N.W. WASHINGTON, D.C. 20005 (202) 736 8000 (202) 736 8711 FAX BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.

jcohn@sidley.com (202) 736-8110

FOUNDED 1866

September 2, 2009

Michael F. Jacobson, Ph.D. Executive Director Center for Science in the Public Interest 1875 Connecticut Ave. N.W. Suite 300 Washington, D.C. 20009

Dear Dr. Jacobson:

Bayer HealthCare LLC ("Bayer") provides you with notice that it may file a lawsuit against the Center for Science in the Public Interest, Stephen Gardner, and any other directors who are responsible (collectively, "CSPI") for CSPI's false, misleading, and defamatory mailing regarding One A Day® Men's & One A Day® Men's 50+ multivitamins (together, "One A Day"), and for similar statements that CSPI previously made in press releases and on its website.

This letter summarizes the basis for legal action against CSPI and offers a settlement to avoid a lawsuit. If litigation is necessary, Bayer plans to seek, among other relief, (1) an injunction prohibiting CSPI from making any further misstatements about One A Day or any of Bayer's other products, (2) monetary damages including punitive damages, (3) a corrective statement sent to all recipients of the unlawful mailing, and (4) attorneys' fees.

Facts Giving Rise to CSPI's Liability

CSPI accuses Bayer of "ripp[ing] off" consumers and "exploiting men's fear of prostate cancer." In support of these unjust and ill-founded claims, CSPI makes no fewer than three material misrepresentations. The falsity of these statements is readily apparent from the very studies and agency decisions that CSPI cited in its June 18, 2009, letter to Bayer, a copy of which is attached for your convenience (Attachment A).

First, CSPI claims that, "[i]n fact, for most men, taking too much selenium may actually promote more aggressive forms of prostate cancer." The alleged established fact, however, appears to be nothing more than a single cross-sectional study, which openly states that its finding was "unexpected," never before observed, "somewhat in contrast to several studies," possibly just "a result of chance," and in need of "further confirmation in humans." June M. Chan et al., Plasma Selenium, Manganese Superoxide Dismutase, and Intermediate- or High-

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Michael F. Jacobson, Ph.D. September 2, 2009 Page 2

Risk Prostate Cancer, Journal of Clinical Oncology, Vol. 27, Issue 22, at 3577-3583 (August 1, 2009) (hereinafter, "JCO study"). Nowhere in its mailing does CSPI share any of this pertinent information with consumers.

Moreover, the observational study did not conclude that higher levels of selenium in the blood caused more aggressive forms of cancer. Rather, the researchers admitted that they could not rule out the possibility that the "inability to adjust for potential confounding factors such as body size or diet, and lack of racial diversity" skewed the results. Id. at 5. This is a major limitation on the study's design and the ability to draw conclusions from its data. See American Cancer Society, Overview: Prostate Cancer What Causes Prostate Cancer? (explaining that obesity, diet, and race can affect likelihood of getting prostate cancer or having more advanced disease). In addition, the researchers did not exclude the possibility that "the slight positive association for selenium and risk of aggressive disease was a result of patients with worse clinical features taking selenium supplements out of concerns about their diagnosis." JCO study at 5. But, instead of informing the public of what the study actually said or what limitations it candidly acknowledged, CSPI presents its own unsubstantiated conjecture in the misleading guise of established "fact."

Second, CSPI states that "previous studies warned against supplementing with selenium since men taking selenium developed more cases of diabetes than men in control groups who did not." CSPI fails to mention, however, that researchers in the SELECT trial emphasized that any observed increase in diabetes was not statistically significant and may have been due entirely to chance. See Scott M. Lippman et al., Effect of Selenium and Vitamin E on Risk of Prostate Cancer and Other Cancers: The Selenium and Vitamin E Cancer Prevention Trial (SELECT), Journal of the American Medical Association, 301(1), at 45 (January 7, 2009); see also National Institutes of Health, National Cancer Institutes, Questions & Answers, Selenium and Vitamin E Cancer Prevention Trial (SELECT), Key Points. The JCO study on which CSPI relies also states that the increase in diabetes risk in the SELECT study was not scientifically significant. See Chan at 5. By misrepresenting the conclusions of the SELECT trial, CSPI misled the public, defamed Bayer, and disparaged its products.

Third, CSPI proclaims that "[i]t's not true" that "mineral selenium helps reduce risk of prostate cancer or otherwise promotes prostate health." As CSPI knows, however, it has no basis for this definitive conclusion. The FDA has never taken such a position and has not banned the selenium claim, not even after the SELECT trial. Selenium and Reduced Risk of Site-Specific Cancers, FDA-2008-Q-0323 (June 19, 2009) ("FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer."). Indeed, from February 2003 until

http://www.cancer.org/docroot/CRI/content/CRI 2 2 2X What causes prostate cancer 36.asp?sitearea

¹ available at



Michael F. Jacobson, Ph.D. September 2, 2009 Page 3

June 2009, FDA permitted the industry to claim that "[s]elenium may reduce the risk of certain cancers" – most notably, prostate cancer – provided that the label also disclosed that "FDA has determined that this evidence is limited and not conclusive." Letter Regarding Dietary Supplement Health Claim for Selenium and Certain Cancers (Docket No. 02P-0457) (February 21, 2003). Bayer included the requisite disclaimer on its label verbatim and did not mislead consumers in the least.

Moreover, CSPI fails to disclose that on or about June 19, 2009 – the day FDA revised its position regarding selenium and specific cancers – Bayer decided to discontinue its use of the prostate qualified health claim. CSPI knew about this decision – we disclosed it both orally and in writing (Attachment B) – yet CSPI never mentions this fact in its mailing. Instead, CSPI represents that "Bayer is exploiting men's fear of prostate cancer" and "ripp[ing] off" consumers, whereas, in reality, Bayer was following FDA's guidance, diligently monitoring the emerging science, and promptly choosing to revise its labels once it became appropriate to do so.

The irony of CSPI's letter is not lost on Bayer. CSPI previously asserted that Bayer misstated the effects of selenium. But, in seeking to turn consumers against Bayer, CSPI itself profoundly misrepresented the effects of selenium. In short, CSPI did precisely what it unjustifiably claimed Bayer had done.

The difference, of course, is that Bayer always included appropriate disclaimers to reflect the uncertainty in the emerging science, and Bayer actively monitored new studies and changed its labels in light of those studies. CSPI, by contrast, has done none of that, opting instead to misrepresent statistical insignificance as metaphysical certainty and scientific disagreement as established fact. The First Amendment does not protect CSPI's false and defamatory statements, which are actionable under state tort law.

CSPI's Violations of State Laws

Under California law, libel is prohibited by statute. See Cal. Civ. Code § 45 ("Libel is a false and unprivileged publication by writing, printing, picture, effigy, or other fixed representation to the eye, which exposes any person to hatred, contempt, ridicule, or obloquy, or which causes him to be shunned or avoided, or which has a tendency to injure him in his occupation"). The elements of the offense track the common law. See, e.g., Restatement (Second) § 559 ("A communication is defamatory if it tends so to harm the reputation of another as to lower him in the estimation of the community or to deter third persons from associating or dealing with him."); § 569 ("One who falsely publishes matter defamatory of another in such a manner as to make the publication a libel is subject to liability to the other although no special harm results from the publication."). Plaintiffs can receive both presumed and punitive damages. See, e.g., Restatement § 621 (including comments); Knox v. Taylor, 992 S.W.2d 40 (Ct. App.

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Michael F. Jacobson, Ph.D. September 2, 2009 Page 4

Tex. 1999) (affirming jury verdict awarding, *inter alia*, presumed damages of \$850,000 and punitive damages of \$100,000); *see also* Restatement (Second) § 561 (recognizing corporations can sue for defamation); *General Motors Acceptance Corp. v. Howard*, 487 S.W.2d 708 (Tex. 1972) (same). Because CSPI maliciously and falsely asserted that Bayer was "exploiting" and "ripp[ing]" off consumers – statements which are naturally intended to tarnish the reputation of the company – Bayer intends to sue CSPI for libel.

Bayer also has a cause of action against CSPI for injurious falsehood (also referred to as business disparagement or trade libel). See Restatement (Second) § 623A ("One who publishes a false statement harmful to the interests of another is subject to liability for pecuniary loss resulting to the other if (a) he intends for publication of the statement to result in harm to interests of the other having a pecuniary value, or either recognizes or should recognize that it is likely to do so, and (b) he knows that the statement is false or acts in reckless disregard of its truth or falsity."); Granada Biosciences v. Forbes, 49 S.W.3d 610 (Ct. App. Tex. 2001) (holding that a statement is actionable as business disparagement if it is "misleading and defamatory when viewed in its entirety," including by "omitting material facts or juxtaposing facts in a misleading way"); Charles Atlas v. Time-Life Books, 570 F. Supp. 150 (S.D.N.Y. 1983). Under this claim, Bayer would seek to recover any pecuniary loss resulting from the mailing as well as the expenditures that are reasonably necessary to counteract the illicit publication, including attorneys' fees. See, e.g., Restatement (Second) § 633.

In addition, CSPI's false statements offend other state laws, such as intentional interference with prospective business advantage. See Restatement (Second) § 766B. And, if CSPI were to contend that its mailing was a solicitation for clients, the statements would implicate the Lanham Act, 15 U.S.C. 1125(a)(1)(B) ("Any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act."), and state bar rules, see, e.g., Texas Disciplinary Rules of Professional Conduct, Rule 7.05 (prohibiting written solicitations that contain "a false, fraudulent, misleading, deceptive, or unfair statement or claim").



Michael F. Jacobson, Ph.D. September 2, 2009 Page 5

Settlement Demand

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

- A corrective statement, approved by Bayer, sent by CSPI to all recipients of the unlawful mailing.
- Entry of a permanent injunction that prohibits CSPI from making any further misstatements against One A Day or any of Bayer's other products.
- Payment of all attorneys' fees incurred by Bayer as a result of CSPI's mailing.

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 becomes null and void.

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

Very truly yours,

Anathan F. Colof 1844

Jonathan F. Cohn

Stephen Gardner, Litigation Director

cc:

TAB A



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.

June 18, 2009 page 2

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.

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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,

Stephen Gardner Litigation Director

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

TAB B



SIDLEY AUSTIN ILP 1501 K STREET, N.W. WASHINGTON, D.C. 20005 (202) 736 8000 (202) 736 8711 FAX BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG

LONDON

LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
SYONEY
TOKYO
WASHINGTON, D.C.

jcohn@sidley.com (202) 736-8110

FOUNDED 1868

July 30, 2009

Stephen Gardner
Director of Litigation
Center for Science
in the Public Interest
1875 Connecticut Avenue, NW
Suite 300
Washington, DC 20009

Re: One A Day® Men's & One A Day® Men's 50+ Multivitamins

Dear Steve:

As per your request during our conference call on July 29, 2009, we write to describe our proposal for addressing the issues and concerns that you have raised regarding One A Day® Men's & One A Day® Men's 50+ Multivitamins. Of course, as you know, Bayer HealthCare LLC ("Bayer") already decided to remove from its labels and advertisements all of the language to which you are objecting. Bayer diligently monitored the emerging science addressing the connection between selenium and prostate health. And, in light of recent studies and the position of the U.S. Food and Drug Administration ("FDA"), Bayer is revising the labels and advertisements.

We have also discussed our willingness to continue working with the Center for Science in the Public Interest ("CSPI") on how to establish best industry standards for qualified health claims. Although we have no doubt that the One A Day® Men's & One A Day® Men's 50+ labels and advertisements are not misleading and are protected by the First Amendment, see, e.g., Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), we are willing to consider alternative standards going forward. To reach agreement on best industry standards, we have offered to have a dialogue with you on how to proceed. One possibility is to file a citizens petition with the FDA, but this is by no means the only way, or necessarily even the best way, to resolve the issue. As previously discussed, we are also willing "to sit down at the table" with you, the FDA, and other members of the industry.

In our view, through such a process, we can reach a satisfactory agreement with you and within the industry on best standards, perhaps with the imprimatur of the agency. And we are confident that this is the most promising path to reaching a resolution that is beneficial to

SIDLEY

Stephen Gardner July 30, 2009 Page 2

the industry and consumers alike. In any event, as explained on the call, we are open to negotiating other possibilities for finding a *prospective* solution.

Finally, although there is no need to reiterate our analysis of the merits (or lack thereof) of a possible lawsuit, we did want to continue our conversation on why CSPI should not be setting its sights on One A Day® Men's and Men's 50+. Not only are the products' claims protected under *Pearson* — which rejects the suppression of a manufacturer's claims where, as here, an FDA-drafted disclaimer cures any alleged misleadingness, see *Pearson*, 164 F.3d at 658-59 — but (1) Bayer had evidence supporting the connection between selenium and prostate health, as the FDA itself acknowledge in 2003, (2) Bayer's decision to speak specifically of "prostate cancer" instead of generically of "certain cancers" accords with the science and FDA's current position, (3) Bayer diligently monitored the science and responded to the new studies as reflected in the FDA's current position, (4) the government was simultaneously examining at length the connection between selenium and prostate cancer, which confirms that the issue was a serious one, and (5) unlike other members of the industry, Bayer did not "split" its claims from the disclaimer in an attempt to hide the disclaimer. Accordingly, we respectfully suggest that, if CSPI concludes that consumers would benefit from a lawsuit, CSPI should identify a different target.

Again, we are willing to chat more about these issues at your convenience.

Very truly yours,

Jonathan F. Cohn

JFC:lea

¹ We further note that, although Bayer has decided to change its labels and advertisements in light of the recent studies and the FDA's current position, others are challenging the FDA's new position on First Amendment grounds. We have learned that a lawsuit will be filed tomorrow, putting before the courts the constitutionality of the FDA's approach to qualified health claims.