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SUPERIOR COURT
SAN DIEGO COUNTY, CA

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*No fee pursuant to Government Code
Section 6103*
SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO

THE PEOPLE OF THE STATE OF CALIFORNIA,

v.
BAYER HEALTHCARE LLC,

Plaintiff,

Defendant.

Case No. **37-2010-00103098-CU-MC-CTL**
COMPLAINT FOR INJUNCTION, CIVIL PENALTIES, AND OTHER EQUITABLE RELIEF

Assign to Master Calendar

Dept:
Judge:

Plaintiff, the People of the State of California (“the People” or “Plaintiff”), by its attorney Edmund G. Brown Jr., Attorney General of the State of California, alleges upon information and belief as follows:

JURISDICTION AND PARTIES

1. Defendant at all relevant times have transacted business in the City and County of San Diego and elsewhere in the State of California. The violations of law alleged herein have

1 been and are being carried out within the City and County of San Diego and elsewhere in
2 California.

3 2. Defendant BAYER HEALTHCARE LLC (“Bayer” or “Defendant”) is a healthcare
4 and medical products company with its U.S. headquarters for one of its divisions, Bayer
5 Consumer Care, in Morristown, New Jersey.

6 3. Defendant at all relevant times has transacted business in the City and County of San
7 Diego, and elsewhere in the State of California. Defendant has violated and is currently violating
8 the law within the City and County of San Diego, and elsewhere in California.

9 4. Bayer manufactures, markets, and promotes One-A-Day Vitamins nationally and in
10 California. The One-A-Day brand is divided into various sub-brands that target particular
11 populations of consumers by age and sex. One-A-Day Men’s Health Formula targets males and
12 One-A-Day Men’s 50+ vitamins target men 50 years of age and older (collectively “One-A-Day
13 Men’s,” “OAD Men’s Products” or “OAD Men’s”).

14 **SUMMARY OF THE ACTION**

15 5. Bayer sought to increase the sale of OAD Men’s Products by deceptively leveraging
16 fear of prostate cancer. Bayer made both express and implied promotional claims that
17 misrepresented that OAD Men’s Products reduce a man’s risk of developing prostate cancer.
18 Bayer made these claims despite the fact that Bayer knew, or should have known, that the
19 ingredients in OAD Men’s Products do not decrease the risk of prostate cancer; in fact, Bayer
20 knew or should have known that for some men, high doses of the ingredients found in Bayer
21 OAD Men’s Vitamins, such as zinc and selenium, may increase the risk of an aggressive and
22 deadly form of prostate cancer. Accordingly, Bayer’s promotion of OAD Men’s Products was
23 deceptive, unfair, untrue, and misleading.

24 **PROSTATE CANCER CLAIMS - LYCOPENE**

25 6. To support its initial prostate cancer claim, Bayer relied upon the ingredient lycopene.
26 Starting in 2005, Bayer television advertisements claimed that “one in three men” had prostate
27 problems and that OAD Men’s Health Formula with lycopene “supports prostate health.” Bayer
28 knew, or should have known, that substantial numbers of viewers understood these claims to

1 mean that OAD Men's Health Formula with lycopene reduced a man's risk of developing
2 prostate cancer. Moreover, Bayer's lycopene advertisements cited "Harvard studies" to
3 substantiate the prostate health claim. These studies, however, related solely to prostate cancer
4 and no other aspect of prostate health. Thus, any consumer who actually obtained and read the
5 studies would know that Bayer intended to make a lycopene cancer claim. Nonetheless, the
6 studies that Bayer cited were not competent and reliable scientific evidence sufficient to
7 substantiate the lycopene prostate cancer claim. In a 2005 enforcement discretion letter issued by
8 the Food and Drug Administration ("FDA") that reviewed the totality of the science concerning
9 lycopene and prostate cancer, the FDA concluded that, although "very limited and preliminary
10 scientific research suggests" tomato products (which contain lycopene) may reduce the risk of
11 prostate cancer, there is "no credible evidence" to substantiate such a claim for lycopene
12 supplements [such as OAD Men's]."

13 PROSTATE CANCER CLAIMS -SELENIUM

14 7. Starting in 2006, Bayer OAD Men's Health Formula advertisements stopped
15 emphasizing lycopene and started using selenium to support the prostate cancer prevention
16 claim. Bayer believed it could make such a claim because in 2003, the FDA issued an
17 enforcement discretion letter announcing that the FDA would not prosecute the qualified health
18 claim "*[s]elenium may reduce the risk of certain cancers. Some scientific evidence suggests that*
19 *consumption of selenium may reduce the risk of certain forms of cancer.*" Bayer's express
20 cancer claims regarding selenium, however, did not comply with the language the FDA
21 announced it would tolerate. Rather, Bayer used language such as: "*Did you know that 1 in 3*
22 *men will face prostate issues*" along side "*emerging research suggests Selenium may reduce the*
23 *risk of prostate cancer.*" A copy of one such print advertisement is attached hereto as Exhibit A.
24 Such language is inconsistent with the 2003 qualified health claim. Moreover, it is deceptive
25 because by 2006, and especially after October 2008, the "emerging science" selenium prostate
26 cancer claim was incorrect and misrepresented the scientific substantiation for the claim. Bayer
27 used this deceptive selenium cancer claim in television and print advertising through June 2009
28

1 and used it in OAD Men's Health Formula packaging that was on store shelves as late as May
2 2010.

3 MAJOR LEAGUE BASEBALL

4 THE "STRIKE OUT PROSTATE CANCER" PROMOTION

5 8. Starting in 2008, Bayer entered into a promotional relationship with Major League
6 Baseball that allowed Bayer to promote OAD Men's Products during baseball games and allowed
7 Bayer to use major league baseball graphics and players to promote OAD Men's Products. As
8 part of this promotion, Bayer engaged in a "strike out prostate cancer" campaign that was
9 ostensibly to raise money for prostate cancer research but in fact, was a vehicle to make deceptive
10 claims that OAD Men's Products helped prevent prostate cancer. Through billboards, print and
11 broadcast advertisements, and interviews with professional baseball spokespersons, Bayer's
12 Major League Baseball promotional campaign made express and implied claims that OAD Men's
13 Products reduced the risk of prostate cancer. Plaintiff attaches a copy of one such print
14 advertisement to this complaint as Exhibit B. In fact, by October 2008, it was clear that OAD
15 Men's Products provided no such benefit.

16 EMERGING SCIENCE SUBMERGES

17 BAYER'S PROSTATE CANCER CLAIMS

18 9. Although in 2003, using the methodology then used by the FDA (which has since
19 been rejected) to evaluate and weight scientific studies, there may have been sufficient science to
20 support the limited qualified health claim approved by the FDA regarding selenium and cancer,
21 over time, the science supporting the qualified claim grew progressively weaker. Rather than
22 strengthening the selenium prostate cancer claim, "emerging science," submerged the claim
23 beneath a rising tide of negative scientific studies.¹ This process culminated in October 2008,
24 when the results of the clinical trial known as The Selenium and Vitamin E Cancer Prevention

25 _____
26 ¹ Li et al., *A prospective study of plasma selenium levels and prostate cancer risk*, Journal
27 of the National Cancer Institute, 2004; 96:696-703. Peters et al., *Serum selenium and risk of*
28 *prostate cancer: a nested case-control study*. American Journal of Clinical Nutrition, 2007;
85:209-217. Peters et al., *Vitamin E and selenium supplementation and risk of prostate cancer in*
the Vitamins and Lifestyle (VITAL) study cohort, Cancer Causes Control, 2008; 19:75-87.

1 Trial (“SELECT”) became public. SELECT was funded by the National Institute of Health and
2 was designed to definitively determine whether vitamin E and/or selenium reduce the risk of
3 prostate cancer. This prospective, randomized, controlled, double-blind study was the largest and
4 best designed clinical trial relating to selenium and prostate cancer ever conducted. At the time
5 SELECT was designed, hopes were high that it would show a benefit for selenium and vitamin E
6 against prostate cancer; however, these hopes were dashed when the Data Safety Monitoring
7 Board² (“DSMB”) for SELECT was forced to stop the study after preliminary results showed
8 selenium provided no such benefit and might actually cause study subjects harm. After SELECT,
9 there was broad scientific consensus that selenium did not prevent prostate cancer. Nevertheless,
10 Bayer continued to promote OAD Men’s Health Formula with the “emerging science” selenium
11 prostate cancer claim.

12 **BAYER IMPROPERLY CONTINUED TO RELY**
13 **ON THE 2003 SELENIUM CANCER CLAIM**

14 10. Although Bayer had an independent duty to ensure that there was competent and
15 reliable scientific evidence to substantiate all promotional claims regarding selenium and prostate
16 cancer, Bayer chose instead to ignore the weight of scientific evidence to the contrary and relied
17 upon the obsolete and inapplicable 2003 the FDA letter to justify continued use of the
18 claim. Bayer relied on the obsolete 2003 selenium enforcement discretion letter even though
19 Bayer knew, as early as 2007, that the FDA was in the process of reviewing the claim and even
20 though Bayer knew, or should have known, that by January 2009, the FDA had finalized and
21 published its revised methodology for evaluating qualified health claims and that under that
22 revised methodology, it was virtually certain that the 2003 selenium discretion letter would be
23 replaced. Yet Bayer continued to rely on weak science³ to actively advertise and promote OAD

24 ² A Data Safety Monitoring Board or “DSMB” is an independent body tasked with
25 ensuring the safety of participants in clinical trials. The DSMB has access to unblended study
26 data which is reviewed to ensure that there is sufficient benefit to justify the risks. If such is not
27 the case, the DSMB is ethically required to terminate the clinical trial.

28 ³ To substantiate its selenium cancer claim, Bayer relied primarily on seven secondary
post-hoc analyses of a single trial, the Nutritional Prevention of Cancer (“NPC”) trial. This
clinical trial evaluated the relationship between supplemental selenium and skin cancer risk,
which was the primary predefined end-point of the study. The seven post hoc analyses sought to
(continued...)

1 Men's Health with a selenium prostate cancer claim. It was not until June of 2009, when the FDA
2 formally issued a revised enforcement discretion letter regarding selenium and cancer that Bayer
3 seriously considered revising its Selenium prostate cancer claim. In the 2009 version, the FDA
4 held that "it is highly unlikely that selenium supplements reduce the risk of prostate cancer."⁴ It
5 was only then that Bayer announced that it would stop making its selenium cancer claim to
6 promote OAD Men's Products; however, Bayer failed to make this change in their product
7 labeling until much later.

8 **BAYER CONTINUED TO DISSEMINATE**

9 **THE DECEPTIVE SELENIUM PROSTATE CANCER CLAIM**

10 11. Even after the FDA formally revised the 2003 selenium cancer claim and after
11 Bayer publicly announced it would stop making the prostate cancer promotional claim, Bayer
12 made no attempt to withdraw or recall OAD Men's Products with deceptive prostate cancer
13 messaging. Rather, Bayer continued to manufacture and distribute OAD Men's Product with the
14 deceptive prostate claim through November 2009. Because of Bayer's failure to take timely
15 action, OAD Men's Products with deceptive prostate packaging remained on store shelves until at
16 least May 2010 – more than 18 months after the SELECT study definitively showed that selenium
17 was ineffective and almost one year after Bayer publicly announced that it would stop making
18 prostate cancer claims in its packaging and promotion of OAD Men's Health.

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(...continued)

23 "data mine" for other types of cancer, including prostate cancer; however, such data mining is
24 only beneficial for generating hypotheses to be tested in future studies and not to substantiate
25 efficacy claims. (In fact, the suggestions raised by NPC generated the hypotheses that were tested
26 by SELECT). In its 2009 review of the scientific evidence concerning the relationship between
27 supplemental selenium and cancer, FDA determined that "scientific conclusions about selenium
28 supplements and secondary cancers [including prostate cancer] could not be drawn from the
seven [NPC] reports. . . ."

⁴In October, 2010, following litigation between FDA and a supplement manufacturer,
FDA revised the qualified health claim to: "Selenium may reduce the risk of prostate cancer.
Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not
agree that selenium may reduce the risk of prostate cancer."

1 **MULTIVITAMINS WITH THE INGREDIENTS FOUND**
2 **IN OAD MEN'S MAY WORSEN PROSTATE CANCER**

3 12. In addition to demonstrating that selenium had no beneficial impact, SELECT
4 raised serious concerns that selenium might have a negative impact on men's health. These
5 concerns were so great that the SELECT DSMB took the extraordinary step of stopping the study
6 midstream. Moreover, starting in 2007, there was mounting scientific evidence that raised
7 significant concerns that multivitamins containing the ingredients found in OAD Men's Products
8 might increase the risk of particularly aggressive prostate cancers in certain people.⁵ Despite the
9 mounting evidence that for some men, the ingredients in OAD Men's vitamins may have a
10 negative impact on prostate health, Bayer unconscionably persisted in promoting OAD Men's
11 Vitamins as supporting prostate health and reducing the risk of prostate cancer, without disclosing
12 that OAD Men's vitamins might very well have the opposite effect.

13
14 **FIRST CAUSE OF ACTION**
15 **Violations of Business and Professions Code**
16 **Section 17500 (Untrue or Misleading Representation)**

17 13. Plaintiff realleges and incorporates by reference paragraphs 1 through 12,
18 inclusive, as though fully set forth in this cause of action.

19 14. Defendant, in violation of Business and Professions Code section 17500, with the
20 intent to induce members of the public to purchase Bayer's One-A-Day Men's Health Formula
21 and One-A-Day Men's 50+ vitamins, made and caused to be made representations concerning
22 One-A-Day Men's Health Formula and One-A-Day Men's 50+ vitamins which Bayer knew, or
23 by the exercise of reasonable care should have known, were untrue or misleading at the time they

24
25 ⁵ Lawson et al., *Multivitamin Use and Risk of Prostate Cancer in the National Institutes of*
26 *Health – AARP Diet and Health Study*, Journal of the National Cancer Institute, 2007; 99:754-64.
27 Zhang et al., *Vitamin and mineral use and risk of prostate cancer: the case-control surveillance*
28 *study*, Cancer Causes Control, 2009; 20:691-698. Chan et al., *Plasma Selenium, Manganese*
Superoxide Dismutase, and Intermediate- or High-Risk Prostate Cancer, Journal of Clinical
Oncology, 2009; 27:3577-3583.

1 were made, by misrepresenting that One-A-Day Men's Health Formula and One-A-Day Men's
2 50+ vitamins reduce a man's risk of developing prostate cancer and "support prostate health."

3 **SECOND CAUSE OF ACTION**
4 **Violations of Business and Professions Code**
5 **Section 17200 (Acts of Unfair Competition)**

6 15. Plaintiff realleges and incorporates by reference paragraphs 1 through 14,
7 inclusive, as though fully set forth in this cause of action.

8 16. Defendant has engaged in unfair competition as defined in Business and
9 Professions Code section 17200, in that:

10 a. Defendant has violated Business and Professions Code section 17500 as
11 alleged in paragraph 14 of the above First Cause of Action.

12 b. Defendant employed deceptive, unfair, untrue, and misleading sales tactics
13 by promoting One-A-Day Men's Health Formula and One-A-Day Men's 50+ vitamins to
14 protect against prostate cancer without disclosing that some of the ingredients in these
15 products that were promoted to support prostate health may *increase* the risk of an
16 aggressive and deadly form of prostate cancer.

17 **WHEREFORE**, Plaintiff prays for relief as follows:

18 1. That an injunction should issue under the authority of Business and Professions
19 Code sections 17203 and 17535 restraining and enjoining Defendant and its agents, employees,
20 and all other persons and entities, corporate or otherwise, in active concert or participating with
21 any of them, from engaging in actions of unfair competition or deceptive conduct or making any
22 untrue or misleading representations, including the following:

23 a) Bayer, in connection with the manufacturing, labeling, advertising, promotion,
24 offering for sale, sale, or distribution of One A Day Men's Health Formula and
25 One A Day Men's 50+ Advantage, in or affecting commerce, shall not make,
26 directly or by implication, including through the use of a product name,
27 endorsement, depiction, or illustration, any representation that such product is
28 effective in the diagnosis, cure, mitigation, treatment, or prevention of any
disease, including but not limited to the representation that One A Day Men's

1 Health Formula and One A Day Men's 50+ Advantage reduces the risk of prostate
2 cancer.

3 b) Bayer, in connection with the manufacturing, labeling, advertising, promotion,
4 offering for sale, sale, or distribution of any Covered Product⁶, in or affecting
5 commerce, shall not make, directly or by implication, including through the use of
6 a product name, endorsement, depiction, or illustration, any representation about
7 the health benefits, performance, or efficacy of any Covered Product, unless the
8 representation is non-misleading, and, at the time the representation is made,
9 Bayer possesses and relies upon Competent and Reliable Scientific Evidence⁷.

10 2. That under the authority of Business and Professions Code sections 17206 and
11 17536, Defendant should be assessed a civil penalty of Two Thousand Five Hundred Dollars
12 (\$2,500) for each violation of Business and Professions code sections 17200 and 17500, as
13 proved at trial.

14 3. That Plaintiff recovers its attorney's fees and costs of suit, including costs of
15 investigation.

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⁶ "Covered Product" shall mean any dietary supplement in Bayer's line of One A Day Multivitamins, including but not limited to One A Day Men's Health Formula and One A Day Men's 50+ Advantage.

⁷ "Competent and Reliable Scientific Evidence" shall mean tests, analyses, research, or studies, that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results, and that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

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4. For such other and further relief that the Court deems just, proper, and equitable.

Dated: Oct. 26, 2010

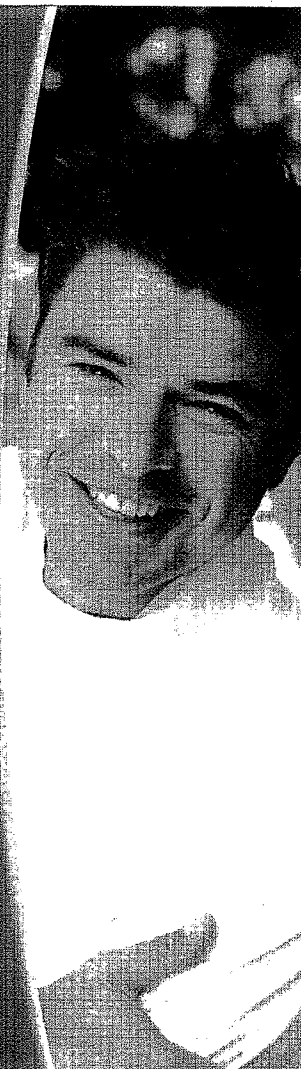
Respectfully Submitted,
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FRANCES T. GRUNDER
Senior Assistant Attorney General
DANIEL A. OLIVAS
Supervising Deputy Attorney General


JUDITH FIORENTINI
Deputy Attorney General
Attorneys for Plaintiff

Exhibit A

MEN'S HEALTH
FORMULA

Did you
know
1 in 3 men
will face
prostate
issues?



*Specially formulated with
Selenium which emerging
research suggests may reduce
the risk of prostate cancer***

Prostate cancer is the most frequently diagnosed cancer in men, and 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 to support a healthy heart, and Selenium to support a healthy prostate.*

A Complete Multivitamin Plus More[†]
for Men to Support:*

- Prostate Health with Lycopene, more[†] Selenium, Vitamin E and Zinc
- Heart Health with Vitamins B6, B12, C, E and Folic Acid
- Healthy Blood Pressure^{††} with Calcium, Magnesium and Vitamin C

Does not contain Iron – Research suggests excess iron may increase a man's risk of heart disease



[†] Compared to ONE A DAY® Essential, and with nearly twice the Selenium in Centrum® for prostate health
^{††} To help maintain blood pressure levels already within the normal range
^{**} See packaging for information about Selenium and certain cancers.

MEN'S HEALTH
FORMULA

Exhibit B

STRIKING OUT PROSTATE CANCER

ONE A DAY

Men's Health

PRESENTS

STRIKEOUT PROSTATE CANCER CHALLENGE

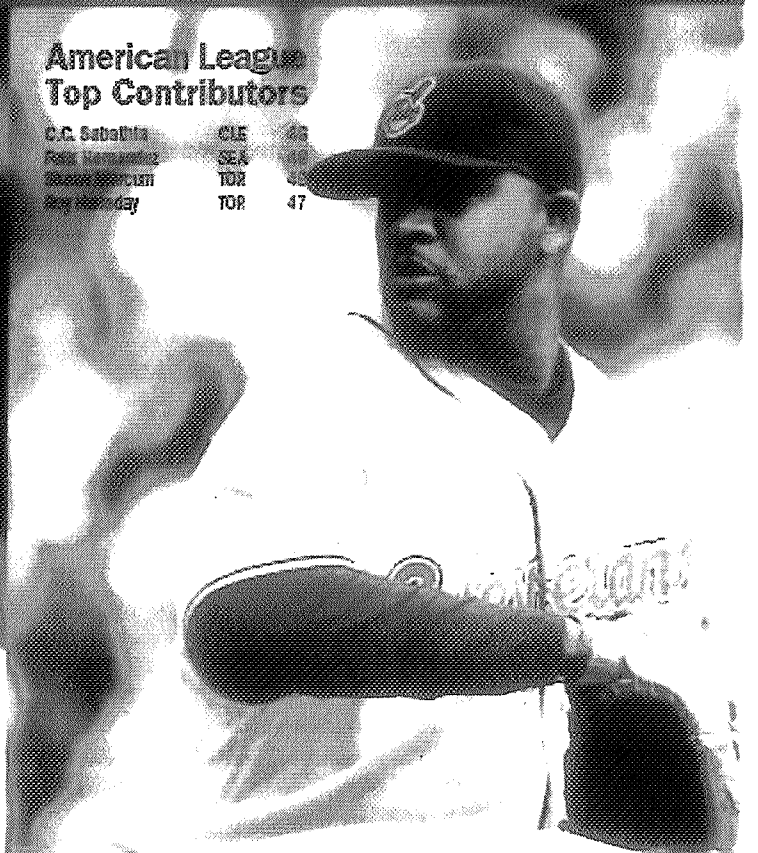
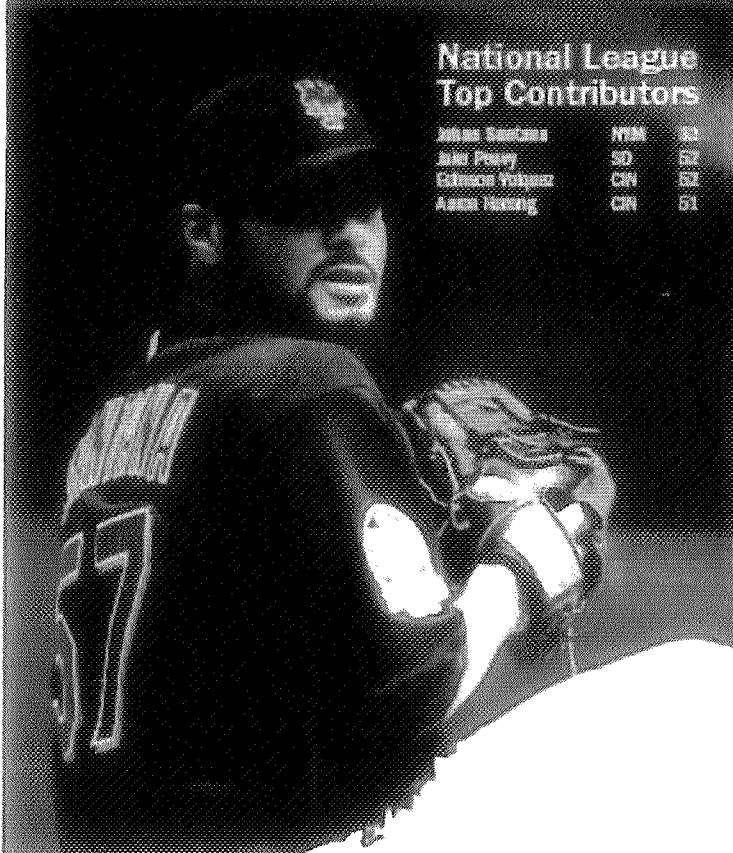
1 in 6 men face prostate cancer and that is why One A Day and MLB will donate \$10 to the Prostate Cancer Foundation for every strikeout this season. Go to mlb.com/oneday for more information.

National League Top Contributors

John Santana	NYM	31
Jake Peavy	SD	52
Edinson Volquez	CIN	52
Adam Wainwright	CIN	51

American League Top Contributors

C.C. Sabathia	CLE	46
Ryan Lincecum	SEA	49
Ryan Howard	TOR	48
Roy Halladay	TOR	47



BAYERMENS03629