



SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN DIEGO

**THE PEOPLE OF THE STATE OF
CALIFORNIA,**

Plaintiff,

v.

BAYER HEALTHCARE LLC,

Defendant.

Case No.

FINAL JUDGMENT

Dept: 25

Judge:

MARGOL L. LEWIS

MARGIE G. WOODS

Plaintiff, the People of the State of California ("the People" or "Plaintiff"), having filed its Complaint and appearing through its attorney Edmund G. Brown Jr., Attorney General of the State of California, and Bayer Healthcare LLC ("Bayer" or "Defendant") by its attorneys, Sidley Austin LLP, by Kristin Graham Koehler, Esq., and by Daron Watts, Esq., having stipulated as follows:

That this Final Judgment ("Judgment") may be signed by any judge of the San Diego Superior Court; and,

1 That Plaintiff has filed its Complaint in this matter pursuant to California Business and
2 Professions Code sections 17200 and 17500 *et seq.*; and Bayer denies the allegations of the
3 Complaint and denies any alleged violations; and,

4 That this Judgment is made without trial or adjudication of any issue of fact or law or
5 finding of wrongdoing or liability of any kind; and that Bayer does not admit any violation of law
6 or any wrongdoing and that no part of this Judgment shall constitute evidence of any liability,
7 fault or wrongdoing by Bayer; and,

8 The Court having considered the pleadings and the Stipulation for Entry of Final Judgment
9 executed by the Plaintiff and Bayer and filed herewith, and good cause appearing,

10 IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

11 **I. PARTIES AND JURISDICTION**

12 1. The People of the State of California is the Plaintiff in this case and Bayer Healthcare
13 LLC, is the Defendant in this case.

14 2. The Court has jurisdiction over the subject matter of this action, jurisdiction over the
15 parties to this action, and venue is proper in this Court.

16 **II. DEFINITIONS**

17 3. The following definitions shall be used in construing this Judgment:

18 A. "Bayer" shall mean Bayer HealthCare LLC, all of its subsidiaries and divisions,
19 predecessors, successors, and assigns marketing Covered Products in the United States.

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

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

1 D. "Covered Conduct" shall mean any and all of Bayer's promotional or marketing
2 practices or dissemination of information regarding One A Day Multivitamins through the
3 Effective Date of the Judgment.

4 E. "Effective Date" shall mean the date on which a copy of this Judgment duly
5 executed by Bayer and by the Signatory Attorneys General, is approved by, and becomes an
6 Order of the Court, whichever is later.

7 F. "Endorsement" shall have the meaning set forth in 16 C.F.R.
8 § 255.0(b).

9 G. "Parties" shall mean Bayer and the Signatory Attorneys General.

10 H. "Signatory Attorney General" shall mean the Attorney General of California,
11 Illinois, or Oregon, or his or her designee.

12 I. "State Consumer Protection Laws" shall mean the consumer protection laws
13 under which the Signatory Attorneys General have conducted their investigation.¹

14 J. The term "including" in this Judgment means "including without limitation."

15 K. The terms "and" and "or" in this Judgment shall be construed conjunctively or
16 disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than
17 exclusive.

18 **III. REPRESENTATIONS: ONE A DAY MEN'S AND**
19 **MEN'S 50+ ADVANTAGE CLAIMS**

20 IT IS HEREBY ORDERED that Bayer, in connection with the manufacturing, labeling,
21 advertising, promotion, offering for sale, sale, or distribution of One A Day Men's Health
22 Formula and One A Day Men's 50+ Advantage, in or affecting commerce, shall not make,
23 directly or by implication, including through the use of a product name, endorsement, depiction,
24 or illustration, any representation that such product is effective in the diagnosis, cure, mitigation,
25 treatment, or prevention of any disease, subject to paragraph V below.

26
27 ¹ CALIFORNIA - Cal. Bus. & Prof. Code §§ 17200 *et seq.* and 17500 *et seq.*; ILLINOIS -
28 Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 *et seq.* (2002);
OREGON - Unlawful Trade Practices Act, Or. Rev. Stat. §§ 646.605 to 646.656.

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V. REPRESENTATIONS: FOOD AND DRUG ADMINISTRATION

ACCEPTED CLAIMS

A. the product that is the subject of the representation is covered by a final OTC drug monograph promulgated by the Food and Drug Administration (FDA) for such use, and conforms to the conditions of such use; or

C. the product that is the subject of the representation is approved pursuant to a new drug application for such use by FDA, and conforms to the conditions of such use; or

E. such representation is a non-misleading qualified health claim and is permitted by an enforcement discretion letter published by the Food and Drug Administration, pursuant to the Nutrition Labeling and Education Act of 1990. After FDA publishes an enforcement discretion letter, Bayer shall monitor the available scientific evidence that is the basis of the qualified health claim. If, in light of the entire body of such evidence, the qualified health claim permitted by the

1 enforcement discretion letter is no longer accurate, Bayer shall not utilize such qualified health
2 claim; provided, however, that Bayer shall have a commercially reasonable period of time to
3 make necessary changes to its marketing, advertising, and promotional materials, and its labeling
4 and packaging; or

5 F. such representation is a non-misleading statement made in accordance with 21
6 U.S.C. § 343(r)(6) and, at the time the representation is made, Bayer possesses and relies upon
7 Competent and Reliable Scientific Evidence.

8 VI. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

9 A. Within thirty (30) days of the Effective Date of this Judgment, Bayer shall pay
10 \$3,300,000.00 to the States by electronic fund transfer made payable to the Oregon Attorney
11 General's Office, which shall divide and distribute these funds as designated by and in the sole
12 discretion of the Signatory Attorneys General. Said payment shall be used by the States for
13 attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the
14 consumer protection enforcement fund, consumer education or litigation or local consumer aid
15 or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses
16 permitted by state law, at the sole discretion of each Signatory Attorney General.² Nothing in
17 this Judgment constitutes any agreement by the Parties concerning the characterization of the
18 amounts paid pursuant to this Judgment for purposes of the Internal Revenue Code or any state
19 tax laws.

20 VII. RELEASE

21 A. Subject to the reservations set forth in Paragraph VII.C. below, by execution of
22 this Judgment, each Signatory Attorney General releases and forever discharges, to the fullest
23 extent permitted by law, Bayer and all of its past and present officers, directors, shareholders,
24 employees, affiliates, subsidiaries, predecessors, assigns and successors (hereinafter referred to
25 collectively as the "Released Parties"), from the following: all civil claims, causes of action,
26 counterclaims, set-offs, demands, actions, suits, rights, liabilities, damages, restitution, fines,

27 ² In OREGON, Oregon's share shall be deposited to the account established pursuant to
28 Or. Rev. Stat. § 180.095.

1 costs, and penalties under the State Consumer Protection Laws arising from the Covered Conduct
2 that were or could have been asserted against the Released Parties by the Signatory Attorneys
3 General on or before the Effective Date of this Judgment. This release does not apply to any
4 conduct occurring after the Effective Date of this Judgment.

5 B. The Signatory Attorneys General acknowledge by their execution hereof that this
6 Judgment terminates their investigations under the State Consumer Protection Laws into the
7 Covered Conduct prior to and including the Effective Date of this Judgment.

8 C. Notwithstanding any term of this Judgment, specifically reserved and excluded
9 from Paragraphs VII.A. and VII.B. as to any entity or person, including Released Parties, are any
10 and all of the following:

11 1. Any criminal liability that any person or entity, including Released Parties,
12 has or may have to any or all of the Signatory Attorneys General;

13 2. Any civil or administrative liability that any person or entity, including
14 Released Parties, has or may have to any or all of the Signatory Attorneys General, under
15 any statute, regulation or rule not expressly covered by the release in Paragraphs VII.A.
16 and VII.B., including, but not limited to, any and all of the following claims:

17 a. State or federal antitrust violations;

18 b. Medicaid violations, including federal Medicaid drug rebate statute
19 violations, Medicaid fraud or abuse, and/or kickback violations related to any
20 State's Medicaid program;

21 c. State false claims violations; and,

22 d. Claims to enforce the terms and conditions of this Judgment.

23 3. Any liability under the State Consumer Protection Laws, which any person
24 or entity, including Released Parties, has or may have to individual consumers or State
25 program payors of said States, and which have not been specifically enumerated as
26 included herein.

1 **VIII. DISPUTES REGARDING COMPLIANCE**

2 A. For the purposes of resolving disputes with respect to compliance with this
3 Judgment, should any of the Signatory Attorneys General have legally sufficient cause to believe
4 that Bayer has violated a provision of this Judgment subsequent to the Effective Date, then such
5 Signatory Attorney General shall notify Bayer in writing of the specific objection, identify with
6 particularity the provisions of this Judgment that the practice appears to violate, and give Bayer
7 thirty (30) business days to respond to the notification; provided, however, that any Signatory
8 Attorney General may take any action where the Signatory Attorney General concludes that,
9 because of the specific practice, a threat to the health or safety of the public requires immediate
10 action. Upon receipt of written notice from a Signatory Attorney General, Bayer shall provide a
11 good-faith written response to such Signatory Attorney General notification, containing either a
12 statement explaining why Bayer believes it is in compliance with the Judgment or a statement
13 explaining how Bayer intends to remedy the alleged breach.

14 B. Upon giving Bayer thirty (30) business days to respond to the notification
15 described in Paragraph VIII.A. above, such Signatory Attorney General shall be permitted to
16 serve a document request for relevant, non-privileged, non-work-product records and documents
17 in the possession, custody, or control of Bayer that relate to Bayer's compliance with each
18 provision of this Judgment. In response to that document request, Bayer will make responsive
19 documents available to the requesting Signatory Attorney General.

20 **IX. PENALTIES FOR FAILURE TO COMPLY**

21 A. The Signatory Attorneys General may assert any claim that Bayer has violated this
22 Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any
23 other relief afforded by law, but only after providing Bayer an opportunity to respond as
24 described in Paragraph VIII.A. above; provided however, that a Signatory Attorney General may
25 take any action if there is a reasonable basis to believe that, because of the specific practice, a
26 threat to the health or safety of the public requires immediate action.

27 B. In any such action or proceeding, relevant evidence of conduct that occurred
28 before the Effective Date shall be admissible on any material issue, including alleged willfulness,

1 intent, knowledge, contempt or breach, to the extent permitted by law. Bayer does not waive any
2 objection it may have to the admissibility of any such evidence, as permitted by law.

3 **X. COMPLIANCE WITH ALL LAWS**

4 A. Except as expressly provided in this Judgment, nothing in this Judgment shall be
5 construed as:

6 1. Relieving Bayer of its obligation to comply with all applicable state laws,
7 regulations or rules, or granting permission to engage in any acts or practices prohibited by such
8 law, regulation or rule; or

9 2. Limiting or expanding in any way any right the State may otherwise have
10 to enforce applicable state law or obtain information, documents or testimony from Bayer
11 pursuant to any applicable state law, regulation, or rule, or any right Bayer may otherwise have to
12 oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed,
13 or otherwise employed by the State pursuant to any such state law, regulation, or rule.

14 **XI. NOTICES UNDER THIS JUDGMENT**

15 A. Any notices that must be sent to the State or to Bayer under this Judgment shall be
16 sent by overnight United States mail. The documents shall be sent to the following addresses:

17 For Oregon:
18 David Anthony Hart
19 Senior Assistant Attorney General
20 1515 SW 5th Ave., Suite 410
21 Portland, Oregon
22 Salem, Oregon 97201
23 Telephone: 971.673.1880
24 Facsimile: 971.673.1902

25 For California:
26 Judith Fiorentini
27 Deputy Attorney General
28 California Attorney General's Office
110 West A Street, Suite 1100
San Diego, California 92101
Telephone: 619.645.2207
Facsimile: 619.645.2062

1 For Illinois:
2 James D. Kole
3 Chief, Consumer Fraud Bureau
4 100 W. Randolph Street, 12th Floor
5 Chicago, Illinois 60601
6 Telephone: 312.814.5018
7 Facsimile: 312.814.2593

8 For Bayer:
9 William Hawxhurst, Esquire
10 Bayer Healthcare LLC
11 36 Columbia Rd.
12 Morristown, NJ 07960
13 Telephone: 973.254.5000
14 Facsimile: 973.408.8000

15 and

16 Kristin Graham Koehler, Esquire
17 Sidley Austin LLP
18 1501 K Street, N.W.
19 Washington, D.C. 20005
20 Telephone: 202.736.8359
21 Facsimile: 202.736.8711

22 The Clerk is ordered to enter this Judgment forthwith.

23 Dated: 26 Oct. 2010

24  MARGIE G. WOODS
25 ~~MARGOL L. LEWIS~~
26 JUDGE OF THE SUPERIOR COURT
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