

## SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF SAN DIEGO

THE PEOPLE OF THE STATE OF CALIFORNIA,

BAYER HEALTHCARE LLC,

Plaintiff,

**V.** 

Defendant.

Case No.

FINAL JUDGMENT

Dept: 25

Judge: MARGOL. LEW

MARGIE G. WOODS

Plaintiff, the People of the State of California ("the People" or "Plaintiff"), having filed its Complaint and appearing though 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,

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

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

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

IT IS HEREBY ORDERED, ADJUDGED AND DECREED as follows:

#### I. PARTIES AND JURISDICTION

- 1. The People of the State of California is the Plaintiff in this case and Bayer Healthcare LLC, is the Defendant in this case.
- 2. The Court has jurisdiction over the subject matter of this action, jurisdiction over the parties to this action, and venue is proper in this Court.

#### II. DEFINITIONS

- 3. The following definitions shall be used in construing this Judgment:
- A. "Bayer" shall mean Bayer HealthCare LLC, all of its subsidiaries and divisions, predecessors, successors, and assigns marketing Covered Products in the United States.
- B. "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.
- C. "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.

- D. "Covered Conduct" shall mean any and all of Bayer's promotional or marketing practices or dissemination of information regarding One A Day Multivitamins through the Effective Date of the Judgment.
- E. "Effective Date" shall mean the date on which a copy of this Judgment duly executed by Bayer and by the Signatory Attorneys General, is approved by, and becomes an Order of the Court, whichever is later.
- F. "Endorsement" shall have the meaning set forth in 16 C.F.R. § 255.0(b).
  - G. "Parties" shall mean Bayer and the Signatory Attorneys General.
- H. "Signatory Attorney General" shall mean the Attorney General of California, Illinois, or Oregon, or his or her designee.
- I. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.<sup>1</sup>
  - J. The term "including" in this Judgment means "including without limitation."
- K. The terms "and" and "or" in this Judgment shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

## III. REPRESENTATIONS: ONE A DAY MEN'S AND MEN'S 50+ ADVANTAGE CLAIMS

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

<sup>&</sup>lt;sup>1</sup> CALIFORNIA - Cal. Bus. & Prof. Code §§ 17200 et seq. and 17500 et seq.; ILLINOIS - 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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#### IV. REPRESENTATIONS: PERFORMANCE CLAIMS

IT IS FURTHER ORDERED that Bayer, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time the representation is made, Bayer possesses and relies upon Competent and Reliable Scientific Evidence.

## V. REPRESENTATIONS: FOOD AND DRUG ADMINISTRATION ACCEPTED CLAIMS

IT IS FURTHER ORDERED that nothing in this Judgment shall prohibit Bayer from making any representation if:

- 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
- B. the product that is the subject of the representation remains covered by a tentative final OTC drug monograph for such use, and adopts 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
- D. such representation is an approved or authorized health claim permitted by regulations promulgated by, or notification-letters issued by, the Food and Drug Administration, pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997, and is compliant with such regulations or notification-letters; 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

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

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

#### VI. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES

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

#### VII. RELEASE

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

<sup>&</sup>lt;sup>2</sup> In OREGON, Oregon's share shall be deposited to the account established pursuant to Or. Rev. Stat. § 180.095.

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

- B. The Signatory Attorneys General acknowledge by their execution hereof that this Judgment terminates their investigations under the State Consumer Protection Laws into the Covered Conduct prior to and including the Effective Date of this Judgment.
- C. Notwithstanding any term of this Judgment, specifically reserved and excluded from Paragraphs VII.A. and VII.B. as to any entity or person, including Released Parties, are any and all of the following:
  - 1. Any criminal liability that any person or entity, including Released Parties, has or may have to any or all of the Signatory Attorneys General;
  - 2. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to any or all of the Signatory Attorneys General, under any statute, regulation or rule not expressly covered by the release in Paragraphs VII.A. and VII.B., including, but not limited to, any and all of the following claims:
    - a. State or federal antitrust violations;
    - b. Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;
      - c. State false claims violations; and,
      - d. Claims to enforce the terms and conditions of this Judgment.
  - 3. Any liability under the State Consumer Protection Laws, which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said States, and which have not been specifically enumerated as included herein.

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#### VIII. DISPUTES REGARDING COMPLIANCE

- A. For the purposes of resolving disputes with respect to compliance with this

  Judgment, should any of the Signatory Attorneys General have legally sufficient cause to believe
  that Bayer has violated a provision of this Judgment subsequent to the Effective Date, then such
  Signatory Attorney General shall notify Bayer in writing of the specific objection, identify with
  particularity the provisions of this Judgment that the practice appears to violate, and give Bayer
  thirty (30) business days to respond to the notification; provided, however, that any Signatory
  Attorney General may take any action where the Signatory Attorney General concludes that,
  because of the specific practice, a threat to the health or safety of the public requires immediate
  action. Upon receipt of written notice from a Signatory Attorney General, Bayer shall provide a
  good-faith written response to such Signatory Attorney General notification, containing either a
  statement explaining why Bayer believes it is in compliance with the Judgment or a statement
  explaining how Bayer intends to remedy the alleged breach.
- B. Upon giving Bayer thirty (30) business days to respond to the notification described in Paragraph VIII.A. above, such Signatory Attorney General shall be permitted to serve a document request for relevant, non-privileged, non-work-product records and documents in the possession, custody, or control of Bayer that relate to Bayer's compliance with each provision of this Judgment. In response to that document request, Bayer will make responsive documents available to the requesting Signatory Attorney General.

#### IX. PENALTIES FOR FAILURE TO COMPLY

- A. The Signatory Attorneys General may assert any claim that Bayer has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing Bayer an opportunity to respond as described in Paragraph VIII.A. above; provided however, that a Signatory Attorney General may take any action if there is a reasonable basis to believe that, because of the specific practice, a threat to the health or safety of the public requires immediate action.
- B. In any such action or proceeding, relevant evidence of conduct that occurred before the Effective Date shall be admissible on any material issue, including alleged willfulness,

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1	For Illinois:
2	James D. Kole Chief, Consumer Fraud Bureau
3	100 W. Randolph Street, 12 <sup>th</sup> Floor Chicago, Illinois 60601
4	Telephone: 312.814.5018 Facsimile: 312.814.2593
5	1 acsimile. 312.814.2373
6	For Bayer:
7	William Hawxhurst, Esquire Bayer Healthcare LLC
8	36 Columbia Rd. Morristown, NJ 07960
9	Telephone: 973.254.5000 Facsimile: 973.408.8000
10	
11	and
12	Kristin Graham Koehler, Esquire Sidley Austin LLP
13	1501 K Street, N.W. Washington, D.C. 20005
14	Telephone: 202.736.8359
15	Facsimile: 202.736.8711
16	The Clerk is ordered to enter this Judgment forthwith.
17	MARGIE G. WOODS
18	
	Dated: 26 Ocl. Zoid MARGOL LEWIS
19	Dated: 26 Od. Zoid MARGOL. LEWIS  JUDGE OF THE SUPERIOR COURT
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