

COPY

ORIGINAL FILED

DEC 09 2005

LOS ANGELES
SUPERIOR COURT

LEE M. GORDON (SBN 174168)
ELAINE T. BYSZEWSKI (SBN 222304)
HAGENS BERMAN SOBOL SHAPIRO LLP
700 South Flower Street, Suite 2940
Los Angeles, CA 90017-4101
Telephone: (213) 330-7150
Facsimile: (213) 330-7152

-and-

STEVE W. BERMAN
HAGENS BERMAN SOBOL SHAPIRO LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Attorneys for Plaintiff

[Additional Counsel Listed on Signature Page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

SUSANNAH K. ALEXANDER, individually)
and on behalf of all others similarly situated,)
Plaintiff,)

v.)

SOLVAY PHARMACEUTICALS, INC.,)
Defendant.)

Case No. BC 300364
(Related to BC 325120 pursuant to Civil
Minute Order Entered June 29, 2005)

CLASS ACTION

**FIFTH AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS OF
THE UNFAIR COMPETITION LAW
AND THE FALSE ADVERTISING LAW**

Complaint Filed: August 7, 2003

COORDINATED PRE-TRIAL PROCEEDINGS)

Dr. Sherrel Howard V. Solvay Pharmaceuticals,)
Inc., et al., Los Angeles Superior Court Case No.)
BC325120)

Plaintiff Susannah K. Alexander, by counsel and for the Fifth Amended Class Action
Complaint for Violations of the Unfair Competition Law ("UCL"), Bus. & Prof. Code § 17200, *et*
seq., and the False Advertising Law, Bus. & Prof. Code § 17500, *et seq.* ("Section 17500"), alleges

1 upon personal knowledge and belief as to her own acts, and upon information and belief (based on
2 the investigation of counsel) as to all other matters, as to which allegations Plaintiff believes
3 substantial evidentiary support will exist after a reasonable opportunity for further investigation
4 and discovery, on behalf of herself and all others similarly situated, as follows:

5 **I. NATURE OF THE ACTION**

6 1. This class action seeks to stop Defendant's unlawful, unfair and fraudulent business
7 practices and false and misleading advertising related to the marketing and sale of its hormone
8 replacement therapies known as Estratest and Estratest HS. An understanding of the history of
9 these products in the context of the Food, Drug & Cosmetic Act is presented herein in order to aid
10 understanding the nature of the violations of Bus. & Prof. Code §§ 17200 and 17500 *et seq.*

11 2. Since 1938, the Food, Drug & Cosmetic Act has required drug companies to obtain
12 Food and Drug Administration ("FDA") approval before they marketing new drugs. In order to
13 obtain FDA approval, a company is required to file a New Drug Application ("NDA") and, since
14 1962, has been required to prove that the product is effective as well as safe.

15 3. Defendant Solvay Pharmaceuticals, Inc. ("Defendant" and "Solvay") has been
16 manufacturing and marketing the drugs Estratest and Estratest H.S. (collectively "Estratest") as a
17 hormone replacement therapy since 1964. Solvay develops, distributes and prints literature,
18 advertisements and promotional materials, which are distributed to physicians, that encourage the
19 use of Estratest for treatment of moderate to severe vasomotor symptoms associated with
20 menopause for those patients not improved by treatment with estrogens alone. The literature
21 distributed to doctors contains express representations that these drugs are appropriate for this
22 purpose. Solvay also posts information about Estratest to be viewed by physicians and patients on
23 its Internet website. Additionally, over the past several years, Solvay expanded marketing of
24 Estratest to include treatment of female sexual dysfunction, *i.e.* loss of libido, also not an approved
25 use by the FDA.

26 ///

27 ///

1 4. Solvay advertised its pharmaceutical products in a variety of media. Solvay has
2 published advertisements in scientific and medical journals including without limitation
3 OBSTETRICS & GYNECOLOGY, and FERTILITY & STERILITY. A typical advertisement
4 contained text in “plain English” urging prescription by physicians of Estratest as well as eye
5 catching illustrations. Each advertisement also had “an adjacent page for brief description of
6 prescribing information” which contained detailed “prescribing information” based upon the
7 “package insert”. Attached hereto as *Exhibit A* and included herein is a typical advertisement
8 published by Solvay in the September 1999 issue of OBSTETRICS & GYNECOLOGY.
9 “Prescribing information” and “package insert” are terms of art, which refer to pharmaceuticals
10 approved for use by the FDA. The use of these terms repeatedly in these advertisements was an
11 artifice to deceive, mislead, and defraud physicians and patients into believing that Estratest had
12 been approved by the FDA.

13 5. Solvay also has caused information about Solvay itself and Estratest to be published
14 in the Physician’s Desk Reference (“PDR”). The PDR is a unique publication, which until 2004
15 stated that it published only “FDA-approved” labeling for, and information about, drug. The
16 Foreward to the PDR for 2003, the 57th edition is attached hereto as *Exhibit B* and incorporated
17 herein together with the listing paid for Solvay, listing *inter alia*, Estratest and Estratest H.S. as
18 drugs eligible for inclusion in the PDR and, consequently, represented by Solvay to be approved
19 for use by the FDA. The Foreward reads in one of its pertinent parts:

20 **How to Use This book**

21 *Physicians’ Desk Reference* is published by Thomson PDR in cooperation with
22 participating manufacturers. Each full length entry provides you with an exact copy of
23 the product’s FDA-approved labeling. Under the federal Food, Drug and Cosmetics
24 (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by
25 the manufacturer for only those uses for which the drug’s safety and effectiveness have
26 been established. The Code of Federal Regulations 201.100(d)(1) pertaining to labeling
27 for prescription products requires that for PDR content “indications, effects, dosages,
28 routes, methods, and frequency and duration of administration and any, relevant
warnings, hazards, contraindications, side effects, and precautions” must be “same in
language and emphasis” as the approved labeling for the products. The Food and Drug
Administration (FDA regards the words *same in language and emphasis* as requiring
VERBATIM use of the approved labeling providing such information. Furthermore,
information that is emphasized in the approved labeling by the use of type set in a box, or
in capitals, boldface, or italics, must be given the same emphasis in PDR.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

* * * * *

The function of the publisher is the compilation, organization, and distribution of this information. Each product description has been prepared by the manufacturer, and edited and approved by the manufacturer's medical department, medical director, and/or medical consultant. In organizing and presenting the material in *Physicians' Desk Reference*, the publisher does not warrant or guarantee any of the products described, or perform any independent analysis in connection with any of the product information contained herein. *Physicians' Desk Reference* does not assume, and expressly disclaims, any obligation to obtain and include any information other than that provided to it by the manufacturer. It should be understood that by making this material available the publisher is not advocating the use of any product described herein, nor is the publisher responsible for misuse of a product due to typographical error. Additional information on any product may be obtained from the manufacturer.

The quoted language is the same as that included in the Forewords to previous editions of the PDR, including, e.g., the 2002 Volume, Edition 56. "Each full-length entry provides you with an exact copy of the product's FDA-approved labeling." Solvay paid for Estratest and Estratest H.S. to be listed in the relevant PDRs during the period at issue in the instant lawsuit. Solvay knew, based upon the Forewords to the relevant Editions, that only FDA-approved drugs were eligible for inclusion in the PDR. Solvay further knew that physicians utilize the PDR to identify FDA-approved drugs to use in FDA-approved applications and uses for treating their patients. Solvay paid the publisher of the PDR to include Estratest and Estratest H.S. in the PDRs as part of an artifice to deceive, mislead, and defraud physicians and patients into the belief that Estratest and Estratest H.S. had received the approval of the FDA for the purposes that Solvay listed in the PDRs.

6. Solvay has, in fact, never received FDA approval for the promotion and sale of Estratest for treatment of women suffering from vasomotor symptoms associated with menopause who are not responding to estrogen treatment. Because Estratest has never been approved for the stated purpose, even more irony abounds when physicians' continue to prescribe Estratest for "off label" uses to menopausal women suffering from sexual dysfunction. Solvay's growing sales reflect its ability to tap into this other related market for treatment of sexual dysfunction in post-menopausal women. Solvay's marketing and sales tactics of Estratest, including representations made in the PDRs and elsewhere from 1962 through at least the year 2003, are false, fraudulent, deceptive, and illegal.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21

III. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this class action pursuant to Bus. & Prof. Code §§ 17204 and 17535. This Court has personal jurisdiction over the parties because Plaintiff submits to the jurisdiction of the Court and Defendant systematically and continually conducted business in the County of Los Angeles and the State of California. The absence of a private right of action under 21 U.S.C. § 337(a) does not divest this Court of jurisdiction over Plaintiff's claim based on Solvay's unlawful business practices for any violations of the Food, Drug & Cosmetic Act.

13. Venue is proper in this Court pursuant to Bus. & Prof. Code §§ 17204 and 17535 because Defendant conducted business in the County of Los Angeles, including marketing, advertising, and sales directed to California residents. Further, at all times mentioned in this Fifth Amended Complaint, Defendant made misrepresentations and material omissions to residents of the County of Los Angeles and resident of the State of California.

14. Federal subject matter jurisdiction over this class action does not exist. Complete diversity of citizenship between Plaintiff and Defendant does not exist. Under applicable federal law, damages, punitive damages, attorneys' fees and costs cannot be aggregated to meet the minimum jurisdictional amount for federal court subject matter jurisdiction. Plaintiff asserts no federal questions and/or violations of federal law. To the extent federal laws are mentioned herein, those laws do not provide a cause of action for their violation. The claims asserted herein are strictly for violations of California law.

22
23
24
25
26
27
28

IV. STATEMENT OF FACTS

A. Solvay Sells Estratest And Estratest H.S. For The Relief Of Symptoms Associated With Menopause

15. Doctors prescribe estrogens for a number of purposes, including:
a. To provide estrogen during a period of adjustment when a woman's ovaries no longer produce it, in order to prevent certain uncomfortable symptoms of estrogen deficiency.

