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LOS ANGELES  
SUPERIOR COURT

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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.

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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 57<sup>th</sup> 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.

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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.



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### 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.

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### 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.

1 (All women normally stop producing estrogens, generally between the ages of 45 and 55; this is  
2 called menopause.);

3 b. To prevent symptoms of estrogen deficiency when a woman's ovaries have  
4 been removed surgically before the natural menopause;

5 c. To prevent pregnancy; and

6 d. To treat certain cancers in women and men.

7 16. In the natural course of their lives, all women eventually experience a decrease in  
8 estrogen production. This usually occurs between the ages of 45 and 55 but may occur earlier or  
9 later. Sometimes the ovaries may need to be removed before natural menopause by an operation,  
10 producing a "surgical menopause."

11 17. When the amount of estrogen in the blood begins to decrease, women may develop  
12 typical symptoms: Feelings of warmth in the face, neck, and chest or sudden intense episodes of  
13 heat and sweating throughout the body (called "hot flashes" or "hot flushes"). These symptoms,  
14 also called vasomotor symptoms, have been described as "recurrent, transient periods of flushing,  
15 sweating, and a sensation of heat, often accompanied by palpitation, feeling of anxiety, and  
16 sometimes followed by chills," and are sometimes very uncomfortable. A few women eventually  
17 develop changes in the vagina (called "atrophic vaginitis") which cause discomfort, especially  
18 during and after intercourse.

19 18. Physicians prescribe estrogen products to treat these symptoms of menopause.  
20 While it is estimated that more than one-half of all women undergoing menopause have only mild  
21 or no symptoms at all and, therefore, do not need estrogens, many other women may need  
22 estrogens for a few months while their bodies adjust to lower estrogen levels.

23 19. Many estrogen products used in the treatment of symptoms of menopause are  
24 estrogen-only products. However, a subset of women experiencing menopausal symptoms are not  
25 improved by estrogens alone, leading drug manufacturers to experiment with combination  
26 estrogen-androgen drug products. Estratest is one such combination drug.

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1           20.     According to Solvay's Internet website, Estratest is a combination of esterified  
2 estrogens and methyltestosterone and is available in two dosage strengths: Estratest contains 1.25  
3 mg esterified estrogens and 2.5mg methyltestosterone and Estratest H.S. is the half-strength  
4 formulation, containing 0.625mg esterified estrogens and 1.25mg methyltestosterone. Solvay  
5 developed, manufactures, distributes and promotes Estratest.

6           21.     In fact sheets appearing on Solvay's website and distributed to doctors, Solvay  
7 promotes Estratest and Estratest H.S. tablets for:

8                     *Indications*

- 9                     • Indicated for the management of moderate to severe vasomotor  
10                    symptoms associated with menopause in patients who do not  
                      respond to estrogens alone.

11           Using the term "indications," which is a term of art within the medical community relating to FDA  
12 approved uses for drugs, implies that Estratest and Estratest H.S. are FDA approved for the uses  
13 specified.

14           22.     Solvay informs doctors that there is a proper "Dose and Administration":

15                    1.     *Given cyclically for short-term use only:*

16                    For treatment of moderate to severe vasomotor symptoms associated with  
17                    the menopause in patients not improved by estrogen alone.

18                    The lowest dose that will control symptoms should be chosen and  
19                    medication should be discontinued as promptly as possible.

20                    Administration should be cyclic (*e.g.*, three weeks on and one week off).  
21                    Attempts to discontinue or taper medication should be made at three to six  
22                    month intervals.

23                    **Usual Dosage Range:** 1 tablet of ESTRATEST® or 1 to 2 tablets of  
24                    ESTRATEST® H.S. daily as recommended by the physician.

25                    Treated patients with an intact uterus should be monitored closely for  
26                    signs of endometrial cancer and appropriate diagnostic measures should be  
27                    taken to rule out malignancy in the event of persistent or recurring  
28                    abnormal vaginal bleeding.

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1                   **HOW SUPPLIED**

2                   ESTRATEST® (Imprinted "SOLVAY 1026")  
3                   Bottles of 100 .....NDC 0032-1026-01  
4                   Bottles of 1000 .....NDC 0032-1026-10

5                   ESTRATEST® (dark green, capsule shaped, sugar-coated oral tablets)  
6                   contains: 1.25 mg of Esterified Estrogens, USP and 2.5 mg of  
7                   Methyltestosterone, USP.

8                   ESTRATEST® H.S. (Imprinted "SOLVAY 1023")  
9                   Bottles of 100 .....NDC 0032-1023-01

10                  ESTRATEST® H.S. "Half-Strength" (light green, capsula shaped, sugar-  
11                  coated oral tablets) contains: 0.625 mg of Esterified Estrogens, USP and  
12                  1.25 mg of Methyltestosterone, USP.

13                  Store at controlled room temperature, 15-30° C (59-86° F).

14 Solvay's use of FDA drug specific terminology in these materials implies to physicians and  
15 patients alike that these products are FDA approved and should be administered as described.

16                  23.     One of the leading resource materials used by physicians in deciding what drugs to  
17                  prescribe is the PDR. Drug manufacturers, including Solvay, sponsor the PDR. In fact, only  
18                  participating manufacturers' may list products in the PDR at a cost to the manufacturer for this  
19                  sponsorship. Recognizing this powerful form of advertising, manufactures, like Solvay make the  
20                  required payments so its products are included in the publication. Drug manufacturers report to the  
21                  PDR's publisher detailed information about their drugs, including proper dosages and appropriate  
22                  treatments for which a drug maybe prescribed. The PDR's 2002 Forward explicitly states "With  
23                  over 3,000 pages of detailed prescribing information approved by the FDA, this volume is  
24                  unquestionably the healthcare community's most fundamental pharmaceutical reference – an  
25                  indispensible source of in-depth data on the efficacy, potential adverse effects, clinical  
26                  pharmacology, and proper use of thousands of prescription medications." Implicit and explicit in  
27                  this self-reporting is the representation that the drugs are approved by the FDA for the uses  
28                  indicated in the manufacturers' description. Solvay, for the years relevant to this lawsuit, sent  
29                  detailed information about Estratest to the PDR's publisher designed to give the appearance of an  
30                  FDA approved drug for the purpose of treating women with vasomotor symptoms associated with

1 menopause in patients who do not respond to estrogens alone. Solvay knew that the PDR is a  
2 widely used reference and the physicians using it believe that the products listed therein are FDA  
3 approved. As a result of this PDR publication referred to by physicians, tens of thousands of  
4 doctors have prescribed Estratest to patients in the State of California. It was not until the 59<sup>th</sup>  
5 Edition, published in 2005, that Solvay admitted that “[Estratest] has not obtained FDA pre-market  
6 approval applicable for new drugs.”

7 24. According to a recent news article, doctors like OB-GYN Steven Ory, who worked  
8 on a review of this category of drugs for the American College of Obstetricians and Gynecologists,  
9 reportedly had no idea that Estratest was not FDA approved and even pointed to the listing in the  
10 PDR as evidence to support his notion that it had been FDA approved. WALL STREET JOURNAL,  
11 March 20, 2003.

12 25. Internet pharmacies regularly pitch Estratest to on-line consumers as if it is FDA  
13 approved and contrast its benefits to those products on the market that have not yet been approved  
14 by the FDA. As a result of this type of marketing, consumers are drawn to Estratest over an  
15 untested or unapproved alternative that may exist.

16 26. Women, in menopause “chat rooms,” also discuss Estratest. In one such forum,  
17 [www.hyster-sister.com](http://www.hyster-sister.com), women ask each other if cheaper “generic” versions of the Estratest are  
18 available and have been tried. Internet chat links like these indicate that women believe that  
19 Estratest is FDA approved and “generic” alternative drugs exist. This impression stems from  
20 Solvay’s deceptive marketing tactics.

21 27. Solvay employs an active sales team to call upon physicians around the country,  
22 including California in order to promote Estratest. In addition to leaving promotional materials,  
23 sales representatives also supply physicians with the package inserts, samples, and physician  
24 labeling materials for the physicians’ benefit. None of the promotional materials disclose that the  
25 FDA has not approved Estratest. Solvay designed these promotional materials to look like  
26 materials that are distributed about FDA approved drugs. Furthermore, the sales calls made by  
27 these representatives reinforce the impression that Estratest is FDA approved. Physicians receive  
28

1 visits from representatives from many pharmaceutical manufacturers and these representatives'  
2 visits signify to physicians that a drug being promoted has been FDA approved. Solvay's  
3 representatives promoting Estratest do not inform physicians that the FDA has never approved  
4 Estratest.

5 28. Solvay advertises in medical journals such as OBSTETRICS & GYNECOLOGY to  
6 promote the use of Estratest. One such advertisement asks physicians and patients to "Consider  
7 Estratest brand Tablets as your first choice when vasomotor symptoms are not relieved by estrogen  
8 alone." Solvay once again uses terms of art like "indicated for the treatment of moderate to severe  
9 vasomotor symptoms..." in order to create the impression that Estratest has been approved by the  
10 FDA. The advertisement does not disclose that the FDA has not approved these products for any  
11 use.

12 29. Solvay maintains a website for consumers and physicians in the United States that  
13 maintains separate pages for each of its products. Anyone visiting Solvay's website can select  
14 Estratest in order to obtain its product information. Until recently, users were directed to a fact  
15 sheet that identified the "indications" or functions of Estratest and gave the visitor an opportunity  
16 to review and print the "Physician Prescribing Information," "Patient Information," and "a printer  
17 friendly version of the Fact Sheet." At some time after November 2003, Solvay modified its home  
18 page about Estratest so it is now entitled "Product Information." Instead of the detailed fact sheet  
19 previously used, it is a more abbreviated listing and notably includes a statement that reads: "This  
20 product has not yet obtained FDA pre-market approval applicable for new drugs." It is apparent  
21 that Solvay added this language after the filing of the original Complaint on August 6, 2003 and  
22 after the filing of the First Amended Complaint, filed on December 5, 2003. However, Solvay's  
23 choice of words could mislead consumers into thinking "pre-market approval" does not mean that  
24 the product is not and has never been FDA approved and the mere fact that Solvay only makes this  
25 type of disclosure on its website after this case was filed and not in its promotional materials  
26 merely perpetuates the deception.

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1           **B.     Estratest Lacks FDA Approval**

2           30.     As set forth below, Estratest has *never* received FDA approval. Abbreviated New  
3 Drug Applications (“ANDAs”) were filed in 1981 but have never been approved. Nonetheless,  
4 Solvay continues to market and sell Estratest as if it were FDA approved. Moreover, it unlawfully  
5 promotes “off label” use of Estratest to treat sexual dysfunction in menopausal women, even  
6 though it does not have an approved label at all. In 2000, Estratest was 199th on the list of the top  
7 200 prescription drugs in retail sales. Sales of the drug were about \$110 million in 2001.

8           31.     In a notice published in the Federal Register of September 8, 1972 (37 FR 18225),  
9 the FDA announced its evaluation of the various indications claimed for the following five  
10 combination estrogen-androgen drug products:

- 11                   (1)     Halodrin Tablets (NDA 11-267) containing fluoxymesterone and ethinyl  
12                             estradiol;
- 13                   (2)     Tylosterone Injection (NDA 8-099), containing diethylstilbestrol and  
14                             methyltestosterone;
- 15                   (3)     Tylosterone Tablets (NDA 7-661), containing diethylstilbestrol and  
16                             methyltestosterone;
- 17                   (4)     Tace with Androgen Capsules (NDA 10-597), containing chlorotrianisene  
18                             and methyltestosterone;
- 19                   (5)     Deladumone Injection and Deladumone OB Injection (NDA 9-545),  
20                             containing testosterone enanthate and estradiol valerate.

21           32.     As announced in that 1972 notice, the FDA found these drugs to be safe and  
22 effective for the “prevention of postpartum breast engorgement” and “for the menopausal  
23 syndrome in those patients not improved by estrogen alone.”

24           33.     In the Federal Register of September 29, 1976 (41 FR 43112), the FDA announced  
25 that the menopausal indication for the aforementioned combination estrogen-androgen drug  
26 products was revised to read as follows:

27                   Moderate to severe vasomotor symptoms associated with the menopause  
28                   in those patients not improved by estrogen alone. (There is no evidence  
                  that estrogens are effective for nervous symptoms or depression which  
                  might occur during menopause, and they should not be used to treat these  
                  conditions.) [41 FR 43112 at 43113].





1           44.     The factual and legal bases of Defendant's misconduct are common to all Class  
2 members and represent a common thread of deception and other misconduct resulting in injury to the  
3 representative Plaintiff and all members of the Class.

4           45.     There are many questions of law and fact common to the representative Plaintiff and  
5 the Class, and those questions substantially predominate over any questions that may affect individual  
6 Class members. Common questions include, but are not limited to, the following:

- 7                   (a)     Whether Defendant's use of false, fraudulent and deceptive  
8                   representations violates the UCL;
- 9                   (b)     Whether Defendant's active concealment of and/or failure to disclose  
10                   the true nature of Estratest's regulatory status in light of Defendant's  
11                   varied misrepresentations violates the UCL and Section 17500;
- 12                   (c)     Whether Defendant made unsubstantiated claims regarding Estratest;
- 13                   (d)     Whether Defendant's misrepresentations constitute false and  
14                   misleading advertising;
- 15                   (e)     Whether Defendant should be declared financially responsible for  
16                   notifying all Class members of the true nature of Estratest's regulatory  
17                   status; and
- 18                   (f)     Whether Defendant should be ordered to disgorge, for the benefit of the  
19                   Class, all or part of its ill-gotten profits received from the sale of  
20                   Estratest, and/or to make restitution to Plaintiff and the members of the  
21                   Class.

22           46.     Plaintiff Alexander will fairly and adequately represent and protect the interests of the  
23 Class. Plaintiff has retained counsel with substantial experience in prosecuting consumer class  
24 actions, including actions involving pharmaceutical sales. Plaintiff and her counsel are committed to  
25 vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so.  
26 Neither Plaintiff nor her counsel has any interests adverse to those of the Class.

27           47.     Plaintiff Alexander and the members of the Class suffered, and will continue to suffer,  
28 harm as a result of Defendant's unlawful and wrongful conduct. A class action is superior to other  
available methods for the fair and efficient adjudication of the controversy. Absent a class action,  
most members of the Class likely would find the cost of litigating their claims to be prohibitive, and

1 will have no effective remedy at law. Because of the relatively small size of each individual Class  
2 member's claims, few Class members likely could afford to seek legal redress for Defendant's  
3 misconduct. Absent a class action, Class members will continue to suffer harm and Defendant's  
4 misconduct will proceed without remedy. The class treatment of common questions of law and fact is  
5 also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of  
6 the courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally,  
7 Defendant has acted and failed to act on grounds generally applicable to the named Plaintiff and the  
8 Class and requires court imposition of relief as to the Class as a whole. Finally, because Plaintiff does  
9 not appear to be able to pursue her claims solely on a representative basis at this juncture, the  
10 availability of that method of proceeding can no longer provide justification for denying class  
11 certification of a UCL claim based on lack of superiority. *See Frey v. Trans Union Corp.*, No.  
12 G031928, 2005 Cal. App. LEXIS 401, \*20-21 (March 24, 2005).

### 13 FIRST CAUSE OF ACTION

#### 14 Violations of Unfair Competition Law 15 (Business & Professions Code §§ 17200 *et seq.*)

16 48. The preceding paragraphs of this Fifth Amended Complaint are realleged and  
17 incorporated by reference as if fully set forth herein. Plaintiff brings this claim on behalf of herself  
18 and members of the Class.

19 49. Defendant's actions, as complained of herein, constitute unfair trade practices that  
20 have the capacity to and do deceive consumers in violation of the Unfair Competition Law, Bus. &  
21 Prof. Code § 17200, *et seq.*:

22 (a) Defendant caused to be published misleading advertisements, promotional  
23 materials and product descriptions for Estratest;

24 (b) Defendant promotes, markets and advertises Estratest for the "indications"  
25 described above despite the fact it has not been approved by the FDA;

26 (c) Solvay omitted material information known to it that would have disclosed  
27 the fact that Estratest lacks FDA approval to consumers, in order to induce members of the general  
28 public to purchase Estratest;

1 (d) Defendant also engages in unlawful business acts and practices in violation  
2 of the Unfair Competition Law by violating state law including, but not limited to, Civil Code  
3 §§ 1572, 1709, 1710, Section 17500 of the Business & Professions Code and Health & Safety  
4 Code §§ 111330 and 111440. Violations of these and other laws constitute unfair practices that are  
5 independently actionable under Section 17200;

6 (e) Defendant's marketing scheme described above is a fraudulent business  
7 practice that is likely to deceive the public;

8 (f) Defendant falsely and deceptively marketed Estratest for women suffering  
9 from moderate to severe vasomotor symptoms associated with menopause who do not respond to  
10 estrogens alone, despite the fact that the FDA has not approved it for those or any other  
11 "indications";

12 (g) Defendant's statements made to promote sales and distribution of Estratest  
13 constitute false advertising made in connection with the sale of goods violating the unfair,  
14 deceptive, untrue or misleading advertising prongs of Section 17200 and Section 17500; and

15 (h) Women in the general public have all been directly and proximately injured  
16 in their business and property by Defendant's wrongful conduct, and such injury includes the  
17 purchase of Estratest, which they would not have purchased were they truthfully and fully  
18 informed of the facts.

19 50. All of the conduct alleged herein occurs and continues to occur in Defendant's  
20 business. Defendant's wrongful conduct is part of a pattern or generalized course of conduct  
21 repeated on thousands of occasions daily constituting an "act" or "practice" within the meaning of  
22 the Section 17200. Thus, Defendant's conduct impacts the public interest.

23 51. Plaintiff requests that this Court enter such orders or judgments as may be necessary  
24 to restore to any person in interest any money which may have been acquired by Defendant by  
25 means of such unfair practices, as provided in Bus. & Prof. Code § 17203 and Civil Code § 3345,  
26 and for such other relief as set forth below.

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**SECOND CAUSE OF ACTION**

**Untrue and Misleading Advertising  
(Business & Professions Code § 17500 *et seq.*)**

52. The preceding paragraphs of this Fifth Amended Complaint are realleged and incorporated by reference. Plaintiff brings this claim on behalf of herself and members of the Class.

53. Bus. & Prof. Code § 17500 provides that “[i]t is unlawful for any . . . corporation . . . with intent . . . to dispose of . . . personal property . . . to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, . . . any statement . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . . .”

54. On its box packaging, advertisements, brochures, PDR inserts, promotional and marketing materials, and on its Internet website and other websites, Solvay holds Estratest out as being FDA approved.

55. Solvay did not disclose, conspicuously or otherwise, on any of these advertisements or marketing materials that such representations were untrue or misleading because:

- a. Solvay knew or should have reasonably known that FDA approval is required before selling a product as a “drug;”
- b. Solvay has continued to seek FDA approval since 1981 and has been unable to obtain it;
- c. Solvay represents falsely that Estratest is FDA approved; and
- d. Solvay has continued to advertise, promote, market and sell Estratest despite the fact that it has been aware that Estratest lacks FDA approval.

56. As a result of the violations of California law described above, Defendant has been, and will be, unjustly enriched at the expense of the general public. Specifically, Defendant has been unjustly enriched by its receipt of monies received from customers who purchased Estratest which is advertised and/or otherwise marketed in this State, and was promoted and sold through advertising and marketing materials which materially misrepresent the status of the product.



1 DATED: December 9, 2005

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14 Attorneys for Plaintiff

# **EXHIBIT A**

# OBS GYNETRICS & GYNECOLOGY



"To report new developments in the field promptly, accurately, and completely."  
(Reis R.A. *Apologia. Obstet Gynecol* 1953;1:1-2.)

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EXHIBIT A



0029-7844(199909)94:3;1-#

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# A NATURAL COMBINATION FOR SELECT MENOPAUSAL PATIENTS

Not only is estrogen  
lost during menopause...<sup>1,2</sup>

- Androgen may drop by more than half in *naturally menopausal* women<sup>1,2</sup>
- A rapid androgen loss of up to 80% may occur in *surgically menopausal* women<sup>3</sup>

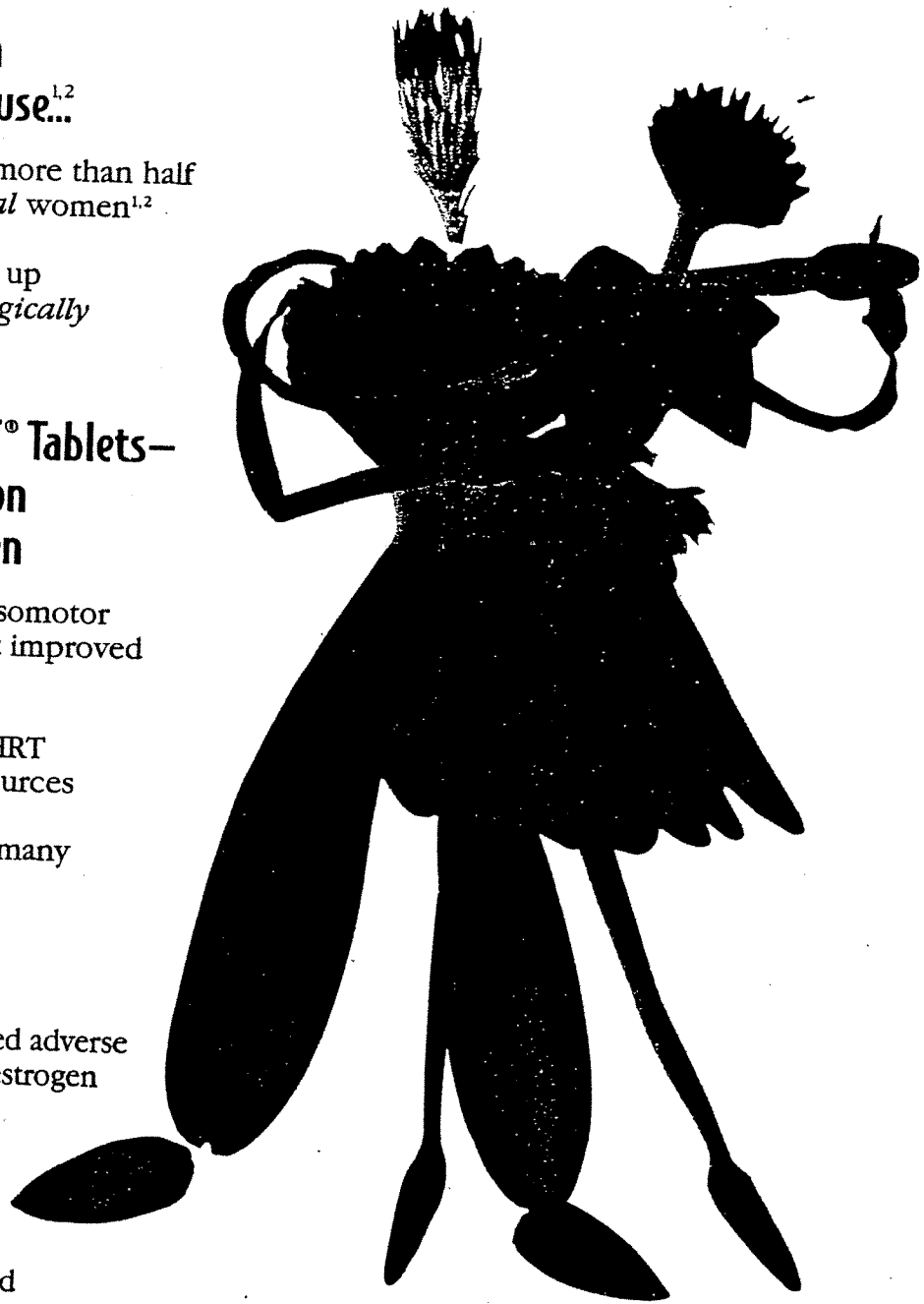
Prescribe **ESTRATEST®** Tablets—  
a natural combination  
of estrogen-androgen

- For treating persistent vasomotor symptoms in patients not improved by estrogen alone
- For patients who prefer HRT synthesized from plant sources
- For replacement therapy many patients can accept<sup>4</sup>

The most commonly reported adverse events are those typical of estrogen therapy (breast tenderness, headache, nausea, edema, abdominal pain) and of androgen treatment (alopecia, acne, hirsutism).

Estrogens are contraindicated for patients with known or suspected pregnancy, breast cancer, current or history of thromboembolic disorders. Estrogens have been reported to increase the risk of endometrial cancer in postmenopausal women. Methyltestosterone is contraindicated in pregnant and lactating women, and in patients with severe liver damage.

Please see adjacent page for brief summary of prescribing information.



**Estratest® H.S.**  
Esterified Estrogens &  
Methyltestosterone Tablets  
0.625 mg/1.25 mg

**Estratest®**  
Esterified Estrogens &  
Methyltestosterone Tablets  
1.25 mg/2.5 mg

**REPLACE WHAT'S LOST**



**Estratest H.S.**  
Esterified Estrogens &  
Methyltestosterone Tablets  
0.625 mg/1.25 mg

**Estratest**  
Esterified Estrogens &  
Methyltestosterone Tablets  
1.25 mg/2.5 mg

**REPLACE WHAT'S LOST**

The shape and color of ESTRATEST<sup>®</sup> Tablets and ESTRATEST<sup>®</sup> H.S. Tablets are trademarks of Solvay Pharmaceuticals, Inc.

**References:** 1. Longcope C. Hormone dynamics at the menopause. *Ann NY Acad Sci* 1990;592:21-30. 2. Abraham GE, Maroulis GB. Effect of exogenous estrogen on serum progesterone, cortisol, and androgens in postmenopausal women. *Obstet Gynecol* 1974;43:271-274. 3. Dessypris A, Procopi BJ. Plasma testosterone in post-menopausal women (normal and with gynaecological diseases) before and after oophorectomy; effect of ACTH and desamethasone tests. *Acta Endocrinol (Copenh)*. 1981;244(suppl):25-27. 4. Data on file, Solvay Pharmaceuticals, Inc.

**Brief Summary** based on package insert E 0978 rev. 7/94. (For full Prescribing Information and Patient Information refer to package insert.)

**ESTRATEST<sup>®</sup> and ESTRATEST<sup>®</sup> H.S.** (Esterified Estrogens and Methyltestosterone) Tablets.

**WARNING**

**1. ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA.**

There is an increased risk, independent of the other known risk factors, of endometrial cancer in postmenopausal women exposed to exogenous estrogens for prolonged periods. This risk was about 4.5 to 13.9 times greater than in nonusers and appears to depend on both duration of treatment and estrogen dose. In view of these findings, the lowest dose of estrogen that will control symptoms should be used and medication should be discontinued as soon as possible. Close clinical surveillance of all women taking estrogens is important. Diagnostic measures, including endometrial sampling, should be undertaken when indicated to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding.

**2. ESTROGENS SHOULD NOT BE USED DURING PREGNANCY.**

The use of estrogens during pregnancy may result in congenital defects in the reproductive organs of the fetus, and vaginal adenosis and vaginal or cervical cancer later in life in those exposed in utero to estrogens. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb reduction defects.

If the patient becomes pregnant while taking ESTRATEST<sup>®</sup> or ESTRATEST<sup>®</sup> H.S., she should be apprised of the potential risks to the fetus and the advisability of pregnancy continuation.

**DESCRIPTION:** ESTRATEST<sup>®</sup> Each pink tablet (Esterified Estrogens USP and Methyltestosterone USP) contains 1.25 mg of Esterified Estrogens, USP and 2.5 mg of Methyltestosterone, USP. ESTRATEST<sup>®</sup> H.S. (Half-Strength) Each light green, capsule-shaped, sugar-coated oral tablet contains: 0.625 mg of Esterified Estrogens, USP and 1.25 mg of Methyltestosterone.

**INDICATIONS AND USAGE:** ESTRATEST<sup>®</sup> and ESTRATEST<sup>®</sup> H.S. are indicated in the treatment of: Moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogens alone. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms, and they should not be used to treat such conditions.)

ESTRATEST<sup>®</sup> and ESTRATEST<sup>®</sup> H.S. HAVE NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND THEIR USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

**CONTRAINDICATIONS:** Estrogens should not be used in patients with any of the following conditions: 1. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2. Known or suspected estrogen-dependent neoplasia. 3. Known or suspected pregnancy (See Boxed WARNING). 4. Undiagnosed abnormal genital bleeding. 5. Active thrombophlebitis or thromboembolic disorders. 6. A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when in treatment of breast malignancy). Methyltestosterone should not be used in: 1. The presence of severe liver damage. 2. Pregnancy and in breast-feeding mothers because of the possibility of masculinization of the female fetus or breast-fed infant.

**WARNINGS: Associated With Estrogens:** 1. Animal data have found an increased incidence of breast, cervical, vaginal, and liver cancer. In humans, endometrial cancer risk among estrogen users was greater than that of nonusers and appeared dependent on treatment duration and estrogen dose (see boxed WARNING). There is no conclusive evidence that estrogen given to postmenopausal women increases the risk of breast cancer, although a recent long-term follow-up has raised this possibility. However, caution should be used in prescribing estrogens for women with a strong family history of breast cancer or who have breast nodules, fibrocystic disease, or abnormal mammograms. 2. A 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens has been reported. 3. Estrogens should not be used in persons with active thrombophlebitis or thromboembolic disorders, and they should not be used (except in treatment of malignancy) in persons with a history of such disorders in association with estrogen use. Estrogens should be used with caution in patients with cerebral vascular or coronary artery disease and only for those in whom estrogens are clearly needed. Blood pressure should be monitored with estrogen use, especially if high doses are used. Glucose-intolerant patients should be carefully observed while receiving estrogens. 4. Administration of estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.

**Associated With Methyltestosterone:** In patients with breast cancer, androgen therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued. Prolonged use of high doses of androgens has been associated with the development of peliosis hepatis, a life-threatening complication, and hepatic neoplasms including hepatocellular carcinoma. (See PRECAUTIONS). Cholestatic hepatitis and jaundice can occur at a relatively low dose. If cholestatic hepatitis with jaundice appears or if liver function tests become abnormal, androgen should be discontinued and the cause determined. Drug-induced jaundice is reversible with drug discontinuation. Edema with or without heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease.

**PRECAUTIONS: Associated With Estrogens:** 1. Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy, with special attention to blood pressure, abdomen, and pelvic organs and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than 1 year without another physical examination being performed. 2. Because estrogens may cause some degree of fluid retention, conditions such as epilepsy, migraine, and cardiac or renal dysfunction require careful observation. 3. Certain patients may develop undesirable manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. 4. Estrogens should be administered with caution in patients with impaired liver function, metabolic bone diseases associated with hypercalcemia, and in patients with renal insufficiency. 5. Certain endocrine and liver function tests may be affected by larger doses of estrogen. 6. The pathologist should be advised of estrogen

therapy when relevant information is available. 7. Estrogens are effective doses for a specific indication. 8. The addition of a progestin for 7 or more days of a cycle of estrogen administration have been reported to lower the incidence of endometrial hyperplasia. Studies of the endometrium suggest that 10 to 13 days of progestin are needed to eliminate any hyperplastic changes, though it has not been clearly established whether this will provide protection from endometrial carcinoma. Additional caution associated with the inclusion of progestin, including adverse effects on carbohydrate and lipid metabolism, may be minimized by the choice of progestin and dosage. **Pregnancy Category X:** Estrogens should not be used during pregnancy. See CONTRAINDICATIONS and Boxed WARNING. **Nursing Mothers:** As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

**Associated with Methyltestosterone:** 1. Discontinuation of androgen at the time of evidence of mild virilism is necessary to prevent irreversible virilization. Such virilization is usual following androgen use at high doses. 2. Prolonged use of androgen may result in sodium and fluid retention, which may present a problem for patients with compromised cardiac reserve or renal disease. 3. Rarely, hypersensitivity may occur. 4. Hypercalcemia may occur; in which case the drug should be discontinued.

Patients should be instructed to report any of the following side effects of androgens: hoarseness, acne, changes in menstrual periods, more hair on the face, nausea, vomiting, changes in skin color or ankle swelling.

Animal data has shown testosterone implants to induce cervical uterine tumors in mice, which metastasized in some cases. Other studies suggest that testosterone increases susceptibility to hepatoma in mice. Testosterone is also known to increase the number of tumors in rats. In humans, there are rare reports of hepatocellular carcinoma in patients receiving long-term androgen therapy. **Pregnancy: Teratogenic Effects.** Pregnancy Category X (see CONTRAINDICATIONS). **Nursing Mothers:** Estrogens and androgens are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, the patient must consider either discontinuing nursing or discontinuing the drug.

**ADVERSE REACTIONS: Associated With Estrogens:** (see also WARNINGS.) The following adverse reactions have been reported with estrogenic therapy: 1. Breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual like syndrome, vaginal candidiasis, change in amount of cervical secretion. 2. Breast tenderness and enlargement. 3. Nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice. 4. Chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism. 5. Steepening of corneal curvature, intolerance to contact lenses. 6. Headache, migraine, dizziness, mental depression, chorea. 7. Increased decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, changes in libido.

**Associated with Methyltestosterone:** 1. Side effects of androgen therapy include amenorrhea and other menstrual irregularities, inhibition of gonadotropin secretion, and virilization, including deepening of the voice and clitoral enlargement. Clitoral enlargement is usually not reversible after androgens are discontinued. Administration during pregnancy causes virilization of the external genitalia of the female fetus. 2. Hirsutism, male pattern baldness, and acne. 3. Retention of sodium, chloride, water, potassium, calcium, and inorganic phosphates. 4. Nausea, cholestatic jaundice, and alterations in liver function test, hepatocellular neoplasms and peliosis hepatis (see WARNINGS). 5. Suppression of clotting factors II, V, VII, and X, bleeding in patients on concomitant anticoagulant therapy, and polycythemia. 6. Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia. 7. Increased serum cholesterol.

**OVERDOSAGE:** Estrogen may cause nausea and withdrawal bleeding. There have been no reports of acute overdosage with androgens.

**DOSAGE AND ADMINISTRATION:** 1. Given cyclically for short-term use only: Moderate to severe vasomotor symptoms associated with the menopause in patients not improved by estrogen alone. The lowest dose that will control symptoms should be chosen and medication discontinued as promptly as possible. Administration should be cyclic (e.g., three weeks on and one week off). Attempts to discontinue or taper the medication should be made at three to six month intervals. Usual dosage range: 1 tablet of ESTRATEST<sup>®</sup> or 1-2 tablets of ESTRATEST<sup>®</sup> H.S. daily.

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# **EXHIBIT B**

