

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Deborah Platt Majoras, Chairman**
 Pamela Jones Harbour
 Jon Leibowitz
 William E. Kovacic
 J. Thomas Rosch

_____)	
In the Matter of)	
)	
THE GREEN WILLOW TREE LLC,)	
a limited liability company, and)	DOCKET NO. C-4207
)	
ROBERT BURNS,)	
individually and as a manager and)	
member of The Green Willow Tree, LLC.))	
_____)	

COMPLAINT

The Federal Trade Commission, having reason to believe that The Green Willow Tree, LLC, a limited liability company, and Robert Burns, individually and as a manager and member of The Green Willow Tree, LLC (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent The Green Willow Tree, LLC is a North Carolina limited liability company with its principal office or place of business at 34 Rocky Ridge Road, Asheville, North Carolina 28806.
2. Respondent Robert Burns is a manager and member of The Green Willow Tree, LLC. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of The Green Willow Tree, LLC, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of The Green Willow Tree, LLC.
3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.
4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the

symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman's risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman's risk of developing breast cancer.

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Progesta Care Plus, EST, and Restored Balance. Respondents advertise and offer the products for sale through the Internet site www.greenwillowtree.com.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Progesta Care Plus, EST, and Restored Balance are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. Progesta Care Plus is a drug labeled as containing Natural Progesterone USP and other ingredients. A four ounce tube costs \$35 plus shipping and handling. EST is a drug labeled as containing 960 mg of USP natural progesterone extracted from wild yam and soybean per two ounce tube and other ingredients. A two ounce tube costs \$24.95 plus shipping and handling. Restored Balance is a drug labeled as containing Natural Progesterone USP (15-20 mg per 1/8 teaspoon dose) and other ingredients. A two ounce tube costs \$24 plus shipping and handling. Progesta Care Plus, EST, and Restored Balance are applied transdermally.

8. To induce consumers to purchase Progesta Care Plus, EST, and Restored Balance, respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondents' website:

A. A BRIEF LOOK AT THE MAJOR HORMONES

* * *

* * *

Prevents endometrial cancer
Helps prevent breast cancer
Stimulates bone building

* * *

Synthetic progestones, like Provera, have many side effects and can be dangerous as well. Natural progesterone is a “human-identical hormone in that it is an exact copy of the molecule produced by the ovaries.

(Exhibit A at 4-5.)

- B. We believe that natural progesterone is the safest and most beneficial form of supplemental progesterone.

U.S.P. bio-identical progesterone is very different from synthetic progestin. Bio-identical progesterone has the same molecular structure as the progesterone produced in the human body and the body recognizes it. Topical creams have been shown to be the most effective mode of administration. When bio-identical progesterone is applied topically, it is absorbed transdermally (through the skin) immediately into the bloodstream and then distributed and utilized in progesterone target tissues. Transdermally absorbed progesterone works within the body in essentially the same manner as the progesterone that is endogenously secreted (produced within the body) to enter the blood stream directly.

(Exhibit A at 8.)

- C. THE BENEFITS OF NATURAL PROGESTERONE

* * *

An essential key, according to an increasing number of researchers and medical professionals, is the neglected substance known as natural progesterone. Their studies indicate that this hormone is beneficial for a wide range of symptoms related to PMS and menopause, and that progesterone may be the key factor in understanding, preventing, and even reversing osteoporosis.

First, let's clarify the difference between natural and synthetic progesterone--a distinction that even many doctors do not make. Natural progesterone is considered extremely safe. Dr. Joel T. Hargrove, director of the PMS and Menopause Clinics at Vanderbilt University in Nashville, says, “I have been prescribing (natural) progesterone for 12 years and I haven't seen any long-term side effects. It doesn't affect cholesterol levels; it doesn't affect Mother Nature--

Dr. Lee describes the case of a 72 year old woman who was especially conscientious in following his therapeutic program. She suffered from back pains and kyphosis and had lost height; x-rays revealed an advanced case of osteoporosis. Dual-photon densitometry tests over a period of 2 ½ years on Dr. Lee's program revealed an average increase of over 29% in the bone density of the lumbar vertebrae. "The vertebrae of lowest mineral density increased over 39% in mineral density," states Dr. Lee. His conclusion offered hope to countless menopausal women: "Osteoporosis would appear to be reversible."

(Exhibit A at 12-14.)

- D. Natural progesterone is technically called "Progesterone USP" or sometimes "USP progesterone". Because it is not cancer causing and because it is such a beneficial hormones, progesterone USP has been considered so safe that a "more is better" attitude has been adopted.

(Exhibit A at 18.)

- E. Since 1995, I have been writing about the positive benefits of natural estrogen and progesterone, as opposed to the dangers of synthetic hormones. . .It is my firm belief that women do not have to choose between heart attacks or cancer on the one hand; and hot flashes, mood swings, premature aging, and other symptoms of low hormone levels on the other. Natural alternatives exist, and they go far beyond the commonly used remedies of using more soy products and herbs. These alternatives are just as effective as the synthetics. While nothing in this life is 100% safe, according to all the research and experience at my disposal, they are

Dr. John Lee's [sic] impressive study involved 100 post-menopausal women, many of whom showed osteoporosis symptoms. The women used a 3% natural progesterone cream for at least three years. Of the 63 women who had bone density tests, instead of the predicted bone loss that would be expected in this group, every single one had an increase in bone mass. Some women showed an

12. The acts and practices alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, on this thirteenth day of November, 2007, has issued this complaint against respondents.

By the Commission.

Donald S. Clark
Secretary

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