

**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-**  
                                 )  
ROBERT BURNS, )  
individually and as a manager and )  
member of The Green Willow Tree, LLC.)  
\_\_\_\_\_ )

**COMPLAINT**

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](http://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. Progest

\* \* \*

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.

basically, it is a wonderful thing.” In England, Dr. Katharina Dalton has been using natural progesterone for over 30 years and has seen no increases in cancer.

Synthetic progestones, such as Provera


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 miner

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 predic

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 \_\_\_\_ day of \_\_\_\_\_, 2007, has issued this complaint against respondents.

By the Commission

Donald S. Clark  
Secretary