

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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

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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

* * *

Because progesterone is the hormone responsible for building bone, we may also start to lose bone during this period [peri-menopause]. And whether or not we decide to use estrogen during or after menopause, we should continue to use progesterone indefinitely to protect our bones. This hormone is generally best absorbed through the skin in the form of a cream or liquid.

* * *

Benefits of progesterone

* * *

Prevents endometrial cancer
Helps prevent breast cancer
Stimulates bone building

* * *

Synthetic progesterones, 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--

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, are called progestins or progestogens, and are known to have a wide range of side effects. David Steinman, author of *Diet for a Poisoned Planet*, writes that “In addition to unpleasant side effects such as fluid retention and salt build-up, synthetic progesterone is known to cause some serious illnesses--blood clots and uterine and breast cancers.” The list of side effects, risks, and warning for Provera is a full page long. Synthetic progesterone causes side effects, says John R. Lee, MD (now deceased) of Sebastopol CA, because “it's not progesterone. The pharmaceutical companies alter the molecular structure so it no longer fits into the bio-chemical machinery of the body.”

* * *

Effects of excess or unbalanced estrogen	Progesterone effects
* * *	* * *
causes endometrial cancer	prevents endometrial cancer
increased risk of breast cancer	helps prevent breast cancer
slightly restrains osteoclast function	stimulates osteoblast bone building

One of the most important actions of progesterone is that it has major implications for bone health, however, the use of natural progesterone for the prevention of osteoporosis in post-menopausal women is very controversial. In the International Clinical Nutrition Review, Dr. Lee reported on his treatment of 100 post menopausal women with natural progesterone. Many of the women had lost height or suffered one or more fractures; both indications of osteoporosis. Bone density tests were used to monitor the effects of the therapy. Although some women were treated with estrogen as well, Dr. Lee concluded that “the bone building benefits of the progesterone therapy were independent of the presence or absence of supplemental estrogen.” This is not surprising when we realize that the function of estrogen pertains to the osteoclast cells which dissolve old or imperfect bone, while progesterone mediates the osteoblast cells which build bone. Osteoporosis occurs when osteoclast activity exceeds osteoblast activity. Thus, estrogen can slow the loss of bone, but progesterone can help to build it. Dr. Lee insured adequate mineral intake for his patients; however, nutritional support cannot account for the impressive results he achieved. “It was common to see a 10% increase (in bone density) in the first 6 to 12 months and an annual increase of 3 to 5% until stabilizing at the levels of healthy 35-year olds,” Lee says. “Neither age nor time from menopause was an apparent factor. The faster increases occurred in those with the lowest initial bone densities. . . The occurrence of osteoporotic fractures dropped to zero.”

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 virtually free of both dangerous complications and uncomfortable side effects.

(Exhibit A at 22.)

- F. Osteoporosis is one of the most serious health concerns for mid-life and mature women, and can affect men as well. The use of natural hormones, such as progesterone, is essential for bone health.

(Exhibit A at 27.)

- G. However, all foremost authorities on this subject agree that progesterone is by far the more important hormone for osteoporosis. Progesterone helps to build new bone. It's [sic] like having a bank balance. Estrogen helps you to spend less, but progesterone puts new cash into your account. Therefore, using progesterone is essential for your bone health. Progesterone levels begin to fall 5-15 years before menopause. This corresponds with the fact that bone loss usually starts when women are in their forties, when estrogen levels are generally still high. Progesterone declines even further after menopause. If you want to keep your bones healthy, use some type of progesterone!

* * *

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 increase of 10% after the first 6 to 12 months of therapy, and others showed a 20-25% increase in the first year. Dr. Lee found that the effects of the therapy were independent of whether the women were receiving estrogen. While Dr. Lee's [sic] results have not been replicated in the US, I have heard that progesterone is the standard treatment for osteoporosis in Europe.

(Exhibit A at 32-34.)

- H. This elegant white cream contains natural progesterone and natural phyto-estrogens, and provides an ideal hormone balance for menopausal and post-menopausal women. A rare find, EST is based on a phyto-estrogen equivalent of bi-estrogen with natural progesterone. It is formulated for quick absorption into the skin with superior bioavailability. This completely natural product can provide relief from menopausal and peri-menopausal symptoms including, hot flashes, night sweats, mood swings, vaginal dryness, and sleep disturbances. May also help improve new bone formation.

(Exhibit A at 37.)

9. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that:

- A. Progesta Care Plus, EST, and Restored Balance are effective in preventing, treating, or curing osteoporosis;
- B. Progesta Care Plus, EST, and Restored Balance are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and
- C. Progesta Care Plus, EST, and Restored Balance do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

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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