

Complaint

IN THE MATTER OF

**THE GREEN WILLOW TREE, LLC,
AND
ROBERT BURNS**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4207; File No. 072 3144

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order addresses the deceptive advertising and promotion of Progesta Care Plus, EST, and Restored Balance transdermal creams in violation of the FTC Act. According to their labels, the creams contained, among other ingredients, natural progesterone. The complaint alleged that the respondent had no substantiation for its claims that the creams were effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The consent order requires that respondents have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health related service or program is effective in preventing, treating, or curing any disease. The order also bars respondents from engaging in similar acts and practices in the future and prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the Commission: Gregory A. Ashe, Laura DeMartino, Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the Respondents: Not represented by counsel.

Complaint

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

Complaint

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

* * *

Complaint

Because progesterone is the hormone responsible for building bone, we may also start to lose bone during this period [perimenopause]. 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 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)

Complaint

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 progesterones, 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

Complaint

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

Complaint

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 22 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

Complaint

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!

* * *

Complaint

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;

Complaint

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.

Complaint

Exhibit A



Natural Hormones and Supplements for Health Conscious Men and Women

contact us
toll free 877-666-4337
local or intl 528-665-3095
info@greenwillowtree.com

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NEW - ORDER WITHOUT AN ACCOUNT - NEW

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- Mood Enhancement
- NEW PRODUCTS!
- Progesterone
- Prostate Health
- Sexual Performance
- Skin Care
- Sleep Easy
- Thyroid
- Urological Health
- Vibrational Essences
- Vitamins & Misc
- Weight Loss



Welcome to The Green Willow Tree!

We offer a wide array of natural supplements to assist you with thyroid health, PMS, menopause, andropause, and other changes in life. We offer phyto-estrogens, natural progesterone, thyroid support, Human Growth Hormone, testosterone precursors, homeopathics, and products for enhancing libido and sexual performance in both men and women.

As well as natural hormones, we also carry the finest supplements for enhancing bone and heart health, skin care, digestive health, detoxification, and more. Everything in our catalog has been selected to be as safe and effective as possible. None of our products have been tested on animals.

At The Green Willow Tree, we value our reputation for giving you personal attention. Your email inquiries and orders will receive a prompt response.

We have been researching natural hormones and related health products for over ten years, and continue to upgrade our product line at every opportunity. For those who enjoy reading more in-depth information, please consult the Articles section on this site. You may wish to begin by reading the selection called The Major Hormones, and/or consult our Product Selection Guide.

Thank you for visiting our site and for giving us the opportunity to serve you. If you have questions, we are only an email away.

All information on this site is for educational purposes only, and is not intended as medical

Featured Product



**Allergies: a
Foundational
Formula 1 by
SafeCareOTC®**

For support of a healthy, balanced immune system, and prevention & relief of allergy & hayfever symptoms including: head/nasal congestion, mucous discharges, headaches, clogged sinuses, red, itchy, watery eyes, sensitive to light, ears ring or itch, sneezing, cough, hoarseness, deep itch in nose or throat, sore or raw throat, dry mucous membranes or lips.

**For best results use
'Allergies: a
Foundational
Formula 1' with the
'Allergies: Regional
Formula 2' specific
for your area.**

SEARCH:



YOUR BASKET

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YOUR ACCOUNT



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THE GREEN WILLOW TREE, INC. (GREENWILLOWTREE.COM) - THE GREEN WILLOW TREE, INC. - TRADEMARK SUPPLEMENTS FOR THERAPEUTIC PURPOSES Page 2 of 2

advice.*

**[For more
information click on
product picture.]**

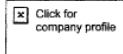
E-mail a friend about The Green Willow Tree.

All products come with instructions for use.
For further information or personal questions, please **email us**.
You may order online, or place your order by phone at 877-968-4337 (toll free) or 828-665-3095.
Please hit "**Reload**" or "**Refresh**" to make sure you are seeing the most current version of this page.

*These statements have not been evaluated by the Food and Drug Administration.
Our products are not intended to diagnose, treat, cure, or prevent disease.

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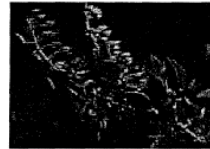
Page 1 of 1



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Men and Women**

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Hormone Health
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For more information, email **The Green Willow Tree**.

A BRIEF LOOK AT THE MAJOR HORMONES
by Elora Gabriel

There are many hormones in the human body. Among the most important are estrogen, progesterone, testosterone, thyroid, and DHEA. Human growth hormone has been studied intensively in recent years and has strong implications for aging reversal.

ESTROGEN is the hormone that makes us women and that makes us feel like women. When estrogen levels begin to drop, usually in our late 40's, we may notice one or more of the symptoms in the table below. Or, we may simply experience a loss of well-being.

Symptoms of estrogen deficiency

Hot flashes	Depression, moodiness	Joint/muscle pain	Vaginal atrophy
Night sweats	Anger/rage	Heart palpitations	Vaginal dryness
Fatigue	Memory loss	Dizziness	Bladder infections

Supplementing with natural estrogen can provide the following benefits:

Stabilizes moods	Improves memory and energy	Restores vaginal lubrication
Relieves hot flashes	Alleviates sleep disturbances	Improves vitality and energy
	Prevents vaginal/bladder	Improves skin & breast

Complaint

Slows bone loss	Infections	tone
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But what about the dangers and side effects of estrogen? First of all, there are different types of estrogen. Some are much, much safer than others and have virtually no side effects. There are three major types of estrogen in our bodies: estradiol, estrone, and estriol. Estradiol and estrone are the highly potent estrogens that may stimulate cancer. Estriol is considered very safe, and clinical evidence indicates that it even protects against breast cancer. All standard estrogen prescriptions are either estradiol or estrone. Premarin, for example, is estrone, and is made of horse estrogens that are not natural for our bodies. For most women, the ideal balance of estrogens is 80% estriol, 10% estrone, and 10% estradiol. This blend, called tri-estrogen, has been found to rapidly alleviate the symptoms of menopause without increasing the danger of breast cancer. Tri-estrogen is the blend of estrogens naturally found in a healthy young woman's body. Please see **The Good News About Natural Estrogen**, for a complete discussion of the different types of estrogen.

Phyto-estrogens are estrogenic compounds found in plants. Research shows that phyto-estrogens can balance either high or low estrogen levels, and may reduce the risk of breast cancer. Phytoestrogens differ remarkably from synthetic estrogens in that they are easily broken down, are not stored in the tissues and spend very little time in the body, thus they are unlikely to cause cancer. And because humans have spent millions of years eating plants and herbs, our bodies easily accept plant estrogens and find them both effective and beneficial. We carry a product called Pro-Estron which is a phyto-estrogen blend based on the tri-estrogen ratio.

Please click [here](#) to view our estrogen products.

PROGESTERONE is a bit more subtle than estrogen, but just as important. It has its own unique benefits, and it balances estrogen. Progesterone might be likened to a healthful meal of protein and vegetables, while estrogen is like a great dessert. It is fine to use only progesterone. But, just as we wouldn't want to eat dessert without the main course, we should never use estrogen without the balancing effect of progesterone. This rule holds true even for women who have had a hysterectomy.

In fact, we should think about progesterone first when we want to balance our hormones. PMS, which is often caused by a lack of progesterone, can occur at any age prior to menopause. As we enter peri-menopause, usually during our 40's, falling progesterone levels can cause increased PMS and menstrual problems, growth of fibroids, insomnia, mood swings, etc. Because progesterone is the hormone responsible for building bone, we may also start to lose bone during this period. 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. For more complete information on progesterone, please see **The Benefits of Natural Progesterone**.

Complaint

Benefits of progesterone

Natural diuretic	Helps thyroid hormone action	Prevents endometrial cancer
Natural antidepressant	Normalizes blood sugar levels	Helps prevent breast cancer
Normalizes blood clotting	Protects against fibrocysts	Stimulates bone building

As with estrogen, progesterone comes in different types. 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. Wild yam extract is an herbal product with many progesterone effects and benefits. Wild yam might be described as a phyto-progesterone (a plant-derived progesterone like substance.)

Please click [here](#) to view our progesterone products.

DHEA is the most abundant hormone in the human body, and is produced by the adrenal glands. Levels drop with age, for both men and women, falling to a fraction of their peak value in the 20's. Most people over the age of 50 are deficient in DHEA and would benefit from supplementation. DHEA can be converted in the body into other sex hormones. Thus it may decrease hot flashes (estrogen) and increase libido (testosterone). DHEA cream is very effective for both of these purposes, and also helps to increase bone density (see **Hormonal and Lifestyle Factors for Bone Health**.) Perhaps the best thing about DHEA is that it just makes you feel better! Supplementation tends to increase energy, well-being, and sleep quality. Many people report reduced joint and muscle pain. Research indicates that DHEA has positive implications for breast cancer, heart disease, diabetes, MS, memory loss, CFS, Alzheimer's, and Parkinson's disease. 5-15 mg./day is the ideal dose for most women, while men can use 25 mg./day. These dosages are considered very safe by hormonal experts and should have no side effects. It is important to buy pure, good quality DHEA, as most DHEA on the market is of inferior quality and may be contaminated with various impurities. For more information on DHEA, please email **The Green Willow Tree**.

TESTOSTERONE is the major sex hormone for men, and is needed by women in smaller quantities. It is responsible for firm muscles and a healthy libido in both sexes, and has other important roles to play in the body as well. Please see **Testosterone, Hormone of Energy and Desire**, for more information. For women, levels of this hormone usually drop before or during menopause. Men also pass through "andropause" which is caused by a lessening of testosterone production, resulting in lowered virility and decreased muscle mass. Many men would benefit by supplementation with natural testosterone. While synthetic methyl testosterone (found in Estratest, for example) can cause liver toxicity and other side effects, natural testosterone is considered very safe.

Complaint

Numerous studies have shown, for example, that it actually has a positive effect upon cardiovascular health. Natural testosterone also protects against breast cancer, according to Dr. William Douglas, editor of Second Opinion health newsletter. Benefits of testosterone may be obtained either by using a prescription form of natural testosterone, or through one of the other hormones which convert into testosterone--DHEA and Androstenedione. For women specifically interested in increasing sex drive, please see **How to Have a Healthy Libido in Mid-Life and Beyond**. Please click [here](#) to view our testosterone enhancing products.

THYROID HORMONE is essential to proper metabolism and for the functioning of almost every organ and system in the body. Low thyroid symptoms include cold hands/feet, sluggish metabolism, low basal temperature, weight gain, slow pulse, depression, dry skin, dry/brittle/thinning hair, fatigue, feeling groggy in the morning but more alert at night, constipation, yellowish coloration on skin (particularly on the palms), slow speech, PMS and/or painful menstrual cramps, recurrent respiratory infections, fluid retention and puffiness in face, ankles, etc. Many doctors and practitioners believe that we are currently experiencing an epidemic in low thyroid function, particularly among women. A large majority of hypothyroid patients are not able to get help with their condition, due to the fact that doctors usually rely solely on the TSH for diagnosing thyroid problems. It is my belief that the TSH test is not always accurate, and that symptoms are an important guide. Please see **The Thyroid Connection** for more information. This article offers resources for getting help, either by prescription or using effective non-prescription alternatives. Please click [here](#) to view our thyroid products.

HUMAN GROWTH HORMONE. Holistic doctors have been excited about human growth hormone for years, but at \$1000/month, the injections have been available only to the rich. Normally produced in the pituitary, HGH is clinically proven to reverse many aspects of the aging process. Extensive studies with HGH have shown the following:

Excellent weight loss w/o exercise	Increased lean muscle mass	Higher energy
Enhanced sexual performance	Greater cardiac output	Hair regrowth
Superior immune function	Improved cholesterol profile	Younger thicker skin
Return of natural hair color	Lowered blood pressure	Improved sleep
Elimination of cellulite	Regeneration of major organs	Better memory

Recently, effective and less expensive forms of HGH have become available. We now have secretagogues, or products which cause the pituitary to produce growth hormone. Even better, actual growth hormone is now available over the counter at very reasonable prices. Please see **Human Growth Hormone, Clinically Proven Rejuvenation**, for more information. Please click [here](#) to view our HGH

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1997

"The overall deterioration of the body that comes with growing old is not inevitable. We now realize that some aspects of it can be reversed." -- Daniel Rudman, MD.

The information in this article is for educational purposes only, and is not intended as medical advice.

*These statements have not been evaluated by the Food and Drug Administration.
Our products are not intended to diagnose, treat, cure, or prevent disease.

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 Fax: 208-330-2445
 info@greenwillowtree.com (product questions)
 customerservice@greenwillowtree.com (order questions)

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THE GREEN WILLOW TREE HUSBANDRY - THE GREEN WILLOW TREE - HUSBANDRY SUPPLIES FOR THE HUSBANDRY - A NEW & OLD



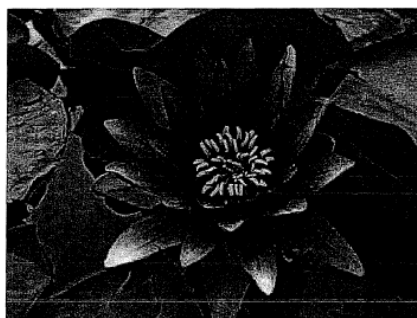
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Digestion & Elimination
Estrogen/Combinations
HGH
Hormone Tests
Immune Boosting
Mood Enhancement
NEW PRODUCTS!
Progesterone
Prostate Health
Sexual Performance
Skin Care
Sleep Easy
Thyroid
Urological Health
Vibrational Essences
Vitamins & Misc
Weight Loss



Progesterone

In our opinion, progesterone is essential for any woman using estrogen.

SEARCH:

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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 (1). 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.

1. Pearson GC, McCullough WL, Taylor PA et al. Topical natural progesterone cream effect on postmenopausal bone loss: a two-year double-blind, randomized, placebo-controlled trial. From IOF

Complaint

THE GREEN WILLOW TREE PROGESTERONE - THE GREEN WILLOW TREE - Natural Supplements for Natural Health Page 2 of 4

World Congress on Osteoporosis Osteoporosis International 2004; 15(suppl 1):abstract OC.

For one opinion on [natural progesterone](#), please click here. For a discussion the problem of [excess progesterone](#), please click here.

Hormone Tests

Please click on the above link to learn about accurate home test kits for your hormone levels.

Products:



1. EST

[REPLACES FEMININE BALANCE PLUS] This elegant white cream contains natural progesterone and natural phytoestrogens, and provides an ideal hormone balance for menopausal and post-menopausal women. A rare find, EST is based on a phytoestrogen 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, mood swings, vaginal dryness, and sleep disturbances. Two ounce tube, a one month supply.* [For more information please click on picture]

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11. Restored Balance

This high quality cream is on Dr. John Lee's approved list of progesterone creams. It is more concentrated than most natural progesterone creams, and comes with an easy to use dispenser. The result is that your tube will last longer. Restored Balance is also pure and chemical free, containing no chemical preservatives or stabilizers. Herbal extracts and Vitamins A and E added for enhanced benefits.* Unconditional money back guarantee if you are not satisfied. (2 oz. pump tube, about an 8 week supply.) [For more information please click on picture]

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1a. Progestacare Plus

[REPLACES FEMININE BALANCE PLUS] ProgestaCare Plus is a convenient way to supplement your estrogen and progesterone levels with one easy application. This pure, chemical-free cream combines bio-identical natural progesterone with the highest quality all natural phytoestrogens. A medium strength product, it should be adequate to support healthy hormonal balance for

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most menopausal or post-menopausal women. The convenient, reasonably priced pump tube dispenses an average dose with one press and contains four ounces of cream (twice that of similar products). Lasts about two months.* **[For more information please click on picture]**

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**38. Vitex**

Vitex is known as the supreme hormonal tonic for women. Traditionally known to be helpful for a wide range of symptoms associated with PMS, menopause, and the entire menstrual cycle. Also indispensable for women with uterine fibroids, fibrocystic breasts, or endometriosis; and **especially good for women experiencing hormonal upsets after coming off the birth control pill.*** (2 oz. bottle. Should last 3-4 weeks.) **[For more information please click on picture]**

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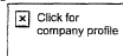
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LAWRENCE ANDERSON, FARMER'S - ADDENDUMS - THE BENEFITS OF NATURAL PROGESTERONE

Page 1 of 10



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THE BENEFITS OF NATURAL PROGESTERONE
by Elora Gabriel

Women's lives are deeply affected by the ebb and flow of our hormones. Like dwellers on the seashore, our lives are patterned by the cycles of nature, whether it is the monthly rhythm of our menstrual cycle, or the greater divides of puberty and menopause. Our female hormones make possible our greatest gifts--for only we can bring forth life. But hormonal lack or imbalance can also be our most consistent enemy, causing the all-too-common miseries of PMS and menopause. Many women are still unaware of the fact that there is help for these problems without resorting to artificial hormones. 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 progesterones, 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-

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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 biochemical machinery of the body." As one woman said to me, "Since I've been using Provera, I scream at my kids, my husband can't stand me, and I've gained 20 pounds. Other than that, I've had no side effects!"

As the mass of baby boomers enters mid-life, increasing attention has been focused upon hormone replacement therapy. So far, the emphasis has largely been upon estrogen. While many women do need and benefit greatly from estrogen, several important points are often missed here. One is that--even for women who have had a hysterectomy--estrogen should always be used with some form of natural progesterone. Progesterone is the one hormone which has the ability to counterbalance the potentially harmful effects of unopposed estrogen. A second consideration for those who need estrogen is the fact that the female body actually produces three major kinds of estrogen--estradiol, estrone, and estriol. Of the three, estriol is by far the safest--in fact, evidence exists to show that it actually protects against breast cancer. For more information on estrogen, please see my article **The Good News About Natural Estrogen**.

What about progesterone? Is this less glamorous hormone a substance that we use only because we need it to balance estrogen? Not necessarily. Progesterone has its own unique spectrum of benefits, and is safer than estrogen. Many researchers now believe that, for many hormonal problems, natural progesterone is the place to start. While the power of estrogen is undeniable, its danger lies in its ability to promote growth, including cancerous growth, in body cells. Progesterone is more of an intermediate building block. At need, the body converts a certain amount of it into estrogen or other hormones. Therefore, using progesterone can help to balance the endocrine system and alleviate other hormonal deficiencies. Dr. Lee, who has done extensive research on the effects of estrogen and progesterone upon menopause, has summarized the effects of these two hormones in his paper "Slowing the Aging Process With Natural Progesterone". Please note that the negative effects of estrogen occur when it is in excess or not adequately balanced with progesterone. In proper balance, estrogen is highly beneficial.

Effects of excess or unbalanced estrogen	Progesterone effects
breast stimulation	protects against fibrocysts
salt and fluid retention	natural diuretic
increased fat in body	helps use fat for energy
decreases libido	restores libido
impairs blood sugar control	normalizes blood sugar levels
increased blood clotting	normalizes blood clotting
reduced oxygen levels in all cells	restores proper cell oxygen levels
causes endometrial cancer	prevents endometrial cancer

Complaint

AMERICAN ANTI-DUMPING LAWYERS - ATTORNEYS - THE EFFECTS OF TRADE PROTECTION

Page 2 of 6

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 1/2 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."

[Ed. Subsequently, clinical studies have shown that natural progesterone given transdermally enters the blood stream as progesterone, but does not show improvement in bone health at the levels that were studied. A study by Pearson GC, McCullough WL, Taylor PA et al. Topical natural progesterone cream effect on postmenopausal bone loss: a two-year double-blind, randomized, placebo-controlled trial. [From IOF World Congress on Osteoporosis Osteoporosis International 2004; 15(suppl 1):abstract OC.] reported: The study involved 45 postmenopausal women, aged 49-70. For the first year, one group used a topical progesterone cream (1.5% USP) containing 40 mg progesterone twice daily, while the other group used placebo. Both groups showed a decrease in mean lumbar spine BMD (bone mass density) at 12 months, and there was no significant difference between the two. During the second year, the trial became an open-label study. The first group doubled the dose and applied 80 mg progesterone twice daily, whereas the placebo group started using the cream, at 40 mg

Complaint

progesterone twice daily, and also took a vitamin and mineral supplement. Both groups again showed a decrease in BMD at 24 months.

Even though the progesterone cream was well absorbed, it did not prevent bone loss or increase bone mass in postmenopausal women, Pearson and colleagues concluded. She suggested that perhaps a different dose or formulation or delivery system would be effective, noting that animal studies have shown that progesterone stimulates bone formation.]

Less dangerous than osteoporosis, yet of monthly concern to millions of women, is the problem of PMS. The cause of this condition has long been a mystery, but it is now believed that a high proportion of PMS sufferers have too much estrogen in their bodies in relation to progesterone. Neils Lauenstein, M.D., co-author of *PMS: Pre-menstrual Syndrome and You* and professor of obstetrics and gynecology at New York Medical College, claims that more than 90% of patients in his practice who have tried natural progesterone have found relief. "When nothing else works, it is the treatment of choice--in my practice, hundreds of women who were severely handicapped by PMS have been completely symptom-free with (natural) progesterone," says Dr. Lauenstein. He adds that synthetic progestogens actually worsen the symptoms of PMS. Because these drugs inhibit a the concentration of natural progesterone in the blood, they exacerbate the imbalance of female hormones, thereby increasing pre-menstrual distress. David Steinman discusses the case of a 40-year old woman whose doctor prescribed Provera for her unpredictable menstrual cycle, which included irritability and wild mood swings. Provera caused nervousness and heart palpitations. When the patient switched to natural progesterone, her cycle became regular and PMS symptoms completely disappeared. Many women have also found that progesterone both relieves and prevents menstrual cramps, from mild to severe.

A great many women are now experiencing what is called the pre-menopausal or peri-menopausal period. This is a period of five to eight years preceding actual menopause when female hormones begin to fluctuate. Symptoms of PMS may worsen, or seem to last all month long. Some women suffer from insomnia and depression; others experience fluid retention, painful breasts and/or the rapid growth of uterine fibroids. These symptoms are often caused by what is termed "unopposed estrogen". During these years, estrogen production may continue unabated, while progesterone production begins to taper off. Thus, supplementing with natural progesterone can alleviate the imbalance and resulting symptoms. It's interesting to note that, even if both estrogen and progesterone are low, estrogen will dominate. Thus, it is crucially important to keep progesterone levels up. Dr. Lee writes, "Supplementation with natural progesterone during the peri-menopausal stage when estrogen dominance often prevails will prevent uterine fibroids. If a woman can prevent or reverse osteoporosis without estrogen (such as with progesterone) she need not risk estrogen-induced fibroids. This is not good news to surgeons."

The story doesn't end here. Researchers like Dr. Raymond F. Peat continue to find other benefits of this remarkable hormone. Peat states that progesterone protects against blood clotting caused by excess estrogen. He also says that progesterone "prevents stress-induced coronary blood vessel spasms in aged hearts", which is probably one

Complaint

18-0811 Natural Progesterone - Complaint - THE RIGHTS OF CONSUMERS

Page 3 Of 6

reason that women have few heart attacks as long as their ovaries are functioning. Dr. Peat continues: "Other studies suggest that progesterone has a role in regeneration of damaged brain cells and prolonged growth of the brain. Delayed aging and longer life span have been very clearly related to extra progesterone. Many types of tumors have been prevented and helped with progesterone." Dr. Peat considers both progesterone and thyroid to be primary regulatory hormones which regulate metabolism directly and have a normalizing effect on the pituitary, the body's master gland. Progesterone can also protect against hypoglycemia as it increases the oxygenation and metabolic efficiency of the cells. And impressive studies have shown that supplemental natural progesterone during pregnancy produces children with higher IQ's (by about 35 points) and better adjusted personalities.

How should we obtain natural progesterone? Dr. Lee used an over-the-counter 3% topical cream in his study. And in fact, the moderate-strength creams (such as those containing 800-900 mg. of progesterone per 2 oz. jar) seem to produce the best results. Natural progesterone is also available in tablet form (oral micronized progesterone). However, according to Dr. Lee, the creams are far superior for supporting bone health. Saliva hormone assays should be used periodically to check progesterone levels. Some laboratories are not helpful in helping a woman determine whether she is actually using too much progesterone, or not. For example, the well-known Great Smokies Diagnostic Laboratory insists that women abstain from the use of any hormones before taking their saliva tests, as "there is no reference range for women using hormones, particularly the transdermal creams." Other testing facilities, such as North Bay Diagnostics, however, have collected enough data from women using both oral and transdermal hormones, so they can accurately determine whether a woman has developed as excess of progesterone. These will be found in our **Hormone Tests** section. Periodic testing is important, at least until your usage pattern is stabilized, since continuous use of progesterone creams can cause a build-up of excess progesterone, leading to undesirable side effects. See my article **The Problem of Excess Progesterone**, for a complete discussion of this topic and suggestions on how to avoid any possibility of progesterone build-up.

Please click [here](#) to view our natural progesterone products.

The information in this article is for educational purposes only and is not intended as medical advice.

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- 16 -

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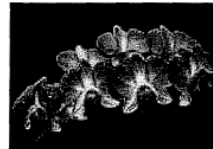
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THE PROBLEM OF EXCESS PROGESTERONE
by Elora Gabriel

In recent years, due to the research of Dr. John Lee and others, the importance of natural progesterone has been well established. Please see my article **The Benefits of Natural Progesterone** for more complete information on this essential hormone, and the difference between natural and synthetic progestones.

Natural progesterone is technically called "Progesterone USP" or sometimes "USP progesterone". Because it is not cancer causing and because it is such a beneficial hormone, progesterone USP has been considered so safe that a "more is better" attitude has been adopted. Whereas the ovaries only produce 20-50 mg./day of progesterone, doctors routinely prescribe 200 mg./day. One of the rationales for using large amounts of progesterone is the belief that progesterone will convert into other hormones in the body, as needed. For example, progesterone is supposed to convert to estrogen and testosterone. And in fact, this is how the progesterone produced by our ovaries does work.

However, with the advent of the more accurate saliva hormone assays, we have learned that there is at least one important distinction between the way that ovarian progesterone and Progesterone USP work in the body. While ovarian progesterone does have the ability to "cascade", or convert into other hormones in the body, there is no evidence that Progesterone USP cascades in the body, beyond a possible slight conversion to testosterone. Upjohn, one of the manufacturers of Progesterone USP, has admitted that this is true, perhaps due to the laboratory processing. Therefore, if a woman takes in more than she needs, she can develop excessive amounts of progesterone. This fact is very often missed even by holistic doctors and health practitioners, and certainly by those selling and promoting natural progesterone.

What are the effects of excess progesterone? Symptoms can begin in a

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LENNY AUGUST'S ARTICLES - HORMONES - THE EFFECTS OF EXCESS PROGESTERONE

PAGE 2 OF 4

very subtle manner, and can mimic many other types of conditions. The first sign could be depression and/or lethargy. Women who are still menstruating may have anovulatory cycles, perhaps because too much progesterone can actually block estrogen. Memory loss, fluid retention, and protracted menstrual hemorrhaging have been observed in some cases. Joy Bucknell from Dr. Lynn August's office in New Fane, Vermont, has written about the problem of progesterone excess. To quote from her article:

"Initially, most women feel a calming effect when they use progesterone. However, after approximately eight months of high active progesterone levels a clinical depression may develop. Often times the cause of this depression is not attributed to the use of the progesterone cream. The second downside of high active progesterone is its effect on active cortisol levels in the body . . . High levels of active progesterone . . . cause a significant increase in free active cortisol . . . High active cortisol over the long term can result in hunger and sugar or carbohydrate cravings, weight gain around the waist, reduced muscle mass, bone thinning, food sensitivities and allergies, reduced athletic endurance, yeast overgrowth, reduced thyroid function, insomnia, PMS, and if not corrected, eventual exhaustion and chronic fatigue."

Strangely enough, the worst cases of this problem that I have personally encountered were two women who were both using a moderate strength non-prescription Progesterone USP cream. In both cases, they had felt so much better when they started on the progesterone, that when they began to feel worse, they assumed that more progesterone was needed. There has been a great deal of press in recent years about estrogen dominance, to the point where some women believe that this is the cause of all hormonal ills. Thinking that they were still estrogen dominant, therefore, these women kept increasing their dosages until they were using very large amounts of cream. Symptoms resolved when they stopped the progesterone and/or switched to wild yam cream. (Wild yam is a plant-derived, progesterone-like substance which provides many of the benefits of natural progesterone.)

For women using progesterone creams, saliva hormone assays will often show excessively high progesterone levels. Some laboratories are not helpful in helping a woman determine whether she is actually using too much progesterone or not. For example, the well-known Great Smokies Diagnostic Laboratory insists that women abstain from the use of any hormones before taking their saliva tests, as "there is no reference range for women using hormones, particularly the transdermal creams". Other testing facilities, however, have collected enough data from women using both oral and transdermal hormones, so that they can accurately determine whether a woman has developed an excess of progesterone. One such laboratory is North Bay Diagnostics. Saliva test kits for this lab can be found in our **Hormone Tests** section. We strongly recommend that women who are using progesterone avail themselves of such testing, on a periodic basis, until an ideal usage pattern has been determined.

Below are some further points which should be helpful.

1. When using progesterone creams, do not apply them on areas which are underlain by fatty tissue. It is the build-up of progesterone in the fatty tissue that seems to cause the problem. Instead, use thin-skinned

Complaint

AMERICAN INSTITUTE OF NATURAL MEDICINE - THE EFFECTS OF EXCESS PROGESTERONE

Page 3 of 4

areas underlain by venous circulation, so that the hormones will be absorbed directly into the blood stream. These areas include the sides of the throat, insides of the arms, wrists, palms and backs of hands, and tops of the feet.

2. When possible, select products which are not oil-based creams, but rather water or alcohol-based gels. Feminine Balance Plus, a combination natural progesterone/phyto-estrogen product carried by The Green Willow Tree, is one such product. The formulator, a nurse practitioner, states that she has seen no problems of progesterone excess with patients using Feminine Balance Plus.

3. Use a physiological dose. Pharmacies dispensing USP normally recommend 200 mg./day. However, we have noted that this is far more than the ovaries ever produce. If we are using estrogen, we certainly want to get enough progesterone to prevent endometrial hyperplasia (a precancerous condition of the uterus caused by using estrogen alone.) Dr. John Lee states that he found 30 mg./day of progesterone to be enough to prevent hyperplasia in women using estrogen. Using 1/4 tsp. of a moderate strength product such as NuGest 900 twice daily will give you approximately 60 mg./day. Given that nothing absorbs 100%, still this amount should be ample. Dr. Lee used a non-prescription cream (Pro-Gest) in his famous study of osteoporosis reversal in 100 women, rather than the high dosages favored by pharmacies. And Dr. Alan Gaby, author of *Preventing and Reversing Osteoporosis*, states that the "therapeutic window" for progesterone appears to be much less than 200 mg./day and that larger doses may be less effective against osteoporosis. Possible excesses of Progesterone USP will be much less likely if you use a moderate dosage. The 10% strength prescription creams from most compounding pharmacies are, in my opinion, at least three times stronger than necessary.

4. For those who find that they have developed excess progesterone, generally this problem resolves itself over a few months when the woman in question stops using her progesterone supplement. In the case of women needing progesterone to balance their estrogen replacement therapy, a good solution is to switch to a pure wild yam cream, such as Progestone Ten, for several months. Wild yam has been denigrated by many advocates of natural progesterone. While it is true that little clinical work has been done with wild yam, particularly in key areas such as bone health, it is undeniable that a good quality wild yam extract provides progesterone benefits. I have observed wild yam to be capable of acting in the same way that progesterone does in opposing (balancing) estrogen. And wild yam does not build up to excess in the body. However, small amounts may convert to estrogen, so wild yam may be contra-indicated for women who must avoid estrogen in any form.

5. There are a few women whose bodies do not tolerate progesterone in any form. This is not a situation of progesterone excess, but a simple intolerance of USP progesterone. These women generally do very well using wild yam creams.

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Page 4 of 4

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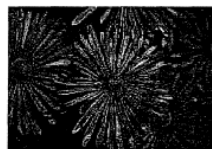
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THE GOOD NEWS ABOUT NATURAL ESTROGEN
by Elora Gabriel

Since 1995, I have been writing about the positive benefits of natural estrogen and progesterone, as opposed to the dangers of synthetic hormones. This article will recapitulate recent medical findings in this regard, and then go on to present several safe and highly effective choices for health conscious women. 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.

Millions of women are still reeling from the recent publicity regarding the dangers of commonly prescribed types of HRT. A long-term study by the National Institutes of Health, in which 16,600 women using PremPro were monitored over a period of years, had to be halted because so many of the participants suffered life-threatening side effects. An article by Loran Neergaard (Washington AP) stated that:

"Government scientists abruptly ended the nation's biggest study of a type of hormone replacement therapy, saying long-term use of estrogen and progestin significantly increased the women's risk of breast cancer, strokes and heart attacks. Six million American women use this hormone combination, either for short-term relief of hot flashes and other menopausal symptoms or because of doctors' longstanding assumptions that long-term use would prevent heart disease and brittle bones and generally keep women healthier longer. Two of those assumptions are wrong, the National Institutes of Health announced

Complaint

Tuesday. In fact, years-long use of estrogen and progestin **increased otherwise healthy women's risk of a stroke by 41 percent, a heart attack by 29 percent and breast cancer by 24 percent...** 'We recommend that clinicians stop prescribing this combination for long-term use,' wrote Dr. Suzanne Fletcher of Harvard Medical School in an editorial accompanying the study results posted on the Web site of the Journal of the American Medical Association. 'Risks from the drug add up over time.'

I was personally unsurprised at the results of this study. I am only relieved that, at last, the dangers of synthetic HRT have come out in the open. Why, indeed, should it be such a revelation to us that if women take hormones which are completely unnatural for our bodies, side effects will not only be unpleasant but dangerous? Hormones directly or indirectly control all of our body processes. It is surely of urgent importance to make sure that we get the very best and safest in hormonal support.

Let's take a moment to look at PremPro, the popular HRT combination used in the study. PremPro is a combination of Premarin and Provera. Premarin is composed of horse estrogens. It is also largely estrone, one of the more dangerous and cancer-causing types of estrogen. As Dr. Jonathan Wright (a leading holistic authority from Kent, WA) says, "The next time I see a menopausal horse, I will be happy to prescribe Premarin, a horse estrogen!" And let me add here that anyone who loves animals would never touch Premarin if she knew how this drug was obtained.

Provera is a synthetic, chemically altered form of progesterone which again, is highly unnatural to the body. Studies with primates using generic Provera resulted in greatly increased incidence of strokes and heart attacks. Researchers were shocked to find that this was such a dangerous drug, yet the study was buried and doctors have continued to prescribe Provera and its synthetic cousins. For more information on progesterone, and the difference between natural and synthetic progesterone, please click [here](#). Our natural progesterone products can be accessed at [this link](#).

Now let's return to the question of estrogen. As menopause approaches, estrogen deficiency makes itself known in the all too familiar symptoms of hot flashes, night sweats, sleep disorders, mood swings, and vaginal dryness. Other symptoms could include fatigue, rapid skin aging, joint pains, dizziness, bladder problems, crawling sensations on skin and scalp, or severe depression. The emotional changes that accompany hormonal deficiency can be particularly difficult.

Supplementing with estrogen turns all of these symptoms around. Hot flashes and night sweats disappear; moods return to normal; mental clarity increases; sleep quality improves; the skin becomes moist and more youthful; and so on. Estrogen also slows bone loss. And in my opinion, it probably does protect the cardiovascular system, if taken in a natural form and particularly when not taken with synthetic progesterones which are so dangerous to the heart and arteries.

Estrogen has had some bad press, but in my opinion this is almost entirely due either to the use of synthetic estrogens, or taking estrogen without progesterone. In fact, estrogen is so vital to the health and well-

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being of women that its absence not only accelerates aging, but can cause a malaise whose intensity is only believable to those who have experienced it. I have spoken to many women over the years who were literally suicidal, simply from lack of estrogen. These women were often prescribed anti-depressants when all they needed was a natural boost to their hormone levels. Too much estrogen is certainly no better than too much of anything else; but this hormone, in the right amount, is the juice of life for the female body. How, then, do we obtain the benefits of estrogen without its downsides? Based upon a decade of research and counseling women, I believe there are two major choices.

1) Phytoestrogens. These substances are estrogenic compounds which occur naturally in plants such as soy, black cohosh, dong quai, licorice root, etc. In countries where large amounts of phytoestrogens are consumed, women suffer very few menopausal symptoms. Phytoestrogens differ remarkably from synthetic estrogens in that they are easily broken down, are not stored in the tissues and spend very little time in the body, thus they are unlikely to cause cancer. And because humans have spent millions of years eating plants and herbs, our bodies easily accept plant estrogens and find them both effective and beneficial.

Phytoestrogens appear to exert a natural balancing action in the body. If estrogen is low, phytoestrogens will increase estrogen activity in the body. When estrogen levels are high, phytoestrogens will compete for estrogen receptor sites, causing a decrease in the estrogen effects. The result is a chemoprotecting action. Numerous studies have indicated that high intake of phytoestrogenic substances may reduce the risk of breast cancer.

Many women have turned to soy products as a source of phytoestrogens. Large amounts of soy may not be appropriate for every woman however, particularly those who are hypothyroid. Fortunately, we have numerous other sources of phytoestrogens. I personally like Feminine Balance Plus (no longer available...see our EST and Progestacare Plus products), a combination gel which contains phytoestrogens from black cohosh along with natural progesterone. Many women may have tried phytoestrogen products but found the results to be disappointing. These products vary greatly in their effectiveness and many are weak or poorly formulated. At The Green Willow Tree we have spent many years locating natural estrogen creams and tablets which really work, even for the woman who has had a total hysterectomy.

2) Tri and bi-estrogen. Other forms of natural, user-friendly estrogen are also available. In order to explain this next section, we need a short lesson on this hormone. There are actually three major forms of estrogen in the female body. They are called estradiol, estrone, and estriol. The commonly prescribed forms of estrogen are universally made of estradiol, estrone, or combinations of the two. For example, Premarin is largely estrone, Estrace and Estraderm are estradiol, and so on. Estradiol and estrone are very potent estrogens, and they both have a stimulating effect upon the cells of the breast and uterine lining. It is this effect which can eventually lead to cancer.

However, there is a third type of estrogen--called estriol--which is often called "the forgotten estrogen" because it has been overlooked in favor

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ESTRONE AND ESTRADIOL - HORMONES - THE GOOD NEWS ABOUT NATURAL ESTROGEN

Page 4 of 4

of its more dangerous cousins. Estriol is the estrogen which dominates during pregnancy, and it has a much less stimulating effect on the breast and uterine lining than estradiol and estrone. **In fact, estradiol is 1000 times more stimulating to the breast tissue than is estriol, according to leading authority Dr. John R. Lee of Sebastopol, CA. Estrone is considered even more risky, and is believed to be the estrogen most responsible for breast cancer.** Since PremPro contains mostly estrone (and horse estrone at that) we can now understand the frightening results of the study discussed at the beginning of this article.

The most exciting thing about estriol is the fact that not only does it not promote breast cancer, but considerable evidence exists to show that it protects against this disease. In 1978, Alvin H. Follingstad, M.D., wrote an article for the Journal of the American Medical Association calling for the use of estriol instead of estrone and estradiol. In support of his position, he cited a group of postmenopausal women with metastatic breast cancer. When given small doses of estriol, 37% of the women experienced either a remission or a complete arrest of the metastasized lesions! In 1966, H. M. Lemon, M.D. demonstrated that women with breast cancer have lowered estriol levels. Later, he showed that women without breast cancer had naturally higher estriol levels (compared to estrone and estradiol) than those with breast cancer.

Dr. Julian Whitaker, well known author and publisher of the *Health and Healing* newsletter, says that "estriol's anti-cancer effect is thought to be due to its anti-estrone characteristics. It apparently blocks the stimulatory effect of estrone on the breast." Estriol is weaker than other types of estrogen, appears to have very little effect on bone density. Therefore, for most women a blend of estriol with small amounts of the more potent estrogens seems to be ideal. Dr. Jonathan Wright, mentioned above, has been experimenting with the use of estriol since the early 1980's. He created a formula called "tri-estrogen" which contains 10% estradiol, 10% estrone, and 80% estriol. Dr. Wright determined that this is the ratio of estrogens naturally occurring in a young woman's body. This formula has been found by Dr. Wright to rapidly alleviate the symptoms of menopause without amplifying the danger of breast cancer. Women who have tried it find it gentle, effective, and free of unpleasant side effects. Tri-estrogen is also believed to be more effective against osteoporosis than pure estriol.

A new refinement on tri-estrogen is bi-estrogen, composed of 80% estriol and 20% estradiol. The rationale for bi-estrogen is that estradiol converts into estrone in the body, so there is no need to supplement with this type of estrogen at all. Opinions vary as to which is better. I like both products and believe that bi and tri-estrogen are infinitely superior to Premarin and virtually all other prescription estrogens.

If you would like a prescription for bi or tri-estrogen, you can ask your doctor to telephone a compounding pharmacy, such as the Women's International Pharmacy at 1-800-279-5708.

Saliva hormone assays should be used initially, and then periodically to check estrogen levels on supplementation. Some laboratories are not helpful in helping a woman determine whether she is actually using enough natural estrogen, or not. For example, the well-known Great Smokies Diagnostic Laboratory insists that women abstain from the use

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of any hormones before taking their saliva tests, as "there is no reference range for women using hormones, particularly the transdermal creams." Other testing facilities, such as North Bay Diagnostics, however, have collected enough data from women using both oral and transdermal hormones, so they can accurately determine whether a woman has initial low estrogen, then adequate level with supplementation. These will be found in our **Hormone Tests** section. Periodic testing is important, at least until your usage pattern is stabilized.

Women have been misinformed and mis-treated for decades with harmful, synthetic hormones, a chemical cocktail which has resulted in untold suffering for many. It has become something of a mission for me to educate my sisters to the fact that many wonderful alternatives do exist. With natural hormones, we really can have our cake and eat it too.

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THE GREEN WILLOW TREE BONE & JOINT HEALTH - THE GREEN WILLOW TREE - NATURAL SUPPLEMENTS FOR NATUR... Page 1 of 2



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Bone & Joint Health

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. In addition, the products below can greatly aid in preserving and even increasing bone density. A major cause of bone loss is an acid constitution; therefore alkalizing the body is essential. See also sections for Progesterone and Hormone Tests.

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ESSENTIAL FACTORS FOR BONE HEALTH

HORMONES	MINERALS	OTHER NUTRIENTS	DIET & LIFESTYLE
Natural progesterone cream	High absorption calcium, 1200 mg/day	Vitamin D-3, 600 IU/day	Regular weight-bearing exercise
Periodic saliva hormone testing for progesterone and cortisol	Magnesium, zinc, manganese, boron, and silica	Vitamin K, 3000 mcg./day	Eat plenty of dark green leafy vegetables

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THE GREEN WILLOW TREE BONE & JOINT THERAPY - THE GREEN WILLOW TREE - Natural Supplements for Natur... Page 2 of 2

Optional--DHEA cream	Trace mineral complex	An alkalizing product of some kind	Avoid coffee, sweets, and sodas
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"Osteoporosis is very common in women who are depressed and that is one in four women. It's because of higher cortisol levels than normal. That is the stress hormone. I think that is the predominant cause of osteoporosis - depression and unabated stress resulting in a hypercortisol state that dissolves the bones over time. Most women, the vast majority, will not get osteoporosis that will lead to a fracture if they take enough calcium and magnesium and also do regular weight bearing exercise." -- Christiane Northrup, M.D. For those concerned about cortisol levels, please see our Adrenals Section

**29. OsteOrganicCal**

An exceptional supplement for those who have lost bone mass. Increases in bone mass have been achieved faster than with drugs such as Fosamax, and with no side effects. This product contains a rare, highly bio-available form of calcium along with magnesium, iron, and manganese. Comes in a 2-bottle set: 60 capsules of the calcium/mineral supplement, and 30 capsules of Vitamin D3 from shark liver oil. Money back guarantee if bone scans do not improve after 6 months (click on photo for details). In many cases adequate levels of bone mass are achieved after 12-24 months of treatment.* (30 day supply.) **[For more information please click on picture]**

OUR PRICE: \$69.00 [Add to Cart](#)**30. Vitamin D-3**

Vitamin D-3 is essential if you're serious about bone health. More active in this regard than regular Vitamin D, the major function of D-3 is to increase calcium absorption from the intestine and promote bone formation and mineralization. A general recommendation is 800 IU per day with whatever form of calcium you are taking.* (A bottle of 90 400 IU capsules. Will last 6 weeks at 2/day.) **[For more information please click on picture]**

OUR PRICE: \$9.95 [Add to Cart](#)**36. Bio-K-Mulsion (Liquid Vitamin K)**

Vitamin K is a critically important nutrient for bone density and for the prevention of heart disease. It is the biological "glue" that plugs calcium into your

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THE GREEN WILLOW TREE BONE & JOINT HEALTH - THE GREEN WILLOW TREE - Natural Supplements for Natur... Page 3 of 3



bone matrix, thus helping to prevent and even reverse osteoporosis. It also assists in the prevention of heart failure and coronary artery disease. Most Americans do not get enough Vitamin K, and most supplements provide much less than the doctor-recommended 3000 mcg, per day. 1 oz. bottle will last 5 months. Drops have no taste.*[For more information please click on picture]

OUR PRICE: \$16.00 [Add to Cart](#)



Acid Redux

Acid Redux is a unique formulation of acid buffering agents that can be helpful in the alleviation of occasional acid indigestion. This product not only comforts the digestive system, but assists in maintaining proper body pH. It has a pH of 9.5 and is up to 11 times more effective than name brand alternatives. Acid Redux increases the pH of the blood, which reduces overall body acidity. Alkalinizing the body is believed by many health professionals to be essential for maintaining health, and is particularly important for bone density.* 90 mint-flavored lozenges; take 1 lozenge 2-3 times daily or as needed. [For more information please click on picture]

OUR PRICE: \$10.00 [Add to Cart](#)



Boswellin Cream

Try this wonderful cream for the temporary relief of minor aches and pains of muscles and joints associated with arthritis. Boswellin Cream provides warm, penetrating pain relief. In addition, it has a pleasant aroma and is both greaseless and stainless. It offers two herbal extracts, Capsaicin and Wintergreen, for fast, effective pain relief--in a soothing base of Boswellia serrata, standardized for Boswellic acids and Vitamin E. Four ounce tube.* [For more information please click on picture]

OUR PRICE: \$15.00 [Add to Cart](#)

High Absorption Magnesium

Magnesium (Mg) is a trace mineral that is known to be required for several hundred different functions in the body. A significant portion of the symptoms of many chronic disorders are identical to

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symptoms of magnesium deficiency. Studies show many people in the U.S. today do not consume the daily-recommended amounts of Mg (or are not absorbing it properly). A lack of this important nutrient may be a major factor in many common health problems in industrialized countries. Common conditions such as migraines, mitral valve prolapse, attention deficit disorder, fibromyalgia, asthma and allergies have all been linked to a Mg deficiency. Perhaps not coincidentally, these conditions also tend to occur in clusters together within the same individual. A magnesium deficiency as a root cause would provide a logical explanation of why some people suffer from a constellation of these types of problems.

Among the several conditions linked to magnesium deficiency, THE GREEN WILLOW TREE would like to single out **migraine headaches**. Recent clinical findings reconfirmed the ability of magnesium to alleviate the symptoms of an acute migraine attack, and other studies have shown the daily intake of magnesium to prevent recurring attacks.

240 tablets suitable for vegetarians; take 2 twice a day between meals. **[For more information please click on picture]**
OUR PRICE: \$26.36 [\[Add to Cart\]](#)



Osteo-Nutrients II - 240 capsules
This product is not available for shipment to Canada!

OSTEO-NUTRIENTS II is a comprehensive bone support formula which contains high amounts of elemental calcium and magnesium, as well as the other essential nutrients for healthy teeth and bones. Calcium and magnesium are also essential to many physiological functions such as helping to maintain and build bone mass and strength before and during menopause. Boron, which also plays a role in bone health, has been added to this formula* Bottle of 240 capsules. Take 4 capsules daily for a total of 1000 mg of calcium (as carbonate/citrate-malate) per day; post menopausal women may need one additional capsule/day.

[For more information please click on picture]
OUR PRICE: \$25.50 [\[Add to Cart\]](#)

Rebuild Osteoporosis Formula
This product is not available for shipment to Canada!

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Our new Osteoporosis product, Rebuild® is formulated to reflect the positive results of research performed by Paul Saltman, Ph.D. at UCSD. By combining the most bioavailable form of Calcium (citrate/malate) with balanced levels of Magnesium Citrate and the exact minerals, Zinc, Copper, Manganese, Boron, Vitamin D3 and Vitamin K, used in university studies, Rebuild® provides the finest Osteopenia and Osteoporosis formula available today.*
180 vegetable cellulose capsules. Preservative and Excipient free. Thirty-day (30) supply..
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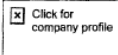
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HORMONAL AND LIFESTYLE FACTORS FOR BONE HEALTH

by Elora Gabriel

HOW THE DIFFERENT HORMONES AFFECT OSTEOPOROSIS

If you have osteoporosis, or if you are at risk for osteoporosis, what hormones should you be taking? What other factors should you consider? Bone loss is a serious and disabling condition. It is important for all of us to make informed choices this subject.

First of all, let's look briefly at the action of the different hormones on bone density. For years, estrogen has been prescribed to protect against osteoporosis, because it is known that it helps to slow bone loss. Little research has been done on the effect of the safer estrogens (estriol and tri-estrogen) upon bone health. It is known, however, that very large amounts of estriol are needed to prevent osteoporosis. Therefore tri-estrogen would be recommended for most women in preference to estriol. While we do not have any studies on tri-estrogen and bone health, Dr. Alan Gaby (author of the highly recommended *Preventing and Reversing Osteoporosis*) states that the information we have on tri-estrogen "suggests that it would also be effective for osteoporosis." Phyto-estrogens found in the Isoflavone complex (derived from soybeans) also have a positive effect upon bone density, according to the *Alternative Medicine Digest*.

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 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

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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! After a brief look at the other hormones, we will return to discuss progesterone in greater depth.

DHEA is a hormone which is produced by the adrenal glands in both sexes; levels peak in our 20's and decline thereafter. Most people over the age of 50 are deficient in DHEA. Researchers are becoming increasingly aware that this hormone has positive implications for osteoporosis. DHEA directly increases levels of estrogen and testosterone (another bone-building hormone) and indirectly increases progesterone levels. Dr. Gaby describes the case of a woman with osteoporosis who was using progesterone and "doing everything right" in terms of lifestyle. Nothing helped her until she began using DHEA. DHEA creams are recommended as the best source of DHEA for this purpose. Dr. Julian Whitaker, editor of *Health and Healing* newsletter, reported very good increases in bone density for post-menopausal women using DHEA cream.

Natural testosterone, as opposed to synthetic methyl testosterone, can also be used by those of us who are especially conscious of bone health. High testosterone levels in men act as a prevention against osteoporosis. Natural testosterone (2% gel) may be obtained from Clark's Pharmacy, 1-800-480-3432.

Human Growth Hormone (HGH) has increasingly come into the limelight for its properties of rejuvenating the body. Its effects on bone density are less recognized, but certainly worthy of note. Dr. Whitaker states that: "The hormone that beats all other agents hands down for reversing osteoporosis is HGH. In a 1993 study of 24 postmenopausal women with osteoporosis, markers for bone remodeling increased by an incredible 30% to 40%, after 12 weeks of using HGH." We do not have any information about the results of over-the-counter HGH precursors or sublingual tablets and sprays for bone health, however. These products may be very helpful, but are probably not the first line of defense.

Women are understandably concerned about taking thyroid hormone since it is reported that using thyroid increases bone loss. Dr. Gaby thoroughly addresses this belief in *Preventing and Reversing Osteoporosis*. He explains that the studies indicating this connection were seriously flawed, and goes on to cite a recent study in *Lancet* which refutes the connection between thyroid and osteoporosis. This long-term study of women who were using thyroid hormone, compared to a control group, showed no difference in bone density. "These findings, combined with earlier reports that the incidence of fractures is not increased in people taking thyroid hormone, indicate that treatment with thyroid hormone does not cause osteoporosis and does not increase the risk of developing fractures," says Dr. Gaby (emphasis added). It is worth noting, however, that the non-prescription product **Thyodine** has been very helpful in normalizing thyroid function without the need for medication.

Now let's return for a more in-depth look at natural progesterone. Dr. John Lee's impressive study involved 100 post-menopausal women, many of whom showed osteoporosis symptoms. The women used a 3%

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LAWRENCE ROSENBERG, FOUNDER - CHESTNUT HILL FOODS, LLC - LIFESTYLE AND NUTRITIONAL TIPS

Page 3 of 4

natural progesterone ream 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 results have not been replicated in the US, I have heard that progesterone is the standard treatment for osteoporosis in Europe.

Regarding dosage for progesterone: Dr. Lee used a moderate strength of progesterone, and we do not know the effect of high-dosage Progesterone USP upon bone density. Dr. Gaby speaks of the important concept of the "therapeutic window" for each hormone, i.e. the amount that is most effective. In other words, if the therapeutic window for progesterone is 30-50 mg./day, giving 4 times that amount may be less effective. While a few women may need larger amounts of progesterone, in general the moderate dosages (about 60 mg./day) would appear to be best. Also, continued use of progesterone has led, in many cases, to excess build-up of progesterone in the body. Periodic screening of progesterone levels is strongly recommended for all women over the age of 40. Saliva hormone assays are recommended over standard blood tests, and they are available without a prescription from Great Smokies Medical Labs, at 1-888-891-3061. Please see my article **The Problem of Excess Progesterone** for a complete discussion of this topic.

Osteoporosis is not just a matter of hormones. Diet and exercise play a very important role. Please read Dr. Gaby's *Preventing and Reversing Osteoporosis* and also Betty Kamen's *Hormone Replacement Therapy, Yes or No?* (Note: Betty Kamen's book is very anti-estrogen, perhaps because tri-estrogen and estriol were not available when she wrote it. However, her section on osteoporosis is excellent.) The notes below are mostly condensed from Dr. Kamen's book.

NUTRITION AND LIFESTYLE TIPS FOR BONE HEALTH

1. Exercise regularly! The best exercise for bone health is weight-bearing, aerobic, and ideally outdoors. Natural light is important for health, as is fresh air. Fast walking is an excellent choice. Walking is recommended for at least 20 minutes 5 times/week.
2. Eat dark green leafy vegetables, especially kale, collards, mustard and turnip greens. These are all very high in bioavailable calcium. Cooked cabbage and green beans are reasonably good sources, as is tahini made from unhulled sesame seeds.
3. Avoid dairy products. Dairy products are very acid forming in the body. This acidic condition must be buffered with large amounts of calcium. If necessary, the body will even rob calcium out of the bones to balance blood pH. Because of its high level of animal protein, milk consumption may cause a greater loss than gain of calcium. Homogenization makes it worse. Women in countries with a high consumption of dairy, like the US, have much more osteoporosis than countries where small amounts of dairy products are consumed.
4. Also avoid sweets and excess carbohydrates. Eating sweets and high-glycemic carbohydrates such as bread, pasta, and potatoes; causes a

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surge in blood sugar and insulin levels. This in turn causes a massive excretion of calcium which again, may be robbed from your bones. You can exercise, use the right hormones, and take the best type of calcium in the world; but all of these good health habits may be in vain if you eat a high glycemic diet. Even fruits and fruit juices should be used in moderation.

5. Reduce phosphorus intake. Too much phosphorus blocks calcium assimilation. Some high phosphorus foods are processed and canned meats (hot dogs, ham, bacon), processed cheese, most baked products, sodas, and meats. Sodas are devastating to bone health.

6. Avoid not only milk, but coffee, which acidifies the blood. In addition, ALL forms of caffeine, whether from coffee, tea, or cola soft drinks, stimulate the release of calcium from the bone.

7. Avoid fluoride in any form. While it can increase bone mass, it also makes bone more brittle. "Nonvertebral fractures increase 300 to 600% in patients undergoing fluoride therapy." If your city water is fluoridated, use filtered or bottled water.

8. Avoid chlorinated water. It reduces calcium absorption.

9. Avoid canned foods, which may contain high levels of tin.

10. Avoid aluminum (found in aluminum cookware, antacids, processed cheeses, many deodorants, some baking powders, etc.) Read labels! There is a correlation between aluminum poisoning and spontaneous bone fractures.

11. Regarding supplements for bone health:

*Two types of calcium which have shown impressive clinical results for increasing bone density are OsteOrganicAL and 3A Calcium. Please see the **Bone & Joint Health** section for further information. We also offer Vitamin D-3 in this section. Vitamin D-3 is slightly different from regular Vitamin D and is more active for bone health.

*Supplemental hydrochloric acid can help with calcium absorption. Taking trace minerals, such as liquid colloidal minerals, is also essential! Our foods today are seriously depleted of minerals.

*Be sure to supplement your calcium with magnesium as well. Most Americans are magnesium deficient.

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1. EST
SKU: est

This product may be used as a replacement for Feminine Balance Plus.

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. Two ounce tube should last about one month.*

Phyto-estrogens are found in many plant sources, primarily soy, wild yam, licorice, black cohosh, and chamomile. In this formulation, the manufacturers have selected phytoestrogens which replicate, as closely as possible, the same molecular structure found in human estrogens. Therefore it is closer to a bio-identical estrogen than most of the phytoestrogen products available. EST is also one of the only over-the-counter creams containing an approximation of bi-estrogen. Bi-estrogen is considered to be the ideal balance of estrogens, containing 80% estriol (the safest but weakest form of estrogen) and 20% of the more potent estradiol. The inclusion of natural progesterone, with its many benefits, makes this a well balanced and convenient product.*

EST contains approximately 1 mg of natural estrogen and 20 mg of natural progesterone per 1/4 tsp dose. Suggested usage: ¼ teaspoon twice daily, rubbed into soft-skin areas of the body such as the throat, insides of the arms, wrists, backs of hands, and tops of feet. Generally this product is used for about 25 days with a break of 5 days, which is taken during the time of menstruation for women who are still having periods.*

Ingredients per 2 ounce tube:

960 mg of USP natural progesterone extracted from wild yam and soybean, with natural phyto-estrogens extracted from Soya, Dong Quai, Black Cohosh, Red Clover Blossom, Licorice Root and Wild Yam, in a 2 ounce base of: deionized water, aloe vera gel,

Complaint

THE GREAT TRADE SHOW AT 2002 THE GREAT TRADE SHOW - Natural Supplements for Natural Health Page 2 Of 2

Relora
Allergies: a Foundat...
Allergies: Desert U...
Allergies: Great Lak...
Allergies: Northeast...
Allergies: Pacific U...
Allergies: Plains U...
Allergies: Rocky Mou...
Allergies: Southern ...
Allergies: Southwest...
Allergies: Total Mol...
Climate Comfort: Col...
Climate Comfort: Col...
Climate Comfort: Hot...
Climate Comfort: Hot...
Climate Comfort: Wea...
NetiPot
*SP-Zyme - Natural A...
Borage Oil
Boswellin Cream
29. OsteOrganlCal
30. Vitamin D-3
36. Bio-K-Mulsion (L...
Acid Redux
High Absorption Magn...
Osteo-Nutrients II ...
Rebuild Osteoporosis...
35a. Ultra One, Ultr...
5d. Enteric Coated O...
Sympathical's Homeop...
*. SP-Zyme
30. Pressure Control
34. Healthy Cholesterol
Water Retention Cont...
Cosmic Essence Catalog
*. OxyPowder
*Uriflow™
3C. DIM Plus
Healthy Addictions C...
Healthy Smoking Cont...
Heavy Metal Test Kit
Floraderm
Super Enzymes (NOW
F...

caprylic/capric triglycerides, polyacrylamide/c13-14,
isoparaffin/laureth 7, vitamin E acetate, ethyl alcohol, grapefruit
seed extract (natural preservative system).

Two ounce tube for \$24.95; 6 or more for \$22.46 each.

OUR PRICE: \$24.95 (6+ \$22.46)

Quantity

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YOUR ACCOUNT 

Complaint

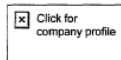
THE GREEN WILLOW TREE, LLC - THE GREEN WILLOW TREE - Natural Supplements for Natural Health Page 3 of 3

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For further information or personal questions, please **email us**.
You may order online, or place your order by phone at 877-968-4337 (toll free) or 828-665-3095.
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*These statements have not been evaluated by the Food and Drug Administration.
Our products are not intended to diagnose, treat, cure, or prevent disease.

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customerservice@greenwillowtree.com (order questions)



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Complaint



**THE
Green
Willow
Tree**

**Natural Hormones and Supplements
for Health Conscious
Men and Women**

contact us
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local or Intl 828-865-3055
info@greenwillowtree.com

Home : Articles : Links : Catalog Search : Contact Us : Order Information : Order Form : Basket Contents

NEW - ORDER WITHOUT AN ACCOUNT - NEW

***Spring Cleaning Sale**
Adrenal Support
Allergy
Anti-Inflammatory
Bone & Joint Health
Candida/Yeast/CFS
Cardiovascular Health
CATALOG/LITERATURE
Detoxification
Digestion & Elimination
Estrogen/Combinations
HGH
Hormone Tests
Immune Boosting
Mood Enhancement
NEW PRODUCTS!
Progesterone
Prostate Health
Sexual Performance
Skin Care
Sleep Easy
Thyroid
Urological Health
Vibrational Essences
Vitamins & Misc
Weight Loss

11. Restored Balance
SKU: 5



Click to Zoom

Restored Balance is on Dr. John Lee's approved list of progesterone creams. It is more concentrated than most natural progesterone creams, and comes with an easy to use dispenser. The result is that your tube will last longer. Restored Balance is also pure and chemical free, containing absolutely no chemical preservatives or stabilizers. Herbal extracts and Vitamins A and E added for enhanced benefits.* Unconditional money back guarantee if you are not satisfied.

2 oz. pump tube, about an 8 week supply, for \$24.00; 6 or more for \$21.60 each. Pump tube automatically dispenses correct dosage. 1/8 tsp. of cream contains 15-20 mg. of natural progesterone; used twice daily this equals about 30-35 mg./day.

INGREDIENTS:
Purified Water, Natural Glycerin, Stearyl Konium Chloride, Tocopherol (Vitamin E), Avocado Oil, Natural Progesterone [(USP) 15-20 mg per 1/8 teaspoon dose], Aloe Vera Oil, Rosemary Extract, Vitamin A Palmitate, Saw Palmetto, Cramp Bark, Sarsaparilla, Carrot Oil, Lemon Grass Oil.

SEARCH:

YOUR BASKET

Catalog
***Natural Cellular De...**
***Syclovir**
A. **3A Magnesia**
Acupeds
CleanseSMART
FiberSMART
***Adrenal Aide**
***Sub-Adrene**
5a. **Maca Capsules**
5b. **Gelatinized Impe...**
5c. **Bulk Maca Powder**
BioDren
Holy Basil
Mental Calm, a Mind ...
Mind-Body Response R...

Try these related products:
43. Estrogen Dominance Panel
44. Menopausal Hormone Panel
44a. Cycling Female Hormone Panel

OUR PRICE: \$24.00 (6+ \$21.60)

Quantity

Email a friend about this Item.

[Return to catalog](#)

THE GREEN PHEASANT AND THE GREEN PHEASANT - National Organizations for National - Page 4 of 5

- 41 -

Complaint

THE GREEN WILLOW TREE - THE GREEN WILLOW TREE - Natural Supplements for Natu... Page 5 of 5

48g. Seven (7) Hormo...
48h. Eight (8) Hormo...
48d. Four (4) Hormo...
*Immune Support
36a. Camu Camu 4:1 E...
36b. Bulk Camu Powder
*LENTRA
5b. L-Tyrosine (NOW...
Calm, a Mind & Body ...
Happy Camper
Healthy Sexuality, a...
Mental Alertness For...
Mental Alertness, a ...
Mind-Body Restore Re...
Healthy Weight Contr...

YOUR ACCOUNT

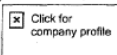


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For further information or personal questions, please **email us**.
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customerservice@greenwillowtree.com (order questions)



Complaint

THE GREEN WILLOW TREE, LLC - THE GREEN WILLOW TREE, LLC - Natural Hormones and Supplements for Health... Page 1 of 1



**Natural Hormones and Supplements
for Health Conscious
Men and Women**

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NEW - ORDER WITHOUT AN ACCOUNT - NEW

*Spring Cleaning Sale
Adrenal Support
Allergy
Anti-Inflammatory
Bone & Joint Health
Candida/Yeast/CFS
Cardiovascular Health
CATALOG/LITERATURE
Detoxification
Digestion & Elimination
Estrogen/Combinations
HGH
Hormone Tests
Immune Boosting
Mood Enhancement
NEW PRODUCTS!
Progesterone
Prostate Health
Sexual Performance
Skin Care
Sleep Easy
Thyroid
Urological Health
Vibrational Essences
Vitamins & Misc
Weight Loss

SEARCH:

YOUR BASKET

Catalog
*Natural Cellular De...
*Syclovir
A. 3A Magnesia
Acupeds
CleanseSMART
FiberSMART
*Adrenal Aide
*Sub-Adrene
5a. Maca Capsules
5b. Gelatinized Impe...
5c. Bulk Maca Powder
BioDren
Holy Basil
Mental Calm, a Mind ...
Mind-Body Response R...



Click to Zoom

1a. Progestacare Plus

SKU: proplus

This product may be used as a replacement for Feminine Balance Plus.

ProgestaCare Plus is a convenient way to supplement your estrogen and progesterone levels with one easy application. This pure, chemical-free cream combines bio-identical natural progesterone with the highest quality all natural phytoestrogens (plant-derived estrogenic substances). A medium strength product, it should be adequate to support healthy hormonal balance for most menopausal or post-menopausal women. The convenient, reasonably priced pump tube dispenses an average dose with one press and contains four ounces of cream (twice that of similar products). Lasts about two months.*

Estrogens work in harmony with progesterone, and the appropriate balance between the two is significant for health and well-being. This product may be helpful for hot flashes, mood swings, fatigue and sleep disturbances caused by falling hormone levels.*

KEY INGREDIENTS:

Natural Progesterone (USP)
-Helps balance hormone levels*
-Reduces estrogen dominance*

Tocotrienols (Natural Super Vitamin E)
-Powerful anti-oxidant*

Primrose Oil
-Helps reduce PMS symptoms*

Aloe Vera
-Soothing skin softener*

MSM (Methyl Sulfonyl Methane)
-Stimulates the immune system*

Grape Seed Extract
-Powerful anti-oxidant*

Complaint

THE GREAT THING ABOUT PROGESTACARE PLUS - THE GREAT THING ABOUT - Natural Supplements for Natu... Page 2 of 2

Relora
Allergies: a Foundat...
Allergies: Desert U...
Allergies: Great Lak...
Allergies: Northeast...
Allergies: Pacific U...
Allergies: Plains U...
Allergies: Rocky Mou...
Allergies: Southern ...
Allergies: Southwest...
Allergies: Total Mol...
Climate Comfort: Col...
Climate Comfort: Col...
Climate Comfort: Hot...
Climate Comfort: Hot...
Climate Comfort: Wea...
NetiPot
*SP-Zyme - Natural A...
Borage Oil
Boswellin Cream
29. OsteOrganicCal
30. Vitamin D-3
36. Bio-K-Mulsion (L...
Acid Redux
High Absorption Magn...
Osteo-Nutrients II ~...
Rebuild Osteoporosis...
35a. Ultra One, Ultr...
5d. Enteric Coated O...
Sympathical's Homeop...
* SP-Zyme
30. Pressure Control
34. Healthy Cholesterol
Water Retention Cont...
Cosmic Essence Catalog
* OxyPowder
*Uriflow™
3C. DIM Plus
Healthy Addictions C...
Healthy Smoking Cont...
Heavy Metal Test Kit
Floraderm
Super Enzymes (NOW
F...
1. EST
15. DHEA/Pregnenolon...

PhytoPro, Red Clover Tops, Dong Quai Extract
-Phyto-estrogens, or natural compounds derived from various
plant sources which exert estrogenic effects in the human body*

COMPLETE FORMULA:
Deionized Water, Aloe Vera Gel, Sunflower Seed Oil,
Caprylic/Capric Triglycerides, Natural Glycerin, Shea Butter,
Stearic Acid, Natural Progesterone USP, Cetearyl Alcohol and
Ceteareth-20, Isopropyl Palmitate, Stearyl Alcohol, Flavonoids
(Extract of Artichoke, Extract of Sarsaparilla),
Methylsulfonylmethane, Lecithin, Carbomer, Disodium EDTA,
PhytoPro™ (Natural Super Phytoestrogen), Red Clover Tops
Extract, Chasteberry Extract, Dong Quai Root Extract, Saw
Palmetto, Tocotrienols (Natural Super Vitamin E), Xanthan Gum,
Hydroxypropyl Methylcellulose, Allantoin, Potassium Sorbate, Oil of
Rosemary, Triethanolamine, Tea Tree Oil, Sorbic Acid, Grape Seed
Extract.

SUGGESTED USE:
Each full pump of ProgestaCare Plus dispenses 20 mg. of natural,
bio-identical progesterone combined with 25 mg of highly effective
phytoestrogens. Rotate the area of application between chest,
abdomen, inner arms, and thighs.*

Menstruating Women: Apply once a day at bedtime on days 12
through 27 of your cycle, or as recommended by your physician.*

Menopausal and Post-Menopausal Women: Apply twice daily for 25
consecutive days followed by a five-day break, or as recommended
by your physician.*

Four ounce pump tube for \$35.00; 6 or more for \$31.50 each.

OUR PRICE: **\$35.00 (6+ \$31.50)**

Quantity

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YOUR ACCOUNT



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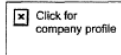
THE GREEN WILLOW TREE, LLC - THE GREEN WILLOW TREE - Natural Supplements for Health... Page 3 of 3

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Fax: 208-330-2445
info@greenwillowtree.com (product questions)
customerservice@greenwillowtree.com (order questions)



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Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act; and

The Respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the Respondents that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent The Green Willow Tree, LLC is a North Carolina limited liability company with its principal office or place of business is at 34 Rocky Ridge Road, Asheville, North Carolina 28806.

Decision and Order

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 Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “Respondents” shall mean:
 - a. The Green Willow Tree, LLC, a limited liability company, its successors and assigns and its managers; and
 - b. Robert Burns, individually and as a member and manager of The Green Willow Tree, LLC.
2. “Competent and reliable scientific evidence” shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or

Decision and Order

synthetic), including but not limited to progesterone (whether produced by the human body or produced outside the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Progesta Care Plus, EST, and Restored Balance.

4. “Food,” shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.
5. “Drug” shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. “Device” shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and

Decision and Order

which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

7. “Covered product or service” shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.
9. “Endorsement” shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

Decision and Order

- A. That such product or service is effective in preventing, treating, or curing osteoporosis;
- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user's risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user's risk of developing breast cancer;
- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner,

Decision and Order

expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.**IT IS FURTHER ORDERED** that:

- A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration;
- B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and
- C. Nothing in this order shall prohibit Respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

Decision and Order

- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

V.

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of the order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change with regard to The Green Willow Tree, LLC or any business entity that any Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name

Decision and Order

or address. *Provided, however,* that, with respect to any proposed change about which Respondents learn less than thirty (30) days prior to the date such action is to take place, Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondents, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment; or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IX.

This order will terminate on November 13, 2027, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an

Decision and Order

accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a Respondent in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that this order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from The Green Willow Tree LLC, a limited liability company, and Robert Burns, individually and as a member and manager of The Green Willow Tree (together, “respondents”).

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves the advertising and promotion of Progesta Care Plus, EST, and Restored Balance, transdermal creams that, according to their labels, contain, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that Progesta Care Plus, EST, and Restored Balance: (1) are effective in preventing, treating, or curing osteoporosis; (2) are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) 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. The complaint alleges that respondents failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or

Analysis to Aid Public Comment

reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**HEALTH SCIENCE INTERNATIONAL, INC.,
AND
DAVID MARTIN**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4205; File No. 072 3145

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order relates to the deceptive advertising and promotion of respondents' transdermal cream, Serenity for Women Natural Progesterone Cream. The complaint alleged that respondents violated the FTC Act by falsely advertising that its cream was effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The complaint alleged that respondents had no substantiation for these claims. The consent order requires that respondents have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing any disease. The order further bars respondents from engaging in similar acts and practices in the future and prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the Commission: *Gregory A. Ashe, Laura DeMartino,
Janice P. Frankle, James A. Kohm, and Michael Ostheimer.*

For the Respondents: *Not represented by counsel.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Health Science International, Inc., a corporation, and David Martin, individually and as an officer of Health Science International, Inc. ("Respondents"), have violated the provisions of the Federal Trade