

Complaint

IN THE MATTER OF

SHELLY BLACK,
TRADING AND DOING BUSINESS AS
PROGESTERONE ADVOCATES NETWORK

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

Docket C-4206; File No. 072 3146

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

This consent order addresses Progesterone Advocates Network's advertising and promotion of Nature's Precise Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. The complaint alleges that the respondents represented that Nature's Precise Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer. The consent 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 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.

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.

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COMPLAINT

The Federal Trade Commission, having reason to believe that Shelly Black, an individual trading and doing business as Progesterone Advocate Network (“respondent”), has 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 Shelly Black is an individual trading and doing business as Progesterone Advocates Network with her principal office or place of business at Post Office Box 1004, Trabuco Canyon, California 92678. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Progesterone Advocates Network, including the acts and practices alleged in this complaint.

2. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

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

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4. Respondent has advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Nature's Precise Cream. Respondent primarily advertises and offers the products for sale through the Internet site www.progestnet.com.

5. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Nature's Precise Cream is a "drug" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

6. Nature's Precise Cream is a drug labeled as containing USP Natural Progesterone (960 mg per 2 ounce tube) and other ingredients. A two fluid ounce tube costs \$19.95 plus shipping and handling. Nature's Precise Cream is applied transdermally.

7. To induce consumers to purchase Nature's Precise Cream, respondent has disseminated or has caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondent's website:

A. NPC-Nature's Precise Cream (Formally known as Natural Progesterone) Product Information

* * *

A topical dietary supplement, designed for women of all ages who experience symptoms relating to PMS, Menopause and Osteoporosis. This completely natural product provides a safe and effective alternative to synthetic Hormone Replacement Therapies (also known as HRT or estrogen replacement) and their undesirable side effects. Menopausal and pre-menopausal women may experience hot flashes due to hormonal imbalance and in some cases, more severe symptoms including

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Endometriosis, Fibroid Tumors, Fibrocystic Breast Disease and Breast Cancer. Awareness of women's health concerns and the demand for natural treatments is at an all time high. Dr. John R. Lee's best selling book: "What your doctor may not tell you about Menopause", outlines the remarkable benefits provided by natural progesterone.

Who Needs Natural Progesterone?

Women who have symptoms of hormone imbalances:

* * *

Osteoporosis

* * *

(Exhibit A at 3.)

- B. Ovarian, uterine, and cervical cancers are all known to be a result of hormonal imbalances. Specifically they are a result of excess estrogen or estrogen dominance.

* * *

Uterine cancer, also known as endometrial cancer, is not as common as ovarian cancer. The usual time in a woman's life when endometrial cancer develops is during the pre-menopausal years when high levels of estrogen and low levels of progesterone are present. The only known cause of endometrial cancer is unopposed estrogen. Progesterone opposes the estrogen thereby decreasing the risk of endometrial cancer.

* * *

Estrogen is the hormone that stimulates cell growth. Cancer is the abnormal growth of cells and comes about

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from an imbalance in the body. Correct the balance and the cancer may go away. One of progesterone's most important roles in the body is to balance or oppose estrogen.

(Exhibit A at 5.)

- C. In the United States there are 175,000 cases of breast cancer reported a year, accounting for over 44,000 deaths. The risk of breast cancer rises with age, but has become more prevalent in younger, pre-menopausal women. For many cancers, the cause is still unknown. However, the cause of breast and endometrial cancers can be directly linked to hormonal factors. The carcinogenic effects of unopposed estrogen and the anticancer benefits of progesterone are well documented for these two cancers.

From the time that the first breast cancer cell emerges, it may be 8-10 years before the growth is large enough to be diagnosed with palpation. A mammogram may detect the growth, at most, 2 years earlier. What this implies is that many breast cancers start during the 10 to 15 years before menopause, when it is common for estrogen to be dominant and progesterone to be deficient. Estrogen stimulates cell growth. Progesterone regulates cell growth by telling it when to stop. Cancer is a result of abnormal cell growth and arises from an imbalance in the body. Correct the imbalance and you've corrected the problem.

After 25 years of using chemicals, radiation, and surgery we are still losing the war on cancer. Because of its many benefits and its great safety, natural progesterone deserves far more attention than is generally given in the prevention and care of women's health problems today.

(Exhibit A at 7.)

- D. **Should estrogen be taken without progesterone?**

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Definitely not! It is very important that natural progesterone be used with any form of estrogen. Estrogen without progesterone can cause endometrial and vaginal carcinomas.

* * *

I'm already on hormone replacement therapy from my doctor. Why should I switch to natural progesterone?

Natural progesterone is simply a NATURAL ALTERNATIVE to hormone replacement therapy. Synthetic progestins have many side effects.

* * *

(Exhibit A at 9.)

- E. With menopause, bone loss accelerates to 3 to 5 percent per year for about 5 years, after which bone loss continues at the rate of about 1.5 percent per year. The indication here is that a lack of progesterone causes a decrease in new bone formation, not a lack of estrogen, which is still at adequate levels prior to menopause. In fact, both during and after menopause, women may still maintain 40% to 60% of their estrogen levels (in fat cells) which is sufficient for maintaining proper health, yet they will have NO progesterone.

(Exhibit A at 11.)

- F. Natural progesterone is safe that is what makes it so great.

. .

* * *

Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen.

* * *

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Research indicates that this loss of bone is due to increased levels of progesterone, not estrogen. Adding natural progesterone supplementation will increase bone density and can reverse osteoporosis.

* * *

(Exhibit A at 12.)

- G. “Estrogen dominance” is a term coined by Dr. John R. Lee. It describes a condition where a woman can have deficient, normal, or excessive estrogen but the body has little or no progesterone to balance its effects. Signs and symptoms of estrogen dominance include:

* * *

Breast cancer

* * *

Uterine cancer

* * *

Pre-menopausal bone loss

* * *

Estrogen “deficiency” that is quite often used as an explanation of menopausal symptoms or health problems is not supported by sound research. When a woman’s menstrual cycle is functioning normally, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. After menopause, estrogen is still present and continues to be manufactured in fat cells. Most menopausal women have too little estrogen to support

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pregnancy, but sufficient amounts for other normal body functions. Few women are truly deficient in estrogen; most become progesterone deficient. If estrogen becomes the dominant hormone and progesterone is deficient, excess estrogen becomes toxic to the body. Progesterone has a balancing effect on estrogen.

(Exhibit A at 14-15.)

- H. Breast and endometrial are both hormone related cancers, and tend to surface in women at the time in their lives when estrogen is dominant and progesterone is deficient. Estrogen stimulates cell growth in the body, while progesterone regulates cell growth. Excess estrogen or estrogen dominance is the only known cause of endometrial cancer.

(Exhibit A at 16.)

- I. Because the safety of natural progesterone is so great, it's harmless to use a little more than you strictly need.

(Exhibit A at 18.)

- J. One of progesterone's most important and powerful roles in the body is to balance or oppose estrogen. Under the normal healthy circumstances of a woman's monthly cycle, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. When our progesterone levels are in balance, the body better handles excess estrogen.

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS & Menopause.

Benefits of Natural Progesterone include:

* * *

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Helps protect against endometrial, breast, ovarian, and prostate cancer

* * *

Increases new bone formation

* * *

Synthetic Progestins are not the same as Natural Progesterone

Medical literature tends to equate natural progesterone/progesterone with synthetic progestins. This assumption is altogether incorrect. Progesterone is a specific molecule made by the adrenal glands and by the ovary during of ovulation. Synthetic progestins are drugs that are manufactured by pharmaceutical companies and are normally available by prescription only. Synthetic progestins are not natural to the body and are known to cause undesirable side effects. . . .

(Exhibit A at 19.)

- K. Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen.

* * *

If you choose to continue using synthetic estrogen, it is imperative that you also use progesterone in conjunction with estrogen. Many physicians prescribe synthetic progestins along with estrogen. Avoid synthetic progestins and instead use natural progesterone. It is not only safer, it has MANY beneficial factors that cannot be seen with the use of progestins.

(Exhibit A at 21.)

- L. **Physiological effects of Progesterone versus Estrogen**

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Progesterone effects

* * *

Prevents endometrial
cancer
Helps prevent breast
cancer
Stimulates osteoblast bone
building

* * *

Estrogen effects

* * *

Increases risk of endometrial
cancer
Increases risk of breast
cancer
Slightly restrains osteoclast
function

* * *

(Exhibit A at 22.)

M. Medical literature tends to equate progesterone with synthetic progestins. This assumption is altogether incorrect.

Synthetic progestins are drugs that are manufactured by drug companies and are normally available by prescription only. Synthetic progestins are not natural to the body and can cause undesirable side effects. Some of the side effects from synthetic progestins include; cardiovascular complications, suspected links to uterine and breast cancer, blood clots, insomnia, menstrual irregularities, depression, masculinizing effects, breast tenderness, fluid retention and edema.

* * *

Progesterone is a specific molecule made by the adrenal glands or by the ovary during ovulation. Natural progesterone cream is derived from organic compounds found in nature and is molecularly identical to

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progesterone manufactured by the human body. Synthetic progestins are molecularly altered and have negative side effects when placed in the human body. For example: Progesterone is essential through out pregnancy, whereas synthetic progestins carry a warning that their use in early pregnancy may increase the risk of miscarriage.

Natural Progesterone Cream contains the natural hormone, which has been accurately synthesized from wild yams. Supplementing with natural progesterone has NO side effects - even during pregnancy.

Compare Effects - Natural Progesterone to Synthetic

Conditions * * *	Natural Proges- terone (real)	Progestins (synthetic)
Protects against endometrial cancer		
Protects against ovarian cancer	X	X
Protects against breast cancer	X	
* * *	X	
Improves new bone formation	X	
* * *		

(Exhibit A at 25-26.)

8. Through the means described in Paragraphs 6 and 7, respondent has represented, expressly or by implication, that:

A. Nature's Precise Cream is effective in preventing, treating, or curing osteoporosis;

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B. Nature's Precise Cream is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

C. Nature's Precise Cream does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer.

9. Through the means described in Paragraphs 6 and 7, respondent has represented, expressly or by implication, that she possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 8, at the time the representations were made.

10. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 8 at the time the representations were made. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

11. 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 respondent.

By the Commission.

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Exhibit A

Natural Progesterone and Natural Supplements at Affordable Pricing

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 Progesterone
 Advocates
 Network

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Providing products for Quality of Life! We provide customers with quality products, information, and personalized guidance. Save as much as 75% off suggested retail with our volume discounts. Our product line is constantly growing so keep checking back!

Natural Hormone Balance

Transdermal Creams

From PMS to Menopause and Beyond
 Your source for promoting hormone balance naturally! We offer the complete line of Sarati's transdermal re-balancing creams, including their most popular NPC - Nature's Precise Cream and EST - Essential Support Treatment Cream.

NPC - Nature's Precise Cream (FKA Natural Progesterone Cream) - Help symptoms that may occur with menstruation and menopause.

EST - Essential Support Treatment (FKA Estro-All) - Hard to find combination progesterone/phyto-estrogen formulation designed for menopausal women.

EMP - Essential Moisture Plus Cream (FKA Feminine Moisture Plus) - Advanced formulation provides soothing relief for vaginal dryness.

D-35 Complex (Formerly known as DHEA Plus) - Androstenedione works best in our formulation to boost DHEA levels and increase testosterone.

Hormone Balance Test Kit

Improve Sexual Response

Our transdermal cream product, topically applied, is designed to safely increase sexual responsiveness. Fempower for women.
[Click here for more](#)

Essential Oils

Eucalyptus Oil is the most versatile essential oil found in nature.
[Click here for more](#)

EstroLogic

EstroLogic is a Herbal Supplement for Natural Estrogen Balance.
[More](#)

Nationwide Doctor Referral Service

In addition to the product and information available here at www.ProgestNet.com, we offer a nationwide referral service with healthcare practitioners who advocate obtaining optimum health naturally through nutrition and hormonal balance.

By providing you with information, quality products, and the availability of [finding a doctor](#) in your area, we intend to positively

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Natural Progesterone and Natural Hormone Supplements at Affordable Pricing

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Influence current mainstream standards of healthcare in our country. Together we can make a difference.

A primary source of information by John R. Lee, M.D.

is falling hormone levels, which is largely responsible for disorders in hormone balance.

Saliva testing can be used to determine your current hormonal state as well as monitor your supplementation with our natural hormone products.

The optimum hormone levels to have tested are: **progesterone, estradiol, DHEA, testosterone and cortisol**. If you only wish to test the minimum hormones then you would test for: **estradiol and progesterone**.

What Your Doctor May Not Tell You About Breast Cancer - Breakthrough book by John R. Lee, M.D., David Zava, M.D., and Virginia Hopkins.

What Your Doctor May Not Tell You About Menopause - The Breakthrough Book On Natural Progesterone by John R. Lee, M.D. with Virginia Hopkins.

What Your Doctor May Not Tell You About Premenopause - Balance Your Hormones and Your Life From Thirty to Fifty by John R. Lee, M.D., Jesse Hanley, M.D., and Virginia Hopkins.

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NPC-Nature's Precise Cream (Formerly known as Natural Progesterone) Product Information

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NPC-Nature's Precise Cream (Formerly known as Natural Progesterone) Product Information

Natural Progesterone - Formulation: 960 mg USP natural progesterone in a 2 ounce base of: deionized water, caprylic/capric triglycerides, polyacrylamide/c13-14, isoparaffin/laureth 7, aloe vera gel, vitamin E acetate, grapefruit seed extract.

A topical dietary supplement, designed for women of all ages who experience symptoms relating to PMS, Menopause and Osteoporosis. This completely natural product provides a safe and effective alternative to synthetic Hormone Replacement Therapies (also known as HRT or estrogen replacement) and their undesirable side effects. Menopausal and pre-menopausal women may experience hot flashes due to hormonal imbalance and in some cases, more severe symptoms including Endometriosis, Fibroid Tumors, Fibrocystic Breast Disease and Breast Cancer. Awareness of women's health concerns and the demand for natural treatments is at an all time high. Dr. John R. Lee's best selling book: "What your doctor may not tell you about Menopause", outlines the remarkable benefits provided by natural progesterone.

Who Needs Natural Progesterone?

Women who have symptoms of hormone imbalances:

- PMS
- Premenopause
- Endometriosis
- Osteoporosis
- Weight Gain
- Low Sex Drive
- Heart Disease

NPC-Nature's Precise Cream (FKA Natural Progesterone) 1 Tube Retail \$19.95

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NPC-Nature's Precise Cream (Formerly known as Natural Progesterone) Product Information

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NPC-Nature's Precise Cream (FKA Natural Progesterone) 3 Tube Purchase \$56.00

Quantity [\[Add to Cart\]](#) [\[View Cart\]](#)

NPC-Nature's Precise Cream (FKA Natural Progesterone) 6 Tube Purchase \$95.00

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NPC-Nature's Precise Cream (FKA Natural Progesterone) 12 Tube Purchase \$130.00

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Ovarian/Cervical/Uterine Cancer

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Ovarian/Cervical/Uterine Cancer

Ovarian, uterine, and cervical cancers are all known to be a result of hormonal imbalances. Specifically they are a result of excess estrogen or estrogen dominance. Most women in western civilization are estrogen dominant, due to environmental exposures such as: pollution, solvents, pesticides, herbicides, fungicides, car exhaust, emulsifiers found in soaps and cosmetics, industrial waste, meat and dairy products from animals fed estrogen, birth control pills, and synthetic estrogens & progestins frequently prescribed to millions of women.

Most ovarian cancer occurs in menopausal women around the age of fifty. Ovarian cancer is particularly scary because by the time it's diagnosed it is likely to have already spread to other parts of the body and increased the likelihood of mortality. Nearly 20 percent of gynecologic cancers are ovarian, and it is fifth in cancer fatalities in women. A 1995 study by C. Rodriguez and Associates published in the American Journal of Epidemiology, showed that in 240,073 women studied, the relative risk of fatal ovarian cancer was 72 percent greater among those women who were given unopposed estrogen for six years or more. The authors concluded; "long-term use of estrogen replacement therapy may increase the risk of fatal ovarian cancer." Fertility drugs may also play a role in the increasing rate of ovarian cancer. One study found that using fertility drugs increased ovarian cancer risk three times, but in women who had never been pregnant the risk was increased to 27 times. Other studies have shown that women who have children later in life, or are infertile, also have a higher risk of ovarian cancer. Since many women are "waiting" to have their children, and so many others have resorted to the use of infertility drugs, we may see ovarian cancer reach epidemic levels in the near future.

Uterine cancer, also known as endometrial cancer, is not as common as ovarian cancer. The usual time in a woman's life when endometrial cancer develops is during the pre-menopausal years when high levels of estrogen and low levels of progesterone are present. The only known cause of endometrial cancer is unopposed estrogen. Progesterone opposes the estrogen thereby decreasing the risk of endometrial cancer. This information has been an available part of medical education for years, but it seems to have been forgotten by doctors who prescribe Hormone Replacement Therapy. The use of HRT is based on drug company advertising rather than sound research data.

Oral contraceptives have been linked to both endometrial and cervical cancers. In the 1960s a Dr. Helen Grant was hired to work in a London clinic to test varying combinations and dosages of birth control pills. After 10 years of working with oral contraceptives, Dr. Grant found that they were very dangerous. Dr. Grant noticed that 'the pill' had many side effects, and that the risk of death from cervical, breast, and endometrial cancer was doubled with the use of oral contraceptives.

When a pre-menopausal women complains to her doctor about PMS, she is likely to leave with a prescription for estrogen or a birth control pill, which is probably the last thing in the world that she needs. Many pre-menopausal women prescribed unopposed estrogen will have an abnormal Pap test within a year, and her risk of breast cancer is significantly increased. If she has an abnormal Pap smear, it is routine for the doctor to suggest removing her uterus. Thus begins a dangerous cycle of HRT and undesirable hormone related symptoms and conditions

Estrogen is the hormone that stimulates cell growth. Cancer is the abnormal growth of cells and comes about from an imbalance in the body. Correct the balance and the cancer may go away. One of progesterone's most important roles in the body is to balance or oppose estrogen.

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Direct Cancer

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Breast Cancer

In the United States there are 175,000 cases of breast cancer reported a year, accounting for over 44,000 deaths. The risk of breast cancer rises with age, but has become more prevalent in younger, pre-menopausal women. For many cancers, the cause is still unknown. However, the cause of breast and endometrial cancers can be directly linked to hormonal factors. The carcinogenic effects of unopposed estrogen and the anticancer benefits of progesterone are well documented for these two cancers.

From the time that the first breast cancer cell emerges, it may be 8-10 years before the growth is large enough to be diagnosed with palpation. A mammogram may detect the growth, at most, 2 years earlier. What this implies is that many breast cancers start during the 10 to 15 years before menopause, when it is common for estrogen to be dominant and progesterone to be deficient. Estrogen stimulates cell growth. Progesterone regulates cell growth by telling it when to stop. Cancer is a result of abnormal cell growth and arises from an imbalance in the body. Correct the imbalance and you've corrected the problem.

After 25 years of using chemicals, radiation, and surgery we are still losing the war on cancer. Because of its many benefits and its great safety, natural progesterone deserves far more attention than is generally given in the prevention and care of women's health problems today.

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Frequently Asked Questions

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Frequently Asked Questions

1. What exactly is natural progesterone and how does it differ from a synthetic progesterone?

Natural progesterone, a cholesterol derivative, comes from a wild Mexican yam plant. It matches exactly the chemical composition of our body's own progesterone. Products that list yam extract among their ingredients may or may not include the saponin, a rich portion of the yam root. In other words, not all natural progesterone creams are created equal. Our progesterone cream contains the pharmaceutical grade natural progesterone created specifically to Dr. John Lee's specifications - at least 400 mg. per ounce! Our progesterone cream is the only cream on the market today with a high potency grape seed extract, which is proven to be a powerful antioxidant and a free radical scavenger. (Estrogen dominance causes free radical damage.)

2. Who should use natural progesterone cream?

Those women who suffer from PMS with: mood swings, cramping, weight gain, bloating, acne, insomnia, decreased sex drive, decreased energy, depression, water retention, heavy and/or irregular periods found relief according to Dr. Lee, by using a natural progesterone cream.

3. Are there any side effects from using natural progesterone?

Most frequently, any side effects from natural progesterone are associated with usage, and can be easily alleviated by changing the amount and frequency of the dosage. In the PMS age group, using too much natural progesterone (over one to four months) can delay the period a day or two. Discontinuing the natural progesterone will cause the period to start, and natural progesterone can be resumed after 7 days, but at a lower dose.

Women with irregular periods might notice some spotting at ovulation upon beginning natural progesterone treatment. What's indicated here is that the period is trying to regulate on a 28-day cycle. With continued use, periods will become regular and the spotting will be alleviated. Menopausal women might also notice some spotting when they begin using natural progesterone. This too should be alleviated with continued use. The postmenopausal and osteoporosis age group should not have any side effects at all.

4. Do I need a prescription for natural progesterone?

No. Natural progesterone in a cream or oil base comes from a wild Mexican yam plant, which is technically a food product, and all of the other ingredients, aside from a trace of some cosmetic ingredients, are natural.

5. Can natural progesterone help with endometriosis or fibrocystic breasts?

There are many factors that affect both of these conditions, one common factor being a higher level of circulating estrogen, indicating a hormonal imbalance. Progesterone is the precursor hormone and it helps to normalize all other endocrine and hormonal activity in the body. It will make or block estrogen as necessary. In the case of endometriosis, or fibrocystic breasts, it assists in lowering the level of estrogen in the body and thus, possibly helps to clear these conditions.

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Frequently Asked Questions

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6. Should estrogen be taken without progesterone?

Definitely not! It is very important that natural progesterone be used with any form of estrogen. Estrogen without progesterone can cause endometrial and vaginal carcinomas. Estrogen alone blocks thyroid and causes water retention, and it can cause fibrocystic breast disease and even fibroid tumors and cysts.

7. I'm already on hormone replacement therapy from my doctor. Why should I switch to natural progesterone?

Natural progesterone is simply a NATURAL ALTERNATIVE to hormone replacement therapy. Synthetic progestins have many side effects. Women with a history of hypertension, diabetes, weight problems, and/or varicose veins should not be on chemical estrogen and progestins.

8. How do I get off synthetics and on the natural?

If someone is taking both synthetic estrogen and progestins, a gradual step might be to at least substitute natural progesterone for the synthetic progestin. Do not go off synthetic estrogen suddenly. You need to wean off slowly; otherwise the symptoms will return (hot flashes, night sweats, mood swings, etc.).

9. I am post menopausal. Will I start menstruating again if I use natural progesterone? What if I have some breakthrough bleeding?

Occasionally, upon beginning use of natural progesterone, a post menopausal woman could experience some breakthrough bleeding, or a "period." This rarely happens, but if it should, it is a perfectly normal response and is nothing to cause alarm. The progesterone is simply causing the body to rid itself of excess stored estrogen which can sometimes stimulate uterine shedding - thus breakthrough bleeding. If this continues for longer than several months, one should consult a physician.

10. Why is transdermal absorption so good?

Natural progesterone being small, fat-soluble molecules, are much better absorbed through the skin than given orally. It goes across the skin to subcutaneous fat layers, then to blood circulation. So first it goes into body fats and then the blood, avoiding first pass loss through the liver.

11. How long before I notice maximum benefits?

It may require 2-3 months of use before maximum benefits are experienced. Some women report immediate improvement.

12. Where is the best place to apply the natural progesterone cream?

Natural progesterone cream can be applied to any area of the body; however, it is best to apply it to thinner, softer skin such as the chest, breasts, neck, or anywhere that you blush. It is recommended that you periodically rotate the area of the body where natural progesterone cream is applied. Natural progesterone is a very effective skin moisturizer and has been used in skin creams in lesser concentrations for years.

13. What do I say to my physician who thinks this is silly?

There is nothing new under the sun. This formula is the same base as 400 FDA drugs, just without chemicals. Also, as an informed individual you have the right to choose ... and the choice should be yours. Remember, physicians only recommend what they know best. Possibly your physician will want to study this further if he or she sees positive results with you. A good starting point will be a careful reading of Dr. John R. Lee's books; "What Your Doctor May

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[Frequently Asked Questions](#)

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Not Tell You About Menopause" and "What Your Doctor May Not Tell You About Pre-Menopause".

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Osteoporosis

Osteoporosis is the loss of normal bone density with thinning bone tissue and the growth of small holes in the bone. Symptoms include pain, especially in the low back, frequent broken bones, and loss of body height. It is identified most often in women who have gone through menopause. In the United States over 45 percent of women age 50 or more have bone mineral density deficiencies and there are 1,500,000 osteoporosis related fractures reported every year.

Unfortunately, proper treatment of this dangerous and easily preventable disease has been overlooked by mainstream medicine. The makers of Premarin and other estrogen manufacturers would like for our doctors and us to believe that lack of estrogen is the leading cause of osteoporosis. Yet significant bone loss occurs during the 10 to 15 years before menopause, when estrogen levels are still normal. Women's bone mass peaks in their mid-thirties and begins declining shortly thereafter at a rate of about 1 to 1.5 percent per year. This is when many women are experiencing irregular ovulation cycles. It is during these anovulatory cycles that progesterone levels fall while estrogen levels remain the same resulting in estrogen dominance.

By the time menopause is reached, osteoporosis is well under way, some women may have already lost as much as 25 percent of their bone density! With menopause, bone loss accelerates to 3 to 5 percent per year for about 5 years, after which bone loss continues at the rate of about 1.5 percent per year. The indication here is that a lack of progesterone causes a decrease in new bone formation, not a lack of estrogen, which is still at adequate levels prior to menopause. In fact, both during and after menopause, women may still maintain 40% to 60% of their estrogen levels (in fat cells) which is sufficient for maintaining proper health, yet they will have NO progesterone.

Estrogen slows the rate of osteoporosis, but not without serious risks. The bone benefits of estrogen replacement after menopause decrease after three to five years. Yet, mainstream medicine persists in the belief that estrogen is the "best" treatment for osteoporosis in women. Information gathered from Dr. John Lee's book "What Your Doctor May Not Tell You About Menopause".

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PROGESTERONE AND ESTROGEN INDEX

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Progesterone and Estrogen Index

About Estrogen

Estrogen dominance is a term coined by Dr. John R. Lee. It describes a condition where a woman can have deficient, normal, or excessive estrogen but the body has little or no progesterone to balance its effects.

Estrogen and Cancer

Cancer cells usually invade and destroy normal tissue cells and is born of an imbalance in the body.

Estrone, Estradiol, and Estriol

Estrone, estradiol, and estriol are all estrogens that are natural to the human body. They belong to the steroid hormones, and are primarily responsible for the growth of female characteristics in puberty and regulating the menstrual cycle.

How To Use Progesterone

Natural progesterone is safe that is what makes it so great... But, we are striving for balance, so avoid the "more is better" mentality when it comes to using progesterone cream.

What is Progesterone

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS & Menopause.

Who Should Use Natural Progesterone

Reports of well being with the use of transdermal natural progesterone are impressive. Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen.

Why Transdermal Application?

Transdermal progesterone is absorbed through the skin and into the layer of fat that lies beneath the surface. Natural progesterone is biologically active and when taken transdermally has an immediate effect on the body.

Wild Yam Extract

Although wild yams do have some effect on the body, it's just not known exactly what it is. Whatever its effects are it does not have the same benefits as progesterone.

Progesterone vs Estrogen

A listing of the physiological effects of Progesterone versus Estrogen.

Estrogen and Osteoporosis

Research indicates that this loss of bone is due to decreased levels of progesterone, not estrogen. Adding natural progesterone supplementation will increase bone density and can reverse osteoporosis.

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progesterone and estrogen index

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Synthetic vs Natural Progesterone

Synthetic progestins are not natural to the body and can cause undesirable side effects.

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About Estrogen

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About Estrogen

Estrogen is not a single hormone. It is a class of hormones and hormone like compounds that have estrogenic properties. There are human estrogens, animal estrogens, synthetic estrogens, phytoestrogens, and xenoestrogens. The three human estrogens are estradiol, estrone, and estrinol, and belong to the steroid hormone family.

"Estrogen dominance" is a term coined by Dr. John R. Lee. It describes a condition where a woman can have deficient, normal, or excessive estrogen but the body has little or no progesterone to balance its effects. Signs and symptoms of estrogen dominance include:

- Speeds up the aging process
- Allergies
- Autoimmune disorders
- Breast cancer
- Breast tenderness
- Cold hands and feet as a symptom of thyroid dysfunction
- Decreased sex drive
- Depression
- Dry eyes
- Early onset of menstruation
- Uterine cancer
- Fat gain in abdomen, hips, and thighs
- Fatigue
- Fibrocystic breasts
- Foggy thinking
- Hair loss
- Headaches
- Hypoglycemia
- Increased blood clotting
- Infertility
- Irregular menstrual periods
- Insomnia
- Memory loss
- Mood swings
- PMS
- Ovarian cysts
- Pre-menopausal bone loss
- Prostate cancer
- Sluggish metabolism
- Thyroid dysfunction
- Uterine cancer
- Uterine fibroids
- Water retention and bloating

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ABOUT US/US/0001

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In industrialized countries such as the United States, diets rich in animal fats, sugar, refined starches, and processed foods can lead to estrogen levels in women twice that of women of third-world countries. We are constantly exposed to xenobiotics (petrochemicals), xenoestrogen-laden meats and dairy products, forms of pollution, and prescriptions for synthetic hormones (such as the 'The Pill' and Premarin). It isn't too surprising that estrogen dominance has become an epidemic in industrialized countries. Over exposure to these potentially dangerous substances has significant consequences, one of which is passing on reproductive abnormalities to offspring.

Estrogen "deficiency" that is quite often used as an explanation of menopausal symptoms or health problems is not supported by sound research. When a woman's menstrual cycle is functioning normally, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. After menopause, estrogen is still present and continues to be manufactured in fat cells. Most menopausal women have too little estrogen to support pregnancy, but sufficient amounts for other normal body functions. Few women are truly deficient in estrogen; most become progesterone deficient. If estrogen becomes the dominant hormone and progesterone is deficient, excess estrogen becomes toxic to the body. Progesterone has a balancing effect on estrogen.

Supplemental estrogen, even in the slightest amounts, in a woman who doesn't need it, or who has no progesterone to balance it, can lead to many serious side effects. When a woman complains of even the slightest menopausal type symptoms, conventional medical doctors will recommend a prescription of estrogen. It is irresponsible and dangerous for doctors to be routinely prescribing estrogen for any type of pre-menopausal or menopausal symptom, and this practice can have tragic consequences. Progesterone should be the first choice. For severe menopausal symptoms not controlled by progesterone supplementation alone, natural phytoestrogens can be added. Please read our additional information regarding Natural Progesterone Cream and Estro-All cream, a safer form of supplemental estrogen.

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ESTROGEN AND CANCER

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Estrogen and Cancer

Cancer is the abnormal growth of cells in our bodies that can lead to death. Cancer cells usually invade and destroy normal tissue cells and is born of an imbalance in the body. Correct the imbalance and the cancer may go away. Billions of dollars have been spent on cancer research and yet we still don't understand exactly what cancer is.

Breast and endometrial are both hormone related cancers, and tend to surface in women at the time in their lives when estrogen is dominant and progesterone is deficient. Estrogen stimulates cell growth in the body, while progesterone regulates cell growth. Excess estrogen or estrogen dominance is the only known cause of endometrial cancer.

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Estrone, Estradiol, and Estriol

Estrone, estradiol, and estriol are all estrogens that are natural to the human body. They belong to the steroid hormones, and are primarily responsible for the growth of female characteristics in puberty and regulating the menstrual cycle. They are made primarily in the ovaries but are also manufactured from androstenedione in fat cells, muscle cells, and skin even after menopause. Progesterone is a precursor or building block to these hormones.

To date, all the available evidence available indicates that estriol is the safest estrogen to use to control menopausal symptoms, and that it may even be protective against breast cancer.

Despite sound marketing by the pharmaceutical industry, **synthetic estrogens are not equivalent to natural hormones**. Harmony and balance, the standard of a healthy body, are lost when biologically active synthetic compounds are thrown into the hormonal equation of a woman's body. They are disruptive, to say the least, to the steroid hormones and are likely responsible for a great deal of hormonal imbalance.

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HOW TO USE PROGESTERONE

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How To Use Progesterone

People differ in almost every aspect of their physiology. We're not all built the same, and there's wide variation in physiologic and metabolic processes from person to person. It's not rational to order the same dose of any given medicine for everybody, and the same is true of natural progesterone.

Although medical professionals can give you guidelines to work within, it's up to you to find the best dose for your body. Ideally, you should be able to find the minimum amount you can use to gain and sustain relief from your symptoms. Because the safety of natural progesterone is so great, it's harmless to use a little more than you strictly need. That gives you plenty of room for experimentation.

We are striving for balance, please avoid the 'more is better' mentality when it comes to using progesterone cream. Use too much and you could cause of a hormonal imbalance. If you are using a physiologic dose (an amount approximating what your body would make itself under normal circumstances) and your symptoms don't go away after four to six months, or if they return, it's best to work in partnership with a competent health care professional to find out why.

At the recommended dosage, (see the brochure that comes with your order of cream) a progesterone-deficient women who starts using the cream will find that in three to four months, the progesterone in her body fat will reach physiologic equilibrium and the amount in the saliva will be consistent with what would be produced normally during an ovulatory cycle.

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What is Progesterone

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What is Progesterone

One of progesterone's most important and powerful roles in the body is to balance or oppose estrogen. Under the normal healthy circumstances of a woman's monthly cycle, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. When our progesterone levels are in balance, the body better handles excess estrogen.

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS & Menopause.

Benefits of Natural Progesterone include:

- Protects against breast fibrocysts
- Helps protect against endometrial, breast, ovarian, and prostate cancer
- Normalizes blood clotting
- Helps prevent hypertension
- Acts as a natural diuretic
- Acts as a natural antidepressant
- Helps relieve anxiety
- Helps normalize blood sugar levels
- Helps thyroid hormone function
- Helps use fat for energy
- Is thermogenic (raises body temperature)
- Increases new bone formation
- Maintains normal cell membrane functions
- Has beneficial anti-inflammatory effects
- Reduces incidence of autoimmune disorders
- Prevents yeast (candida) infections
- Maintains the lining of the uterus for nurturing a fertilized ovum
- Makes the cervical mucus accessible by sperm
- Stops ovulation by the other ovary
- Prevents rejection of the developing baby
- Allows for full development of the fetus throughout pregnancy
- Increases libido at time of ovulation

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Synthetic Progestins are not the same as Natural Progesterone

Medical literature tends to equate natural progesterone/progesterone with synthetic progestins. This assumption is altogether incorrect. Progesterone is a specific molecule made by the adrenal glands and by the ovary during of ovulation. Synthetic progestins are drugs that are manufactured by pharmaceutical companies and are normally available by prescription only. Synthetic progestins are not natural to the body and are known to cause undesirable side effects. See [table](#) for more details.

The pharmaceutical companies who manufacture and market synthetic progestins, do not market natural progesterone

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because they cannot patent a natural product. As a result these companies do not provide funding for further clinical research nor promote it to healthcare professionals. This dynamic has hindered western medicine from becoming more informed of the benefits of natural progesterone.

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WHO SHOULD USE NATURAL PROGESTERONE

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Who Should Use Natural Progesterone

Likely nearly all of us! Reports of well being with the use of transdermal natural progesterone are impressive. Less anxiety and depression, increased vitality and reduced sleep disturbances, not to mention enhanced libido, are all benefits of a product with a track record of total safety.

Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen. Most people who live in industrialized countries have a hormonal imbalance due to such factor as; stress, constant exposure to xenohormones, anovulatory cycles, or as a consequence of synthetic hormone prescriptions. Restoring proper progesterone levels is what is known as restoring hormone balance.

If you are currently using synthetic hormones, you will want to wean off of them slowly. If you choose to continue using synthetic estrogen, it is imperative that you also use progesterone in conjunction with estrogen. Many physicians prescribe synthetic progestins along with estrogen. Avoid synthetic progestins and instead use natural progesterone. It is not only safer, it has MANY beneficial factors that cannot be seen with the use of progestins.

Progesterone cream can be used without the guidance of a health care provider, yet one may be able to attain a better hormonal balance with the help of a physician who is experienced in balancing hormones - naturally. Some people will find immediate relief from symptoms, others find that it may take from one to four months to turn things around. This is a natural product, not a drug. Healing will take place naturally, on your body's own schedule.

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PROGESTERONE VS. ESTROGEN

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Progesterone Vs. Estrogen

Physiological effects of Progesterone versus Estrogen

Progesterone effects

Maintains secretory endometrium
 Protects against fibrocystic breast
 Helps use fat for energy
 Natural diuretic
 Natural antidepressant
 Facilitates thyroid hormone action
 Normalizes blood clotting
 Restores sex drive
 Normalizes blood sugar levels
 Normalizes zinc and copper levels
 Restores proper cell oxygen levels
 Prevents endometrial cancer
 Helps prevent breast cancer
 Stimulates osteoblast bone building
 Restores normal vascular tone
 Necessary for survival of embryo
 Precursor of corticosteroids

Estrogen effects

Creates proliferative endometrium
 Causes breast stimulation
 Increases body fat
 Salt and fluid retention
 Depression and headaches
 Interferes with thyroid hormone
 Increases blood clotting
 Decreases sex drive
 Impairs blood sugar control
 Loss of zinc and retention of copper
 Reduces oxygen levels in all cells
 Increases risk of endometrial cancer
 Increases risk of breast cancer
 Slightly restrains osteoclast function
 Reduces vascular tone
 Increases risk of gall bladder
 Increases risk of autoimmune disorders

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PROGESTERONE VS. ESTROGEN

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Estrogen and Osteoporosis

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Estrogen and Osteoporosis

Bone mass in women peaks around their mid-thirties, after which a gradual decline of about 1 to 1.5 percent a year occurs. During the approximate five year period of menopause, bone density decrease rises to about 3 to 5 percent a year, after which it returns to the previous 1 to 1.5 percent loss.

The makers of Premarin would have us all believing that estrogen loss is the major cause of osteoporosis. If this is true, why is there a bone density decrease in the years prior to menopause when estrogen levels are still within the 'normal' range? Research indicates that this loss of bone is due to decreased levels of progesterone, not estrogen.

Supplementation of synthetic estrogen cannot reverse osteoporosis, but instead only reduce the rate of bone density loss and not without the risks of serious side effects. Any benefits osteoporosis benefits from estrogen are lost after the first 3 to 5 years of menopause onset. Mainstream medicine still persists in the misguided belief that estrogen is the mainstay of osteoporosis treatment for women. Even the most authoritative medical textbooks do not support this notion.

Could it be that the makers of Premarin are promoting the usage just to make a profit?

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SYNTHETIC VS NATURAL PROGESTERONE

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Synthetic vs Natural Progesterone

Medical literature tends to equate progesterone with synthetic progestins. This assumption is altogether incorrect.

Synthetic progestins are drugs that are manufactured by drug companies and are normally available by prescription only. Synthetic progestins are not natural to the body and can cause undesirable side effects. Some of the side effects from synthetic progestins include; cardiovascular complications, suspected links to uterine and breast cancer, blood clots, insomnia, menstrual irregularities, depression, masculinizing effects, breast tenderness, fluid retention and edema.

Pharmaceutical companies (who manufacture and market synthetic progestins) do not market natural progesterone because they cannot patent compounds that occur in nature. As a result neither do they provide funding for clinical research on natural progesterone, or promote it to healthcare professionals.

Progesterone is a specific molecule made by the adrenal glands or by the ovary during ovulation. Natural progesterone cream is derived from organic compounds found in nature and is molecularly identical to progesterone manufactured by the human body. Synthetic progestins are molecularly altered and have negative side effects when placed in the human body. For example: Progesterone is essential through out pregnancy, whereas synthetic progestins carry a warning that their use in early pregnancy may increase the risk of miscarriage.

Natural Progesterone Cream contains the natural hormone, which has been accurately synthesized from wild yams. Supplementing with natural progesterone has NO side effects - even during pregnancy.

Compare Effects - Natural Progesterone to Synthetic

	Conditions Natural Progesterone (real)	Progestins (synthetic)
Increases sodium and water in body cells		X
Causes loss of mineral electrolytes from cells		X
Causes intracellular edema		X
Causes depression		X
Increases birth defect risks		X
Causes facial hirsutism, loss of scalp hair		X
Causes thrombophlebitis, embolism risk		X
Decreases glucose tolerance		X
Causes allergic reactions		X

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		Age 40+
Increases risk for cholestatic jaundice		X
Causes acne, skin rashes		X
Protects against endometrial cancer	X	X
Protects against ovarian cancer	X	
Protects against breast cancer	X	
Normalizes libido	X	
Causes less hirsutism, regrowth Of scalp hair	X	
Improves lipid profile	X	
Improves in vitro fertilization	X	
Improves new bone formation	X	
Increases risk of coronary vasospasm		Modestly
Decreases risk of coronary vasospasm	X	
Facilitates thyroid hormone action	X	
Usually effective in treating PMS	X	
Prevents implantation of fertilized ovum	X	
Is essential for successful pregnancy	X	
Is essential for myelinization of nerves	X	
Restores normal sleep patterns	X	
Is a precursor of other steroid hormones	X	
Is essential also for males	X	

Published Studies

Synthetic progestins and natural progesterone have only one common function: ability to sustain secretory endometrium. Progestins don't have the full spectrum of progesterone's activity. Clinic Use of Sex Steroids, 1980

Progestins have an adverse effect on insulin resistance. They can also raise triglycerides, and are related to breast cancer risk. American Journal of Obstetrics & Gynecology, 1994 Monographs/National Cancer Institute, 1994

Synthetic progestins have a wide variety of side effects. Clinic Use of Sex Steroids, 1980

Natural progesterone shows improved lipid profile, amenorrhea without endometrial problems, and has no side effects when compared with medroxyprogesterone acetate (Provera). Optimal Health Guidelines, 1993

Any change in the molecular configuration of steroids alters their effects. Optimal Health Guidelines, 1992

Synthetic progestins induce proliferation of breast tumor cells. Molecular and Cellular Endocrinology, 1994

The risk of cancer with long-term perimenopausal estrogen treatment may be increased with the addition of progestins. New England Journal of Medicine, 1989

During the past decade, several isolated reports have linked an increased incidence of breast cancer with the use of synthetic progestins. Cancer, 1993

Overwhelming evidence shows that breast cancer risk is closely related to exposure to synthetic estrogens and

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Synthetic Estrogen & Progesterone

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progestogens. Monograph, National Cancer Institute, 1994

Synthetic estrogen and progestin therapy have an adverse effect on bone because of their impact on magnesium excretion. Magnesium and Trace Elements, 1991-1992

Synthetic progestens suppress the immune system. Cleveland Clinical Journal of Medicine, 1994

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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 Respondent named in the caption hereof, and the Respondent 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 Respondent with violation of the Federal Trade Commission Act; and

The Respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondent 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 Respondent 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 Respondent has 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 Shelly Black is an individual trading and doing business as Progesterone Advocates Network with her principal office or place of business is at Post Office Box 1004, Trabuco Canyon, California 92678. Individually, or in concert with others,

Decision and Order

she formulates, directs, controls, or participates in the policies, acts, or practices of Progesterone Advocates Network.

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

ORDER**DEFINITIONS**

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

1. Unless otherwise specified, “Respondent” shall mean Shelly Black, individually and trading and doing business as Progesterone Advocates Network.
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 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 Nature’s Precise Cream.
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.

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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 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

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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 Respondent, 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:

- 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;

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- 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, Respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondent, 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, 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 Respondent 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;

Decision and Order

- B. Nothing in this order shall prohibit Respondent 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 Respondent 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 Respondent 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;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in her 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 Respondent shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees,

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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. Respondent 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 Respondent shall notify the Commission at least thirty (30) days prior to any change with regard to Progesterone Advocates Network or any business entity that 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 or address. *Provided, however*, that, with respect to any proposed change about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent 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 Respondent, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of her current business or employment; or of her affiliation with any new business or

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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 Respondent 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 she has 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 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

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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 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 Shelly Black, an individual trading and doing business as Progesterone Advocates Network (“respondent”).

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 Nature’s Precise Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. According to the FTC complaint, respondent represented that Nature’s Precise Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of

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estrogen-induced endometrial (uterine) cancer; and (3) does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer. The complaint alleges that respondent failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondent 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 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 respondent 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 respondent 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 respondent to keep copies of relevant advertisements and materials substantiating claims made in

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the advertisements; to provide copies of the order to certain of her 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

**MERILOU BARNEKOW,
TRADING AND DOING BUSINESS AS
WOMEN'S MENOPAUSE HEALTH CENTER**

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

Docket C-4208; File No. 072 3143

Complaint, November 19, 2007 – Decision, November 19, 2007

This consent order addresses the deceptive advertising and promotion of Preserve Progesterone Cream and Return to Eden Progesterone Cream 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 respondent 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 any disease. The order further prevents the respondent from engaging in similar acts and practices in the future and prohibits the respondent 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.