

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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

)	
In the Matter of)	
)	
SHELLY BLACK,)	
an individual trading and doing business)	DOCKET NO. C-
as PROGESTERONE ADVOCATES)	
NETWORK.)	
)	

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.

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 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 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?

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.

* * *

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 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:

* * *

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**

Progesterone effects

Estrogen effects

* * *

Prevents endometrial cancer
Helps prevent breast cancer
Stimulates osteoblast bone building

* * *

(Exhibit A at 22.)

* * *

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

* * *

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 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)
* * *		
Protects against endometrial cancer	X	X
Protects against ovarian cancer	X	
Protects against breast cancer	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;
- 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 ____ day of _____, 2007, has issued this complaint against respondent.

By the Commission

Donald S. Clark
Secretary