#### 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-4206
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.

Osteoporosis

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

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 \* \* \*

\* \* \*

\* \* \*

Prevents endometrial cancerIncreases risk of endometrial cancerHelps prevent breast cancerIncreases risk of breast cancerStimulates osteoblast bone buildingSlightly 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 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	Х	Х
Protects against ovarian canc	er	Х	
Protects against breast cance	r	Х	
* * *			
Improves new bone formatio	n	x	
improves new bone formatio		4 <b>b</b>	

\* \* \*

## (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 estrogeninduced 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