

UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION

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                            **Pamela Jones Harbour**  
                            **Jon Leibowitz**  
                            **William E. Kovacic**  
                            **J. Thomas Rosch**

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**In the Matter of** )  
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 )  
**MERILOU BARNEKOW,** )  
**an individual trading and doing business** )     **DOCKET NO. C-4208**  
**as WOMEN’S MENOPAUSE HEALTH** )  
**CENTER** )  

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**COMPLAINT**

The Federal Trade Commission, having reason to believe that Merilou Barnekow, an individual trading and doing business as Women’s Menopause Health Center (“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 Merilou Barnekow is an individual trading and doing business as Women’s Menopause Health Center with her principal office or place of business at 1026 Blue Water Highway, Surfside Beach, Texas 77541, 709-2 Plaza Drive #105, Chesterton, Indiana 46304, and 3900 Orange Grove Boulevard #54, North Fort Myers, Florida 33903. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Women’s Menopause Health Center, 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 Preserve Progesterone Cream and Return to Eden Progesterone Cream. Respondent primarily advertises and offers the products for sale through the Internet site [www.womens-menopause-health.com](http://www.womens-menopause-health.com).

5. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Preserve Progesterone Cream and Return to Eden Progesterone Cream are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

6. Preserve Progesterone Cream is a drug labeled as containing USP Natural Progesterone and other ingredients. A 3.5 ounce bottle costs \$34.95 plus shipping and handling. Return to Eden Progesterone Cream is a drug labeled as containing USP Progesterone. A 2 ounce jar costs \$19.95 plus shipping and handling. Preserve Progesterone Cream and Return to Eden Progesterone Cream are applied transdermally.

7. Until on or about August 1, 2007, to induce consumers to purchase Preserve Progesterone Cream, Respondent disseminated or 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. Women today, armed with educated health information, know that there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned that it is clinically proven that one of the benefits of natural progesterone like that found in Preserve natural progesterone cream is that it can actually rebuild bone tissue with no known side effects.

With large studies\* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead. The Preserve superb quality progesterone cream formula was developed by a team of physicians based on Dr. John Lee's research.

\* \* \*

A natural course of action makes a lot more sense with progesterone cream's proven safety. Researchers have conducted clinical tests proving progesterone cream to be effective and safe with no side effects.

\* \* \*

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast cancers. Dr. Lee calls this "estrogen dominance." Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by adequate progesterone like that found in Preserve progesterone cream.

Estrogen levels drop only 40% to 60% during menopause, but progesterone levels may drop to near zero in some women. Because progesterone is the precursor to so many other steroid hormones, its use can enhance hormone balance after menopause. Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone provides many benefits and combats estrogen dominance providing protection against cancers of the breast, ovaries, uterus, (endometrium), and in men, the prostate.

(Exhibit A at 5-7.)

B. The benefits of natural progesterone cream are said to be many:

\* \* \*

Rebuilds lost bone mass at a rate of 5-15% per year.  
Improves new bone formation.

\* \* \*

Reduces risk of breast cancer.  
Reduces risk of uterine cancer.

(Exhibit A at 9-10.)

C. Research and study information also shows that natural progesterone - in addition to diet and lifestyle changes - provides far greater benefit to bone health.

\* \* \*

Progesterone works to actively build new bone tissue. By supplying the body with adequate supplies of bone-building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

\* \* \*

Research shows that osteoporosis prevention measures of a healthy calcium-rich diet, exercise and progesterone work better than using hormone replacement therapy.

(Exhibit A at 13, 15.)

- D. An increasing number of studies show that progesterone as a natural alternative to traditional osteoporosis treatment is highly effective in not only preventing bone loss but in actually increasing bone density. This natural alternative to traditional osteoporosis treatment not only helps build bone mass, but also helps decrease menopause symptoms without side effects associated with hormone replacement therapy or drugs used for the treatment of osteoporosis.

\* \* \*

For women seeking osteoporosis treatment while simultaneously addressing menopause related symptoms and health concerns, progesterone is the perfect natural alternative. The lack of progesterone causes a decrease in new bone formation. Using progesterone cream as a natural osteoporosis alternative can increase bone mass and actually reverse osteoporosis!

In addition to improving new bone formation and warding off osteoporosis, progesterone balances estrogen dominance, improves lipid profile, improves blood sugar control, improves the ability to burn body fat. Progesterone cream eliminates hot flashes, helps with sleep disorders, normalizes and restores sexual desire, promotes youthful skin appearance and reduces the risk of breast cancer and uterine cancer.

\* \* \*

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone less while progesterone aids the body in building new bone.

\* \* \*

This is the good news. Even if bones have lost density, there is opportunity to gain it back.

(Exhibit A at 16-17.)

- E. Fortunately, women have safe and effective natural hormone replacement therapy alternatives to ease them through menopause without the risks associated with non-natural hormone replacement therapy.

In addition to the multi-dimensional plant-based estrogen complex in Preserve, the Preserve formula also contains the following ingredients found effective in reducing menopause symptoms:

\* \* \*

Progesterone: A naturally occurring hormone which works with estrogen compounds, important for its abilities to correctly balance estrogen activity, and helps to maintain bone density.

(Exhibit A at 21.)

- F. Excess fatty tissue is a source of circulating estrogen in your body, and breast cancer risk is directly linked to how much estrogen you're exposed to during your lifetime. (Another significant reason to avoid synthetic estrogen replacement therapy (ERT) and balance hormones with Preserve Progesterone Cream or Preserve as a part of your breast cancer prevention regimen [sic].

(Exhibit A at 24.)

- G. Natural progesterone cream helps:

\* \* \*

-Rebuild lost bone mass.  
-Improves new bone formation.

\* \* \*

-Reduce risk of breast cancer.  
-Reduce risk of uterine cancer.

\* \* \*

If you have not already kicked the hormone replacement therapy [sic], now is as good a time as any. Order a bottle of Preserve and a pump container of Preserve Natural Progesterone Cream and experience healthy menopause for yourself.

(Exhibit A at 27-28.)

- H. The next step in the osteoporosis prevention plan is to begin using a high quality progesterone cream like Preserve to give the body the hormonal building block components for new bone growth. Progesterone serves a dual purpose. While providing positive effects on osteoporosis by promoting the building of new bone mass, progesterone also decreases menopause symptoms typical in the age group of women at risk for osteoporosis.

(Exhibit A at 29.)

8. From on or about August 1, 2007, to induce consumers to purchase Return to Eden Progesterone Cream, Respondent has disseminated or has caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit B. These advertisements contain the following statements and depictions, among others, on Respondent's website:

- A. Women today armed with educated health information, know there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned what women in Great Britain and Europe have known for decades - the benefits of natural progesterone like that found in Return to Eden natural progesterone cream. These women believe, from decades of use, that it can actually rebuild bone tissue with no known side effects.

With large studies\* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead.

\* \* \*

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast

cancers. Dr. Lee calls this “estrogen dominance.” Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by adequate progesterone like that found in Return to Eden all-natural progesterone cream.

\* \* \*

Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone may provide many benefits and combats estrogen dominance.

(Exhibit B at 5, 7.)

- B. The benefits of natural diosgenin (nicknamed progesterone) cream are said to be many:

\* \* \*

Balances estrogen dominance.

(Exhibit B at 9.)

- C. Given the positive benefits of progesterone cream and the low incidence of progesterone side effects, many women choose this natural alternative to achieve normal progesterone levels.

\* \* \*

To achieve the optimal benefits of progesterone cream without progesterone side effects to achieve normal progesterone levels, use the natural progesterone cream 500 mg/oz Return to Eden formula.

(Exhibit B at 12.)

- D. The Federal Drug Administration recently mandated a new boxed warning on the danger of estrogen therapy and estrogen/progestin products such as Premarin and Prempro. This is the highest FDA warning level for drug labeling. The FDA estrogen information warning states an increased risk for heart disease, heart attacks, strokes, and breast cancer and also emphasizes that estrogen products are not approved for heart disease prevention.

\* \* \*

The government report cites data from human epidemiology studies that show a connection between estrogen therapy and an increase in endometrial cancer and breast cancer.

\* \* \*

Stopping hormone replacement therapy would be a difficult choice without effective alternatives to hormone replacement therapy. Fortunately, there are effective alternatives for women who no longer wish to take hormone replacement therapy.

A quality progesterone cream like Return to Eden natural progesterone cream, may gently alleviate menopause symptoms as well as hormone replacement therapy.

**Natural progesterone cream helps:**

\* \* \*

Balances estrogen dominance.  
(Exhibit B at 14-15.)

- E. Women in Great Britain and Europe have found that progesterone is a natural alternative to traditional osteoporosis treatment. This natural alternative to traditional osteoporosis treatment is believed by them to build bone mass, and help decrease menopause symptoms without side effects associated with synthetic hormone replacement therapy or drugs [sic] used for the treatment of osteoporosis.

\* \* \*

For women seeking osteoporosis treatment while simultaneously addressing menopause related symptoms and health concerns, progesterone may be the perfect natural alternative. The lack of progesterone is thought to cause a decrease in new bone formation.

Progesterone balances estrogen dominance. . .

\* \* \*

For a natural alternative to osteoporosis treatment, postmenopausal women may use up to one teaspoon of high quality progesterone cream daily for three weeks each month. The week off progesterone maintains the sensitivity of the



progesterone receptors. We recommend Return to Eden natural USP progesterone cream.

\* \* \*

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone loss while progesterone aids the body in building bone.

\* \* \*

This is the good news. Even if bones have lost density, there is opportunity to gain it back. But, in order for new bone to be made, bones need an adequate supply of nutrients like calcium, regular weight-bearing exercise and hormonal balance conducive to bone growth.

(Exhibit B at 17-18.)

- F. Given the serious health risks associated with estrogen and the lack of long-term benefit, hormone replacement therapy is one of the least appropriate osteoporosis treatment methods women should take.

Women in Great Britain and Europe have been using natural progesterone like that found in Return to Eden all-natural progesterone cream for decades to combat osteoporosis.

\* \* \*

Progesterone is thought to actively build new bone tissue. By supplying the body with adequate supplies of bone-building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

(Exhibit B at 21.)

- G. Post Menopausal symptoms include . . . osteoporosis. . .

\* \* \*

The above symptoms of menopause are successfully relieved for the majority of women when using Return to Eden as directed.

(Exhibit B at 24.)

- H. The answer to managing menopause symptoms requires a multi-pronged approach that includes healthy lifestyle choices, natural hormone replacement therapy and the use of progesterone cream to encourage hormonal balance and harmony.

\* \* \*

Many women find that by supplementing their hormone production with natural progesterone that they will reduce many or most of their menopausal symptoms. The presence of progesterone in the body sensitizes estrogen receptor sites enabling estrogen to work more efficiently without being dominant.

\* \* \*

The benefits of natural progesterone cream are said to be many:

\* \* \*

Balances estrogen dominance.

\* \* \*

Rebuilds lost bone mass at a rate of 5-15% per year.  
Improves new bone formation.

\* \* \*

Reduces risk of breast cancer.  
Reduces risk of uterine cancer.

(Exhibit B at 28-29.)

9. Through the means described in Paragraphs 6 through 8, Respondent has represented, expressly or by implication, that:

- A. Preserve Progesterone Cream and Return to Eden Progesterone Cream are effective in preventing, treating, or curing osteoporosis;
- B. Preserve Progesterone Cream and Return to Eden Progesterone Cream are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

- C. Preserve Progesterone Cream and Return to Eden Progesterone Cream do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

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

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

12. The acts and practices alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, on this nineteenth day of November, 2007, has issued this complaint against respondent.

By the Commission.

Donald S. Clark  
Secretary

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