

**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION**

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

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<b>In the Matter of</b>	)	
	)	
<b>ELATION THERAPY, INC.,</b>	)	
<b>a corporation, and</b>	)	<b>DOCKET NO. C-</b>
	)	
<b>ROBERT RUTLEDGE,</b>	)	
<b>individually and as an officer of</b>	)	
<b>Elation Therapy, Inc.</b>	)	
	)	

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Elation Therapy, Inc., a corporation, and Robert Rutledge, individually and as an officer of Elation Therapy, Inc. (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Elation Therapy, Inc. is a Georgia corporation with its principal office or place of business at 3605 Sandy Plains Rd, Ste 240 #138, Marietta, Georgia 30066.
2. Respondent Robert Rutledge is an officer of Elation Therapy, Inc. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Elation Therapy, Inc., including the acts and practices alleged in this complaint. His principal office or place of business is the same as Elation Therapy, Inc.
3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.
4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the

use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman's risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman's risk of developing breast cancer.

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Elation Therapy™ Natural Progesterone Cream. Respondents advertise and offer the products for sale through the Internet sites [www.superb-progesterone-cream.com](http://www.superb-progesterone-cream.com) and [www.gorillavitamins.com](http://www.gorillavitamins.com).

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Elation Therapy™ Natural Progesterone Cream is a “drug” as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. Elation Therapy™ Natural Progesterone Cream is a drug labeled as containing Natural Progesterone USP (560 mg per ounce), Mexican Wild Yam (2000 mg per ounce), and other ingredients. Two four ounce tubes cost \$29.96 plus shipping and handling. Elation Therapy™ Natural Progesterone Cream is applied transdermally.

8. To induce consumers to purchase Elation Therapy™ Natural Progesterone Cream, respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondents' websites:

A. Dr. Senay said there is no direct evidence that bioidenticals are not safe because they have not gone through rigorous clinical trials, which also means that there is no proof that the products are safe. Well, what about the tens of millions of women who had to “go it on their own” and try Natural Progesterone Cream against their doctor's wishes. They have proven Bioidentical Natural Progesterone IS safe and IS effective.

(Exhibit A at 5.)

B. The Benefits of Natural Progesterone Compared to Estrogen  
Estrogen Effects: . . . Increased risk of endometrial cancer; Increased risk of breast cancer; Helps decrease bone loss slightly.

Progesterone Effects: . . . Prevents endometrial cancer; Helps prevent breast cancer; Increases bone building.

(Exhibit A at 8.)

C. A superb progesterone cream, like Elation Therapy, can help with symptoms of pms (premenstrual syndrome), menopause, osteoporosis, (bone loss), migraines, loss of libido, anxiety attack, mood swings, postpartum depression, and perimenopause.

(Exhibit A at 11.)

D. The cure for hormonal imbalance and the secret to ending estrogen dominance is a substance called natural progesterone.

\* \* \*

Natural progesterone is becoming the alternative treatment choice for thousands of women suffering from the effects of Depression, PMS, Menopause, Osteoporosis, and Hormone Imbalance.

\* \* \*

Natural Progesterone has been known to:

\* \* \*

- Help prevent breast cancer

\* \* \*

- Prevent endometrial cancer

\* \* \*

- Stimulate the growth of new bone cells even in women already suffering from osteoporosis

Natural progesterone supplies what the body cannot produce on its own, without the dangerous side effects of synthetic hormones.

\* \* \*

Synthetic estrogens and progestins also increase the probability of developing many conditions including:

- Uterine cancer  
(Exhibit A at 13-14.)

E. It would seem, natural progesterone is much safer than those synthetic alternatives created by pharmaceutical companies.  
(Exhibit A at 16.)

F. We don't have to promote the benefits of natural progesterone creams like Elation Therapy. Dr. John Lee, MD. and author Raquel Martin do that for us. Women throughout the world are becoming better acquainted with the health benefits of natural progesterone. Natural progesterone, according to these authors, reduces the symptoms and discomfort of Menopause, PMS and Perimenopause (sometimes called Pre-menopause) without the side effects often associated with synthetic hormone replacement therapy.

Dr. John Lee's best selling books list the following benefits of natural progesterone:

- Reverses bone loss by stimulating osteoblast

\* \* \*

- Helps prevent breast cancer  
(Exhibit A at 19.)

G. Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS, Menopause and Osteoporosis.  
(Exhibit A at 21.)

H. I was showing them that people with osteoporosis get better when you add progesterone. That's never happened before in the history of womankind.

There isn't any other study that shows that, and that estrogen doesn't do it. It's kind of like if somebody says, "All sheep are white." You do not have to do a double blind control, all you have to do is find one black sheep. Right? And you've disproved that.

If you say osteoporosis cannot be reversed and I do it on 100 patients, I don't need a control group, I'm doing something that's reversing osteoporosis and they ought to be looking into it. I wasn't in a position to do the double blind studies because people were coming to me for advice on how to use the progesterone they could buy over the counter.

\* \* \*

I'd given talks at our local hospitals, Marin General, and Ross Hospital, showing these bones getting better on these people. I mean, I ordered the tests but I had nothing to do with making the tests, and the people were using the progesterone. There was no way I could interfere with the results.

\* \* \*

(Exhibit A at 23-24.)

- I. Natural Transdermal Progesterone Cream, applied topically to the face, neck, arms, chest and fatty tissue areas of the body such as the breasts, the abdominal area, the buttocks, the inner thighs, etc., is stored in these fatty tissues for use as required by the body and has been shown to reverse the effects of Estrogen Dominance listed below:

\* \* \*

- Increased Risk of Breast Cancer
- Increased Risk of Ovarian Cancer
- Increased Risk of Endometrial Cancer
- Restraint of Osteoclast Function (bone loss)

\* \* \*

It is also important that we distinguish Natural Progesterone from its counterparts in the drug industry - PROGESTINS. Although these drugs are commonly referred to as Progesterone, this is a misnomer.

In some ways they mimic the effects of Natural Progesterone in the body, but in other important ways they gravely interfere with Natural Progesterone and can create and exacerbate hormone related health problems, and be a primary contributor to Estrogen Dominance.

(Exhibit A at 25-26.)

- J. Q: Why do women need progesterone?

A: Progesterone is needed in hormone replacement therapy for menopausal women for many reasons, but one of its most important roles is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for breast cancer and reproductive cancers.

\* \* \*

Progesterone also stimulates bone-building and thus helps protect against osteoporosis.

(Exhibit A at 21.)

- K. Why not just use the progestin Provera as prescribed by most doctors? Progesterone is preferable to the synthetic progestins such as Provera, because it is natural to the body and has no undesirable side effects when used as directed.

\* \* \*

Q: What is estrogen dominance?

A: Dr. Lee has coined the term “estrogen dominance,” to describe what happens when the normal ratio or balance of estrogen to progesterone is changed by excess estrogen or inadequate progesterone. Estrogen is a potent and potentially dangerous hormone when not balanced by adequate progesterone.

\* \* \*

Estrogen dominance is known to cause and/or contribute to cancer of the breast, ovary, endometrium (uterus), and prostate.

(Exhibit A at 29.)

- L. One of the most important factors in osteoporosis is a lack of progesterone, which causes a decrease in new bone formation. Years of clinical experience giving women progesterone showed me that using a natural progesterone cream will actively increase bone mass and density and can reverse osteoporosis. These patients consistently show as much as a 29 percent increase in bone mineral density in three years or less of progesterone therapy. After treating hundreds of patients with osteoporosis over a period of 15 years, I found that those women with the lowest bone densities experienced the greatest relative improvement, and those who had good bone density to begin with, maintained their strong bones.

(Exhibit A at 31.)

- M. Most women also don't know that they need to balance supplemental estrogens with natural progesterone, not the synthetic progestins used in HRT. Maintaining this estrogen-progesterone balance will protect against breast cancer and the many other adverse effects of unopposed estrogen.

(Exhibit A at 34.)

- N. Osteoporosis (bone loss) starts after age 40 when normal bone breakdown is accelerated by estrogen loss. Dr. John Lee states this can be prevented [sic] and even reversed with natural progesterone cream.

(Exhibit A at 36.)

- O. Prescription medications will sometimes alleviate most premenstrual syndrome symptoms, but they are often accompanied with harsh and often deadly side affects. Millions are turning to natural alternatives like progesterone cream.  
(Exhibit A at 38.)
- P. The following is a list of symptoms that can be caused or made worse by estrogen dominance. . . . Uterine cancer, . . . Osteoporosis. . . .

Many women find that by supplementing their hormone production with natural progesterone they will reduce many or most of their menopausal symptoms.

\* \* \*

“The signs and symptoms of osteoporosis is cleared away in every patient using progesterone cream and incidence of fractures dropped to zero.” — John R. Lee, M.D.

(Exhibit A at 41-42.)

- Q. Progesterone’s primary functions include: acting as a precursor to estrogen and testosterone; it maintains uterine lining and aids in gestation; protects against fibrocystic breasts, endometrial and breast cancer; acts as a natural diuretic, helps use fat for energy; can be a natural antidepressant; aids thyroid hormone action; normalizes blood clotting; restores sex drive; normalizes blood sugar, zinc and copper levels; restores proper cell oxygen levels, has a thermogenic effect; builds bone and helps to protects against osteoporosis.

\* \* \*

Some doctors feel that menopausal symptoms, osteoporosis and heart disease may not be due to a deficiency of estrogen, but to a relative estrogen excess due to progesterone deficiency.

Synthetic progestins, such as an HRT drug called Provera (a synthetic chemical), do not have the same biological effects as natural progesterone and have been known to cause side effects including: fluid retention, depression, breast tenderness, stroke, jaundice, blood clotting, and cervical erosions.

On the other hand, natural progesterone has no known side effects and has been found to be helpful in alleviating symptoms such as PMS and hot flashes. It has also been credited with helping to prevent osteoporosis.

(Exhibit A at 43.)

- R. It has been estimated that if women, beginning at the age of 25, routinely used natural progesterone, breast and uterine cancers in women could be reduced by 70%. How much is your health worth? Men, how much is your wife's, mother's, or sister's health worth?

The important thing to keep in mind is that progestins are not progesterone. Progesterone protects against breast cancer. Progestins are synthetic drugs that supposedly mimic real progesterone but in fact do not. Since it is well established that excess estrogen can cause and promote breast cancer, why is the HRT combination worse than estrogen alone? Progestins occupy progesterone receptors more tenaciously than progesterone, and thereby block progesterone from its functions.

Dr. John Lee believes that progesterone is a potent protector against the 80 percent of breast cancer that is hormone-related. Dr. Lee and his colleagues have asked thousands of women the following question: "Of all the women you know who got breast cancer, how many were using natural progesterone cream?" According to Dr. John Lee except for a handful of women who by coincidence (or intuition) started using a natural progesterone cream a few weeks or months before their diagnosis none were found.

(Exhibit A at 45.)

- S. However, there are steps you can do to prevent osteoporosis, such as:
- Start using progesterone cream now

\* \* \*

(Exhibit A at 48.)

- T. Breast Cancer as well as other cancers are best treated preventatively. It is far easier to prevent them in the first place than to fight them later on. Studies have directly linked estrogen dominance to cancers in women. Estrogen stimulates cell proliferation (uncontrolled and unstructured growth of immature cells). This is not good with cancer cells. Progesterone inhibits the proliferation in favor of cell maturation.

Thus natural progesterone, as found in Natural Progesterone Cream, causes the cancer to stop multiplying and is a natural preventor of cancer. It would seem only wise to supply estrogen dominant women with natural progesterone. This should begin in the 10 to 15 years before menopause when estrogen dominance is so common.

(Exhibit A at 49.)



- U. For example, Progestin, the molecular compound found in Prempro, is a synthetic form of progesterone whose molecular structure has been changed. It can trigger dangerous side effects in the body. Bio-identical progesterone is very different from synthetic progestin. “Bio-identical progesterone is not only safe to use, it can help decrease a woman’s risk for developing cancer,” says Dr. Randolph. “I currently lecture to physicians around the country sharing clinical studies and medical data that validates the fact that bio-identical progesterone has many cancer-protective benefits. The bio-chemistry of why this is so is actually quite simple: progesterone neutralizes the cancer-promoting properties associated with too much estrogen in the body. While estrogen promotes cell proliferation, or cell growth, progesterone decreases cell growth. Too much cell growth is a precursor for cancer.”

“In my gynecology practice, I have prescribed bio-identical progesterone for over a decade and I have never had a patient on my bio-identical hormone regimen develop cancer. I even have patients who are breast cancer survivors who I prescribe bio-identical progesterone because my experience, and the research shows, that the progesterone can play a key role in preventing a recurrence of the original cancer.”

\* \* \*

“Obviously, more studies are needed to validate the cancer-protective properties of bio-identical progesterone.”

(Exhibit A at 52.)

9. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that:
- A. Elation Therapy™ Natural Progesterone Cream is effective in preventing, treating, or curing osteoporosis;
  - B. Elation Therapy™ Natural Progesterone Cream is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and
  - C. Elation Therapy™ Natural Progesterone 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.
10. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

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

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

THEREFORE, the Federal Trade Commission, on this \_\_\_\_ day of \_\_\_\_\_, 2007, has issued this complaint against respondents.

By the Commission

Donald S. Clark  
Secretary