

**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)	
)	
HEALTH SCIENCE)	
INTERNATIONAL, INC.,)	
a corporation, and)	DOCKET NO. C-4205
)	
DAVID MARTIN,)	
individually and as an officer of)	
Health Science International, Inc.)	
)	

COMPLAINT

The Federal Trade Commission, having reason to believe that Health Science International, Inc., a corporation, and David Martin, individually and as an officer of Health Science International, 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 Health Science International, Inc. is a Florida corporation with its principal office or place of business at 1648 Taylor Road, Suite 118, Port Orange, Florida 32128.
2. Respondent David Martin is an officer of Health Science International, Inc. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Health Science International, Inc., including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Health Science International, 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 Serenity for Women Natural Progesterone Cream. Respondents advertise and offer the products for sale through the Internet sites www.health-science.com and www.progesterone.com.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Serenity for Women Natural Progesterone Cream is a "drug" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. Serenity for Women Natural Progesterone Cream is a drug labeled as containing Natural Progesterone USP (2.25%) and other ingredients. A 60 gram jar costs \$32 plus shipping and handling. Serenity for Women Natural Progesterone Cream is applied transdermally.

8. To induce consumers to purchase Serenity for Women 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' website:

- A. Does Progesterone or Estrogen increase or decrease my risk for cancer? Molecular biologist, Dr. Ben Formby of Copenhagen, Denmark and Dr. T.S. Wiley at the University of California in Santa Barbara have researched two genes, BCL2 and P53, and their effect on female-specific cancers and prostate cancer.

Cells of breast, endometrium, ovary and prostate, were grown in the laboratory. Estrogen (estradiol) was added to the cells. This hormone turned on the BCL2 gene, causing the cells to grow rapidly and not die. Then, progesterone was added to the cell cultures. Cell reproduction stopped and the cells died on time (apoptosis).

This methodology was applied to all the above types of cancer. The BCL2 gene, therefore, stimulates the growth of these cells and the risk of cancer. On the other

hand, the P53 gene promotes apoptosis or programmed cell death and thereby, reduces the risk of cancer. Estradiol upregulates or stimulates the production of the BCL2 gene, while progesterone upregulates or stimulates the production of the P53 gene.

Therefore natural progesterone decreases the risk for several types of cancer, while unopposed estradiol causes these same types of cancer. Since Breast cancer is considered to be a hormone dependent cancer it is critically important to maintain optimal levels of natural progesterone and avoid the factors that would promote too much estradiol.

* * *

Clearly the underlying causes of breast cancer are too much estrogen relative to too little natural progesterone, especially in the presence of trans fatty acids (hydrogenated fats).

“When faced with decisions on critically important health issues such as breast cancer, ovarian cancer, endometriosis, fibrocystic breast disease, migraine headaches, infertility & osteoporosis, Informed Women demand and deserve the finest natural progesterone cream formula available anywhere in the world
“Serenity for Women Certified Potency Progesterone Cream.”

(Exhibit A at 2.)

- B. Natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.
(Exhibit A at 4.)
- C. Because the female body uses natural progesterone to make natural estrogen, a properly formulated natural progesterone cream is the natural safe choice for menstruating women and for post-menopausal women seeking to establish the correct balance of their two primary female hormones.

This balance of Natural Progesterone and Natural Estrogens will protect them from the effects of the condition known as “Estrogen Dominance”.*

The resultant Benefits of natural progesterone include

* * *

Helps Protect Epithelial cells against Breast Cancer
Helps Prevent Endometrial Cancer
Helps prevent Ovarian Cysts and Ovarian Cancer

* * *

Stimulates Osteoblast Cells (Osteoporosis Reversal)

As you can see, natural progesterone counterbalances the effects of too much estrogen discussed here.

(Exhibit A at 5.)

- D. Bone tissue should be broken down and rebuilt continuously, just like all of the cells in our body. This process takes place when Osteoclasts help to dissolve old bone tissue, while osteoblasts stimulate new bone growth. Because estrogen has a rate limiting effect on Osteoclasts, Estrogen Dominance delays the breakdown of bone tissue but does not support bone building (osteoblast function).

Natural progesterone, on the other hand, stimulates osteoblast production which results in new bone tissue growth. Consequently, estrogens only slow down bone loss, not promote the formation of new bone tissue.

Osteoporosis Research

The efficacy of natural progesterone is verified by a three year study of 63 post-menopausal women with osteoporosis.**

Women using transdermal progesterone cream experienced an average 7-8% bone mass density increase the first year, 4-5% the second year and 3-4% the third year!

Untreated women in this age category typically lose 0.7% to 2.0% bone mineral density per year!!!

These results have not been found with any other form of hormone replacement therapy, prescription medication or dietary supplement!

Conclusion

Maintaining proper levels of natural progesterone, giving due attention to dietary choices, dietary calcium, managing stress and regular exercise are all vital components of strong, healthy bones.

(Exhibit A at 6.)

- E. Side Effects: There are no reports of any significant side effects or health problems associated with natural progesterone.

(Exhibit A at 8.)

F. Dear Health & Science

I am 54 and have been using Serenity for Women for over 3 years now.

Recently, I had my first bone density test. I was very scared because I had a number of risk factors for osteoporosis. The results of my test?

Bones of a 25 year old!

My Doctor had never seen such a high rating for someone my age.

I am amazed!

(Exhibit A at 10.)

G. Because estrogen has a rate limiting effect on Osteoclasts, Estrogen Dominance delays the breakdown of bone tissue but does not support bone building (osteoblast function). Natural progesterone, on the other hand, stimulates osteoblast bone cell activity which results in new bone tissue growth. Consequently, estrogens only slow down bone loss, not promote the formation of new bone tissue.

Osteoporosis Research

The efficacy of natural progesterone is verified by a three year study of 63 post-menopausal women with osteoporosis. **** Women using transdermal progesterone cream experienced an average 7-8% bone mass density increase the first year, 4-5% the second year and 3-4% the third year!**

Untreated women in this age category typically lose 0.7% to 2.0% bone mineral density per year!!! These results have not been found with any other form of hormone replacement therapy or dietary supplementation!...

Vital, necessary factors for the maintenance of strong, healthy bones are:

- Maintaining proper levels of natural progesterone;

* * *

(Exhibit A at 11-12.)

H. It is also important that we distinguish Natural Progesterone from Yam extract and 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 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 the condition referred to as Estrogen Dominance:

* * *

Increased Risk of Breast Cancer

* * *

Increased Risk of Endometrial Cancer
Increased Risk of Uterine Cancer

* * *

When the above list of ill-effects is compared to the benefits of Natural Progesterone, we see a nearly one-to-one correlation.

(Exhibit A at 13.)

- I. Dr. John Lee, of California, U.S.A., used natural progesterone creams in his practice for 19 years. He states in his books that natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.

(Exhibit A at 15.)

- J. The more natural method of raising progesterone levels is free from side-effects. This has been well documented by the high rate of success reported by Dr. John R. Lee, M.D., using Transdermal Natural Progesterone in his practice for approximately 19 years and the success reported to the *Health & Science Research Institute* from thousands of women around the world.

Finally, oral progesterone will produce a sharp rise in serum progesterone levels followed by a rapid drop within about an hour. Progesterone administered via a properly formulated progesterone cream will raise systemic progesterone levels for eleven or twelve hours. This offers informed women continual and stable progesterone levels which may play a critical role in the prevention of female specific cancers, the amelioration of the symptoms of PMS & Menopause, the ability to get and stay pregnant, and the reversal of Osteoporosis. (Bone loss in women who live in industrialized countries begins, on average, at age 35).

In thirty years of clinical practice, seventeen recommending transdermal natural progesterone, Dr. Lee has observed the **consistent benefits** and safety of natural progesterone therapy.

(Exhibit A at 19.)

- K. 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 20.)

- L. Serenity for Women has been carefully formulated for women who suffer with the unpleasant symptoms of Menopause & PMS, and who are experiencing the conditions of Infertility and Osteoporosis.
(Exhibit A at 23.)

- M. When faced with decisions on critically important issues such as breast cancer, ovarian cancer, endometriosis, fibrocystic breast disease, migraine headaches, infertility and osteoporosis, informed women demand and deserve the finest cream available anywhere in the world.

Serenity for Women, Certified Potency, Natural Progesterone Cream
(Exhibit A at 24.)

- N. Dear Health & Science,

I used the Serenity cream for over four months after I was diagnosed with abnormal Endometrial cells.

My Doctor insisted I get a hysterectomy. His reasoning that I was 48 years old, had three children, no plans for more and the cells could end up cancerous. I told him I wanted to use the cream for a few months and then have another biopsy. He became quite angry with me saying “Why don't you just do what I say?!” and he went on to say that the cream could not be regulated and would not help me.

Before the biopsy this first doctor had recommended HRT for me.

Needless to say, I switched to another doctor. When I investigated on the internet I found out about Serenity. I used it for over 4 months and then my new doctor did a D&C. She said we will try it but 95% of the cases are the same - but maybe we will have a miracle.

Well, we did - **my cells were all 100% normal.**

So I am very grateful to Serenity for Women.

* * *

(Exhibit A at 25.)

- O. Estrogens (estradiol, estrone, estriol) are predominately female hormones, and in adults, they are important for maintaining the health of the reproductive tissues, breasts, skin and brain. Excessive estrogens can cause fluid retention, weight gain, migraines and over stimulation of the breasts, ovaries and uterus, leading to cancer, endometriosis, polycystic ovaries, uterine fibroid tumors.

* * *

Most scientists now agree that by-products of estrogen metabolism are the cause of breast cancer, ovarian cancer and prostate cancer.

Progesterone is a hormonal balancer, particularly of estrogens. It enhances the beneficial effect of estrogens while preventing the problems associated with estrogen excess. . .

* * *

All of the research we have reviewed, the many years of clinical experience of Dr. John Lee (California, USA) and the six years clinical experience we have with tens of thousands of women worldwide cause us to conclude that natural

progesterone is safe and free of side effects (when administered topically) and addresses the underlying causes of many hormone related health problems that plague women, including infertility, polycystic Ovaries and ovarian cancer.
(Exhibit A at 26-27.)

- P. A commonality of the worlds' industrialized societies is the prevalence of uterine fibroids, fibrocystic breast disease, breast and/or uterine cancer, PMS, pre-menopausal bone loss as well as a high incidence of post-menopausal osteoporosis.

* * *

Because natural progesterone is the biological precursor for the production of natural estrogen, it is the natural choice for menopausal women as well as for pre-menopausal women to enjoy optimal health, free of the risks and side effects associated with synthetic hormones. Additionally, natural progesterone will stimulate the body's natural bone building cells (osteoblasts), offer significant protection against stroke and heart disease and benefit virtually every cell and organ of the body.

* * *

Natural Progesterone has been found to be safe and effective when applied topically, in a cream formula free from petrochemicals and animal by-products.
(Exhibit A at 28.)

- Q. There are no reports of any significant side effects or health problems associated with natural progesterone when it is administered in a properly formulated Natural Progesterone Cream.
(Exhibit A at 30.)

- R. According to Dr. Stanley West, Chief Endocrinologist at St. Vincent's Hospital in New York, U.S, 90% of the hysterectomies performed in the United States each year are unnecessary surgery. According to Dr. John Lee those women who are told that they have "pre-cancerous" cells after a gynecological exam, need only supplement with a properly formulated natural progesterone cream and implement the known dietary/lifestyle modifications, and the so called "pre-cancerous" cells will diminish along with the need for surgery.
(Exhibit A at 32.)

9. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that:

- A. Serenity for Women Natural Progesterone Cream is effective in preventing, treating, or curing osteoporosis;

- B. Serenity for Women Natural Progesterone Cream is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and
- C. Serenity for Women 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. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that clinical testing proves that Serenity for Women Natural Progesterone is effective in preventing, treating, or curing osteoporosis.

13. In truth and in fact, clinical testing does not prove that Serenity for Women Natural Progesterone is effective in preventing, treating, or curing osteoporosis. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

14. 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 respondents.

By the Commission.

Donald S. Clark
Secretary

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