

Complaint

IN THE MATTER OF

**HEALTH SCIENCE INTERNATIONAL, INC.,
AND
DAVID MARTIN**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4205; File No. 072 3145

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order relates to the deceptive advertising and promotion of respondents' transdermal cream, Serenity for Women Natural Progesterone Cream. The complaint alleged that respondents violated the FTC Act by falsely advertising that its cream was effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The complaint alleged that respondents had no substantiation for these claims. The consent order requires that respondents have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing any disease. The order further bars respondents from engaging in similar acts and practices in the future and prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the Commission: *Gregory A. Ashe, Laura DeMartino,
Janice P. Frankle, James A. Kohm, and Michael Ostheimer.*

For the Respondents: *Not represented by counsel.*

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

Complaint

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.

Complaint

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

Complaint

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.)

Complaint

- 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,

Complaint

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.)

Complaint

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!...

Complaint

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

Complaint

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:

Complaint

* * *

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.)

Complaint

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.

Complaint

* * *

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

Complaint

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;

Complaint

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.

Complaint

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

By the Commission.

Complaint

Exhibit A

NATURAL PROGESTERONE AND WOMEN'S HEALTH :: HEALTH-SCIENCE.COM ::

Page 1 of 1

[Home](#) | [Sign In](#)

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

The Informed Woman:
[OverView](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility & Progesterone](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Natural Progesterone](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More:
[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic-Progesterone](#)
[Tissue Cleansing](#)

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

Page 1 of 4

| Home | Sign In

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

The Informed Woman:

- Overview
- Breast Cancer
- Depression
- Estrogen Dominance
- Fertility & Progesterone
- Hot Flashes
- Insomnia
- Libido
- Menopause
- Migraines
- Natural Progesterone
- Osteoporosis
- Ovarian Cancer
- PMS

Learn More:

- Brain Function & Aging
- Diet/Lifestyle
- Fluoride Toxicity
- And Osteoporosis
- Infertility
- Intestinal Health
- Microwave Hazards
- Synthetic Progesterone
- Tissue Cleansing

Estrogen, Progesterone And Breast Cancer

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.

Are Birth Control Pills Safe?
In order for natural progesterone to stimulate the production of the P53 gene it must attach itself to progesterone receptors found in abundance in breast, ovarian, and endometrial cells. If a woman is taking birth control pills or any other form of synthetic progesterones (progestins, progesterone acetate, medroxy-progesterone acetate) these synthetic progesterones will occupy progesterone receptors and prevent natural progesterone from occupying the receptor site. Synthetic progesterones not only fail to produce the P53 gene but prevent it's production by blocking natural progesterone from occupying the progesterone receptor and in the presence of excess estradiol, dramatically increase a woman's risk for female-specific cancers.

There are 12 references to tests on BCL2 and P53, and how they are affected by progesterone & estrogen. This information has been published, in part, in the following journals:

- The American Cancer Society Journal
- The Journal of Clinical Endocrinology
- The American Journal of Pathology
- International Journal of Cancer
- The Journal of the American Medical Association (JAMA)
- Fertility and Sterility - Journal of the American Society For Reproductive Medicine

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."



Premature Birth



Osteoporosis



Infertility

Complaint

LAWSON, KUGLER AND DICKSON :: HEALTH-SCIENCE.COM ::

Page 2 of 2

Sign In | Literature Request | Contact Us | Site Map | FDA Disclaimer | Copyright Information

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

Page 1 of 1

[Home](#) | [Sign In](#)

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

The Informed Woman:

- Overview
- Breast Cancer
- Depression
- Estrogen Dominance
- Fertility & Progesterone
- Hot Flashes
- Insomnia
- Libido
- Menopause
- Migraines
- Natural Progesterone
- Osteoporosis
- Ovarian Cancer
- PMS

Learn More:

- Brain Function & Aging
- Diet/Lifestyle
- Fluoride Toxicity
- And Osteoporosis
- Infertility
- Intestinal Health
- Microwave Hazards
- Synthetic-Progesterone
- Tissue Cleansing

What Is Progesterone?

Progesterone is the single most important hormone made by the female body. It is critically important for the health of virtually every cell and organ of the body.

Because progesterone is a master hormone, it is used as a precursor for the production of other important hormones, such as estrogen and cortisone.

Progesterone production, however, can be suppressed by environmental antagonists, such as the hormones found in most commercially grown meats & dairy products, pesticides, petro-chemicals, prescription hormones and stress.

Informed women have restored progesterone levels by removing these environmental antagonists, successfully managing stress, implementing a high fiber diet and consistent use of a properly formulated natural progesterone cream.

Some of the other benefits of Natural Progesterone can be accessed from the Natural Progesterone Page!

The molecule for Natural Progesterone looks like this:



Natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.

SAFE PROGESTERONE



Premature Birth



Osteoporosis



Infertility

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

Page 1 of 1

| Home | Sign In

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

The Informed Woman:

- [OverView](#)
- [Breast Cancer](#)
- [Depression](#)
- [Estrogen Dominance](#)
- [Fertility & Progesterone](#)
- [Hot Flashes](#)
- [Insomnia](#)
- [Libido](#)
- [Menopause](#)
- [Migraines](#)
- [Natural Progesterone](#)
- [Osteoporosis](#)
- [Ovarian Cancer](#)
- [PMS](#)

Learn More:

- [Brain Function & Aging](#)
- [Diet/Lifestyle](#)
- [Fluoride Toxicity](#)
- [And Osteoporosis](#)
- [Infertility](#)
- [Intestinal Health](#)
- [Microwave Hazards](#)
- [Synthetic-Progesterone](#)
- [Tissue Cleansing](#)

Natural Progesterone

Natural progesterone is made by the ovaries prior to menopause and by the adrenal glands and fat cells after menopause and is the precursor for natural estrogen. It is the single most important hormone in the female body. [\[+\] More](#)

When the female body fails to produce enough progesterone between ovulation and menstruation and during menopause, natural transdermal progesterone cream can address the underlying cause of most symptoms.

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 Use Fat for Energy
- Facilitates Thyroid Hormone Action
- Natural Anti-depressant
- Natural Diuretic
- Normalizes Blood Sugar Levels
- Restores Proper Cell Oxygen Levels
- Restores Libido
- Normalizes Menstrual Cycles
- Normalizes Zinc & Copper Levels
- Normalizes Blood Clotting
- Protects Against Breast Fibrocysts
- Helps Protect Epithelial cells against Breast Cancer
- Helps Prevent Endometrial Cancer
- Helps prevent Ovarian Cysts and Ovarian Cancer
- Precursor for Cortisone Production (Arthritis)
- Stimulates Osteoblast Cells (Osteoporosis Reversal)

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



Premature Birth



Osteoporosis



Infertility

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

Osteoporosis and Natural Progesterone .. Health-Science.Com ..

Page 1 of 2

[Home](#) | [Sign In](#)[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)**The Informed Woman:**

[Overview](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility & Progesterone](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Natural Progesterone](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More:

[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic-Progesterone](#)
[Tissue Cleansing](#)

Osteoporosis & Natural Progesterone

Osteoporosis is a disorder in which progressive bone mass loss and demineralization increase ones risk of fracture. This condition permits us to observe how prescription progestins and estrogens compare to Natural Progesterone.

The standard medical protocol for osteoporosis is to use estrogen, (commonly synthesized from pregnant mare's urine), in spite of the fact that the most authoritative medical textbooks do not support it.

The following article illustrates:

"Estrogens decrease bone resorption" but "associated with the decrease in bone resorption is a decrease in bone formation. Therefore, estrogens should not be expected to increase bone mass."**

Scientific American's Updated Medicine Text, 1991.

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.

- [Osteoporosis & Calcium](#)
- [Read what some of our visitors have written](#)
- [Some Observations from Medical Doctors](#)



Premature Birth



Osteoporosis



Infertility

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

U.S. DEPARTMENT OF JUSTICE

Page 2 of 2

Complaint

Suggested Use Of Natural Progesterone Cream .. Health-Science.Com ..

Page 1 of 2

[Home](#) | [Sign In](#)[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)**The Informed Woman:**

[Overview](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility & Progesterone](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Natural Progesterone](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More:

[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic-Progesterone](#)
[Tissue Cleansing](#)

Suggested Use Of Natural Progesterone Cream

Progesterone is very well absorbed transdermally (through the skin) where it is stored in the fatty tissues for use as needed and unlike progesterone taken orally, it is not subject to being intercepted by the liver. For those women who are especially deficient in progesterone, it may take three to twelve months to restore optimal levels. For men with prostate disorders results may be felt within one or two days, but long term benefits may require six months.

In the morning and at bedtime, the cream should be gently massaged by the palms of the hands to areas of the body where one blushes: the face, neck, chest, upper arms and other areas of the body that may benefit from progesterone, e.g. breasts, abdomen, back of neck.

Serenity for Women is a Certified Potency Cream that contains not less than 1,260 mg. of Natural Progesterone per (60 grams) 2.1 ounces. Informed women have chosen a procedure that is in the following paragraph.

PMS & Infertility

Begin using crème 12 days from the first day of menstruation. Use approximately 1/8 teaspoon twice per day (morning and at bedtime). Stop using the cream on day 26. Women with more severe PMS or endometriosis have chosen to initially use twice the suggested amount of cream (1/4 teaspoon twice daily) for the first one or two months. In addition, women who experience uterine cramping have chosen to apply the cream just above the pubic area at the onset of cramps. Women who experience hormone related headaches have applied the cream to the sides of the neck and just behind the earlobe, at the onset of headaches.

Menopause or Post Hysterectomy

The crème should be applied 24 days out of the month and then discontinued for 6-7 days. Apply 1/8 teaspoon twice per day morning and at bedtime for all 24 days. Women who have severe menopausal symptoms have chosen to initially apply twice as much cream (1/4 teaspoon twice daily) for the first one or two months. In addition, women who are experiencing hot flashes have chosen to apply a small dab of the cream to the inside of the wrist at the onset of a hot flash. For those few women who still experience hot flashes, night sweats and/or vaginal dryness a natural estriol cream can be safely used for several months.

Osteoporosis

The cream should be applied 24 days of the month and then discontinued for 6-7 days. Apply 1/8 teaspoon twice per day morning and at bedtime for all 24 days.

Informed Men have used Serenity 1/16th of a teaspoon at bedtime, 24 days per month.

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

A few women may experience temporarily experience an increase in the symptoms caused by too much estrogen such as incidental spotting and/or swelling of the breasts. This is normally alleviated within a few days or weeks with the normalizing of hormone levels.

Any persistent problems should always be checked by a qualified physician.



Premature Birth



Osteoporosis



Infertility

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

Complaint

OSTEOPOROSIS PREVENTION AND FIBROCYSTIC BREAST DISEASE .. HEALTH-SCIENCE.COM ..

Page 1 of 1

| Home | Sign In

[Index of Diseases](#)
[The Experts](#)
[Product Information](#)
[Shop Online](#)
[Contact Us](#)
The Informed Woman:

[OverView](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility & Progesterone](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Natural Progesterone](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More:

[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic-Progesterone](#)
[Tissue Cleansing](#)

Osteoporosis Prevention

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!

Barbara McCrady
 Maine, U.S.



Premature Birth



Osteoporosis



Infertility

Fibrocystic Breast Disease

Dear Health & Science,

I want to congratulate you on the production of Serenity for Women, Natural Progesterone Cream.

Although I had tried other "natural progesterone" creams in the past, Serenity for Women has been, by far, the most effective, consistent, and reliable one for the symptoms I was experiencing.

It has virtually stopped my hot flashes, eliminated the pain and swelling I had from cystic breasts, and even stabilized my moods!

Truly, this one product has made this time of my life much smoother and easier. I wish I had it 20 years ago!

On behalf of my husband and myself, a hearty, Thank You!

Yours Truly,
 Sandra Thomas,
 Registered Nurse
 Naturopathic Doctor
 New Hampshire, U.S.

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

Home | Sign In

The Informed Woman

- OverView
- Breast Cancer
- Depression
- Estrogen Dominance
- Fertility
- Hot Flashes
- Insomnia
- Libido
- Menopause
- Migraines
- Osteoporosis
- Ovarian Cancer
- PMS

Learn More

- Brain Function & Aging
- Diet/Lifestyle
- Fluoride Toxicity
- And Osteoporosis
- Infertility
- Intestinal Health
- Microwave Hazards
- Synthetic-Progesterone
- Tissue Cleansing

Calcium And Osteoporosis



Weight Loss



Dietary Consideration



Hot Flashes

Bone Architecture

Bone structure is made up of calcium and phosphorous crystals embedded in a framework of interlocking protein fibers. Hydroxyapatite (Bone-Up™) is the form of calcium found in human bone tissue and is the predominant structural form of calcium. It is responsible for 67% of the total bone weight, the remaining 33% being composed by collagen fibers (Rheumatol Forte™).

The mineral crystals give the bone hardness, strength and rigidity. The collagen fibers impart flexibility. Magnesium, fluoride, sodium, potassium, citrate and other trace elements act as a "mortar" that bonds the calcium phosphorous crystals.

The hormone calcitonin from the thyroid gland triggers the deposition of calcium by the osteoblast (bone building) cells while parathyroid hormone (parathormone) releases calcium from the osteoclast bone cells.

Vitamins compose 1% of our total body weight, minerals 4% and calcium and phosphorous account for 75% of mineral weight. 99% of all calcium is in the bone and teeth with the remaining 1% in the blood and soft tissues. The average adult contains 1,000-1,200 grams of calcium or 2.2-2.6 pounds.

Osteoporosis Defined

Although the percent of circulating calcium is relatively minute, the body's homeostatic mechanism will continuously cause the bones to release calcium into the bloodstream in order to maintain proper blood levels. So, while serum levels of calcium can test normal, in the absence of sufficient available dietary calcium, bone loss can be significant, this process being a primary cause of osteoporosis.

Between 2-4% of a person's skeleton is dissolved and rebuilt annually. This process is implemented by the osteoclast and osteoblast bone cells. Poor nutrition and a suppression of progesterone levels due to stress and other environmental antagonists result in a suppression of the osteoblast bone cell function, in spite of the fact that osteoclast cells continue to dissolve old bone tissue. This condition, especially when there is a loss of collagen, also results in osteoporosis.

In the U.S. more than one million fractures occur annually in women 45 years or older, 70% of whom are diagnosed with osteoporosis. Hip fractures carry a mortality rate of 12-15% and are the second leading cause of death in people 47-74 years of age. Of the 190,000 hip fractures that occur annually, 2/3 are due to osteoporosis which costs the U.S. \$5 billion each year. Post-menopausal women lose 0.7% to 2.0% of their bone per year; men lose 0.3%-0.7%. Between the ages of 45 to 70, women lose 30% of their skeletal structure and men lose 15%. Calcium supplementation of 1,000-1,500 mg. per day for persons who consume a high protein diet and 500-750 mg. per day for vegetarians can reduce fracture rates by 50%.

Hormonal Influences

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

Complaint

Calcium and Osteoporosis .. HUGOBONIC.COM ..

Page 4 of 4

per year!!! These results have not been found with any other form of hormone replacement therapy or dietary supplementation! Conclusion

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

1. Maintaining proper levels of natural progesterone;
2. Giving due attention to dietary choices;
3. Maintaining Optimal Levels of Friendly Bacteria (Vitamin K), Vitamin D and Calcium;
4. Learn to successfully manage stress.
5. Regular exercise (30-45 minutes four or five days per week).

| [Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#) |

© 1995 - 2007 Health Science Research, NY, NY, U.S.A.

Complaint

1 4 9 5 1 0 1 1

[Index of Diseases](#)
[The Experts](#)
[Product Information](#)
[Shop Online](#)
[Contact Us](#)

Home | Sign In

The Informed Woman

OverView

Breast Cancer

Depression

Estrogen Dominance

Fertility

Hot Flashes

Insomnia

Libido

Menopause

Migraines

Osteoporosis

Ovarian Cancer

PMS

Learn More

Brain Function & Aging

Diet/Lifestyle

Fluoride Toxicity

And Osteoporosis

Infertility

Intestinal Health

Microwave Hazards

Synthetic-Progesterone

Tissue Cleansing

Estrogen Dominance

Natural progesterone is produced by the corpus luteum after ovulation and balances the side effects of otherwise unopposed estrogen.

Under influences of anovulatory cycles, menopause, stress and dietary antagonists, progesterone production ceases or is suppressed and the effects of Estrogen Dominance, can be observed. Many women experience otherwise unexplained weight gain from the lack of progesterone that is required for proper thyroid function.*

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 Body Fat
- Interference with Thyroid Hormone Activity (hypo-thyroid)
- Depression & Headaches
- Salt and Water Retention
- Blood Sugar Irregularities (Food Cravings)
- Reduced Oxygen In All Cells
- Decreased Libido (Sex Drive)
- Loss of Zinc and Retention of Copper
- Excessive Blood Clotting
- Increased Risk of Breast Cancer
- Reduced Vascular Tone
- Increased Risk of Endometrial Cancer
- Endometriosis
- Uterine Cramping
- Infertility
- 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.



Weight Loss



Hot Flashes



Osteoporosis



Premature Birth

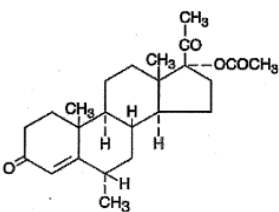
[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#)

© 1995 - 2007 Health Science Research, NY, NY, U.S.A.

Complaint

PROVERA (medroxyprogesterone acetate) ... 1061061061.COM

A 450 x 100

Index of Diseases The Experts Product Information Shop Online Contact Us	
Home Sign In	
The Informed Woman Overview Breast Cancer Depression Estrogen Dominance Fertility Hot Flashes Insomnia Libido Menopause Migraines Osteoporosis Ovarian Cancer PMS Learn More Brain Function & Aging Diet/Lifestyle Fluoride Toxicity And Osteoporosis Infertility Intestinal Health Microwave Hazards Synthetic-Progesterone Tissue Cleansing	Following are Contraindications, Warnings, Precautions, and Adverse Reactions published by the manufacturer of "Synthetic Progesterone" (medroxy-progesterone acetate) Provera (Medroxyprogesterone Acetate, Progestins) Warning: The use of Medroxyprogesterone Acetate during the first four months of pregnancy is NOT recommended. Progestational agents have been used beginning with the first trimester of pregnancy in an attempt to prevent habitual abortion. There is no adequate evidence that such use is effective when such drugs are given during the first four months of pregnancy. Furthermore, in the vast majority of women, the cause of abortion is a defective ovum, which progestational agents could not be expected to influence. In addition, the use of progestational agents, with their uterine-relaxant properties, in patients with fertilized defective ova may cause a delay in spontaneous abortion. Therefore, the use of such drugs during the first four months of pregnancy is not recommended. Several reports suggest an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and genital abnormalities in male and female fetuses. The risk of hypospadias, 5 to 8 per 1,000 male births in the general population, may be approximately doubled with exposure to these drugs. There are insufficient data to quantify the risk to exposed female fetuses, but insofar as some of these drugs induce mild virilization of the external genitalia of the female fetus, and because of the increased association of hypospadias in the male fetus, it is prudent to avoid the use of these drugs during the first trimester of pregnancy. If the patient is exposed to PROVERA Tablets (medroxyprogesterone acetate) during the first four months of pregnancy or if she becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus. Description PROVERA Tablets contain medroxyprogesterone acetate, which is a derivative of progesterone. It is a white to off-white, odorless crystalline powder, stable in air, melting between 200 and 210 C. It is freely soluble in chloroform, soluble in acetone and in dioxane, sparingly soluble in alcohol and in methanol, slightly soluble in ether, and insoluble in water. The chemical name for medroxyprogesterone acetate is Pregn-4-ene-3,20-dione, 17-(acetyloxy)-6-methyl-, (6a)-. The structural formula is:  Each PROVERA tablet for oral administration contains 2.5 mg, 5 mg or 10 mg of medroxy-progesterone acetate. Inactive ingredients: calcium stearate, corn starch, lactose, mineral oil, sorbic acid, sucrose, talc. The 2.5 mg tablet contains FD&C Yellow

Complaint

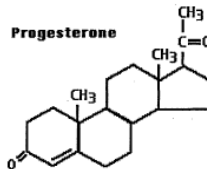
A 100% NATURAL PROGESTERONE CREAM // 1.8UGESTERONE.COM //

Page 2 of 3

no. 6.

The information contained in the box only is not from the manufacturer of synthetic progesterone

Contrastingly, the molecule for Natural Progesterone looks like this:



This is the molecule made by the female body and the exact same molecule found in a properly formulated natural progesterone cream. 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.

Actions

Medroxyprogesterone acetate, administered orally or parenterally in the recommended doses to women with adequate endogenous estrogen, transforms proliferative into secretory endometrium. Androgenic and anabolic effects have been noted, but the drug is apparently devoid of significant estrogenic activity. While parenterally administered medroxyprogesterone acetate inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation, available data indicate that this does not occur when the usually recommended oral dosage is given as single daily doses.

Indications and usage

Secondary amenorrhea; abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer.

Contraindications for Medroxyprogesterone Acetate

1. Thrombophlebitis, thromboembolic disorders, cerebral apoplexy or patients with a past history of these conditions.
2. Liver dysfunction or disease.
3. Known or suspected malignancy of breast or genital organs.
4. Undiagnosed vaginal bleeding. 5. Missed abortion.
5. As a diagnostic test for pregnancy.
6. Known sensitivity to PROVERA Tablets.

Warnings for Medroxyprogesterone Acetate

1. The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately.
2. Beagle dogs treated with medroxyprogesterone acetate developed mammary nodules some of which were malignant. Although nodules occasionally appeared in control animals, they were intermittent in nature, whereas the nodules in the drug-treated animals were larger, more numerous, persistent, and there were some breast malignancies with metastases. Their significance with respect to humans has not been established.
3. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is a sudden onset of proptosis, diplopia or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be withdrawn.
4. Detectable amounts of progestin have been identified in the milk of mothers

Complaint

receiving the drug. The effect of this on the nursing infant has not been determined.

5. Usage in pregnancy is not recommended (See WARNING Box).
6. Retrospective studies of morbidity and mortality in Great Britain and studies of morbidity in the United States have shown a statistically significant association between thrombophlebitis, pulmonary embolism, and cerebral thrombosis and embolism and the use of oral contraceptives.¹⁻⁴ The estimate of the relative risk of thromboembolism in the study by Vessey and Doll³ was about sevenfold, while Sartwell and associates⁴ in the United States found a relative risk of 4.4, meaning that the users are several times as likely to undergo thromboembolic disease without evident cause as nonusers. The American study also indicated that the risk did not persist after discontinuation of administration, and that it was not enhanced by long continued administration. The American study was not designed to evaluate a difference between products.

Precautions for Medroxyprogesterone Acetate

1. The pretreatment physical examination should include special reference to breast and pelvic organs, as well as Papanicolaou smear.
2. Because progestogens may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation.
3. In cases of breakthrough bleeding, as in all cases of irregular bleeding per vaginum, nonfunctional causes should be borne in mind. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated.
4. Patients who have a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree.
5. Any possible influence of prolonged progestin therapy on pituitary, ovarian, adrenal, hepatic or uterine functions awaits further study.
6. A decrease in glucose tolerance has been observed in a small percentage of patients on estrogen-progestin combination drugs. The mechanism of this decrease is obscure. For this reason, diabetic patients should be carefully observed while receiving progestin therapy.
7. The age of the patient constitutes no absolute limiting factor although treatment with progestins may mask the onset of the climacteric.
8. The pathologist should be advised of progestin therapy when relevant specimens are submitted.
9. Because of the occasional occurrence of thrombotic disorders, (thrombophlebitis, pulmonary embolism, retinal thrombosis, and cerebrovascular disorders) in patients taking estrogen-progestin combinations and since the mechanism is obscure, the physician should be alert to the earliest manifestation of these disorders.
10. Studies of the addition of a progestin product to an estrogen replacement regimen for seven or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of endometrium suggest that 10-13 days of a progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimen. The potential risks include adverse effects on carbohydrate and lipid metabolism. The dosage used may be important in minimizing these adverse effects.
11. Aminoglutethimide administered concomitantly with PROVERA may significantly depress the bioavailability of PROVERA.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term intramuscular administration of PROVERA has been shown to produce mammary tumors in beagle dogs (see WARNINGS). There was no evidence of a carcinogenic effect associated with the oral administration of PROVERA to rats and mice. Medroxyprogesterone acetate was not mutagenic in a battery of in vitro or in vivo genetic toxicity assays.

Medroxyprogesterone acetate at high doses is an antifertility drug and high doses would be expected to impair fertility until the cessation of treatment.

Adverse reactions to Medroxyprogesterone Acetate

Pregnancy-(See WARNING Box for possible adverse effects on the fetus).

Breast-Breast tenderness or galactorrhea has been reported rarely. Skin-Sensitivity reactions consisting of urticaria, pruritus, edema and generalized rash have occurred in an occasional patient. Acne, alopecia and hirsutism have been reported in a few cases.

Complaint

Thromboembolic Phenomena-Thromboembolic phenomena including thrombophlebitis and pulmonary embolism have been reported.

The following adverse reactions have been observed in women taking progestins including PROVERA Tablets: breakthrough bleeding, spotting, change in menstrual flow, amenorrhea, edema, change in weight (increase or decrease), changes in cervical erosion and cervical secretions, cholestatic jaundice, anaphylactoid reactions and anaphylaxis, rash (allergic) with and without pruritus, mental depression, pyrexia, insomnia, nausea, somnolence.

A statistically significant association has been demonstrated between use of estrogen-progestin combination drugs and the following serious adverse reactions: thrombophlebitis; pulmonary embolism and cerebral thrombosis and embolism. For this reason patients on progestin therapy should be carefully observed.

Although available evidence is suggestive of an association, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions: neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been observed in patients receiving estrogen-progestin combination drugs: rise in blood pressure in susceptible individuals, fatigue, backache, hirsutism, premenstrual-like syndrome, loss of scalp hair, erythema multiforme, changes in libido, erythema nodosum, changes in appetite, hemorrhagic eruption, cystitis-like syndrome, headache, itching, nervousness, dizziness.

In view of these observations, patients on progestin therapy should be carefully observed.

The following laboratory results may be altered by the use of estrogen-progestin combination drugs: Increased sulfobromophthalein retention and other hepatic function tests. Coagulation tests: Increase in prothrombin factors VII, VIII, IX and X. Metyrapone test. Pregnenediol determination. Thyroid function: Increase in FBI, and butanol extractable protein bound iodine and decrease in T3 uptake values.

Dosage and administration for Medroxyprogesterone Acetate

Secondary Amenorrhea-PROVERA Tablets may be given in dosages of 5 to 10 mg daily for from 5 to 10 days. A dose for inducing an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen is 10 mg of PROVERA daily for 10 days. In cases of secondary amenorrhea, therapy may be started at any time. Progestin withdrawal bleeding usually occurs within three to seven days after discontinuing PROVERA therapy.

Abnormal Uterine Bleeding Due to Hormonal Imbalance in the Absence of Organic Pathology-Beginning on the calculated 16th or 21st day of the menstrual cycle, 5 to 10 mg of medroxyprogesterone acetate may be given daily for from 5 to 10 days. To produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen, 10 mg of medroxyprogesterone acetate daily for 10 days beginning on the 16th day of the cycle is suggested. Progestin withdrawal bleeding usually occurs within three to seven days after discontinuing therapy with PROVERA. Patients with a past history of recurrent episodes of abnormal uterine bleeding may benefit from planned menstrual cycling with PROVERA.

How supplied

PROVERA Tablets are available in the following strengths and package sizes:

- 2.5 mg (scored, round, orange)
- Bottles of 30 NDC 0009-0064-06
- Bottles of 100 NDC 0009-0064-04
- 5 mg (scored, hexagonal, white)
- Bottles of 30 NDC 0009-0286-32
- Bottles of 100 NDC 0009-0286-03
- 10 mg (scored, round, white)
- Bottles of 30 NDC 0009-0050-09
- Bottles of 100 NDC 0009-0050-02
- Bottles of 500 NDC 0009-0050-11
- DOSEPAK-3 Unit of Use (10) NDC 0009-0050-12

Store at controlled room temperature 15-30 C (59-86 F).

References

Complaint

PROVERA (medroxyprogesterone acetate) ... HUGOBOSCH.COM

Page 3 of 4

1. Royal College of General Practitioners: Oral contraception and thromboembolic disease. J Coll Gen Pract 13:267-279, 1967.
2. Inman WHW, Vessey MP: Investigation of deaths from pulmonary, coronary, and cerebral thrombosis and embolism in women of child-bearing age. Br Med J 2:193-199, 1968.
3. Vessey MP, Doll R: Investigation of relation between use of oral contraceptives and thromboembolic disease. A further report. Br Med J 2:651-657, 1969.
4. Sartwell PE, Masi AT, Arthes FG, et al: Thromboembolism and oral contraceptives: An epidemiological case-control study. Am J Epidemiol 90:365-380, 1969.

Patient Information

PROVERA Tablets contain medroxyprogesterone acetate a synthetic progesterone.

The information below is that which the U.S. Food and Drug Administration requires be provided for all patients taking medroxyprogesterone acetates. The information below relates only to the risk to the unborn child associated with use of medroxyprogesterone acetate during pregnancy. For further information on the use, side effects and other risks associated with this product, ask your doctor or read the information.

WARNING FOR WOMEN

Medroxyprogesterone acetate or progesterone-like drugs have been used to prevent miscarriage in the first few months of pregnancy. No adequate evidence is available to show that they are effective for this purpose. Furthermore, most cases of early miscarriage are due to causes which could not be helped by these drugs.

There is an increased risk of minor birth defects in children whose mothers take this drug during the first 4 months of pregnancy. Several reports suggest an association between mothers who take these drugs in the first trimester of pregnancy and genital abnormalities in male and female babies. The risk to the male baby is the possibility of being born with a condition in which the opening of the penis is on the underside rather than the tip of the penis (hypospadias). Hypospadias occurs in about 5 to 8 per 1,000 male births and is about doubled with exposure to these drugs. There is not enough information to quantify the risk to exposed female fetuses, but enlargement of the clitoris and fusion of the labia may occur, although rarely.

Therefore, since drugs of this type may induce mild masculinization of the external genitalia of the female fetus, as well as hypospadias in the male fetus, it is wise to avoid using the drug during the first trimester of pregnancy.

These drugs have been used as a test for pregnancy but such use is no longer considered safe because of possible damage to a developing baby. Also, more rapid methods for testing for pregnancy are now available.

If you take PROVERA and later find you were pregnant when you took it, be sure to discuss this with your doctor as soon as possible.

Complaint

A PRO, TRANSDERMAL AND SUCCESSFUL TREATMENTS - PROGESTERONE.COM ..

Page 1 of 1

[Index of Diseases](#)
[The Experts](#)
[Product Information](#)
[Shop Online](#)
[Contact Us](#)

[Home](#) | [Sign In](#)

The Informed Woman

- [Overview](#)
- [Breast Cancer](#)
- [Depression](#)
- [Estrogen Dominance](#)
- [Fertility](#)
- [Hot Flashes](#)
- [Insomnia](#)
- [Libido](#)
- [Menopause](#)
- [Migraines](#)
- [Osteoporosis](#)
- [Ovarian Cancer](#)
- [PMS](#)

Learn More

- [Brain Function & Aging](#)
- [Diet/Lifestyle](#)
- [Fluoride Toxicity](#)
- [And Osteoporosis](#)
- [Infertility](#)
- [Intestinal Health](#)
- [Microwave Hazards](#)
- [Synthetic-Progesterone](#)
- [Tissue Cleansing](#)

PMS - Traditional & Successful Treatments

Traditional PMS Treatments

Traditional treatments have included tranquilizers, diuretics, dietary changes, thyroid supplements, herbs, vitamins, exercise, acupuncture and psychiatric counseling. While these may provide some easing of **symptoms**, the underlying **causes** remain.

Successful Treatments

Dr. Joel T. Hargrove of Vanderbilt University Medical Center has seen some success in treating PMS with oral doses of natural progesterone.* The problem with oral progesterone administration, however, is that the liver intercepts approximately 90% of the hormone. So, in order to achieve a net dose of 20 mg. the typical dose prescribed is 200 mg. per day. The liver thus converts progesterone to progesterone metabolites, which work against natural hormone function.

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. He makes this statement:

"Though not completely understood, PMS most commonly represents an individual reaction to estrogen dominance, secondary to relative progesterone deficiency. Appropriate treatment requires correction of this hormone imbalance in conjunction with known dietary lifestyle modifications and the most effective technique, at present, for achieving this is supplemental Transdermal Natural Progesterone."**



Premature Birth



Hot Flashes



Weight Loss

[Letters from Our Ladies](#)
[Some Observations from Medical Doctors](#)

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#) |

© 1995 - 2007 Health Science Research, NY, U.S.A.

Complaint

LAWSON AND COMPANY, INC. • PROGESTIONS.COM

Page 1 of 4

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

[Home](#) | [Sign In](#)

The Informed Woman
Overview
Breast Cancer
Depression
Estrogen Dominance
Fertility
Hot Flashes
Insomnia
Libido
Menopause
Migraines
Osteoporosis
Ovarian Cancer
PMS

Learn More
Brain Function & Aging
Diet/Lifestyle
Fluoride Toxicity
And Osteoporosis
Infertility
Intestinal Health
Microwave Hazards
Synthetic-Progesterone
Tissue Cleansing

Libido & Natural Progesterone

The Female Body manufactures many types of Estrogen but only one Progesterone and Natural Progesterone is the Source of Libido or Sex Drive in Women!

Sources of Natural Progesterone
Natural Progesterone is normally produced by the female ovaries right after ovulation and balances the side effects of otherwise unopposed estrogen.

Under the Influences of dietary estrogens, petrochemicals, stress, and menopause, Progesterone production ceases or is suppressed and the effects of Estrogen Dominance, can be observed.

Most women experience Loss of Libido, mood swings, irritability, anger, depression, headaches and weight gain from the lack of Progesterone that is required for proper thyroid function.

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 Body Fat	• Anger, Rage
• Depression	• Uterine Cramping
• Migraine Headaches	• Water Retention
• Blood Sugar Irregularities	• Loss of Zinc, Retention of Copper
• Excessive Blood Clotting	• Increased Risk of Breast Cancer
• Reduced Vascular Tone	• Increased Risk of Ovarian Cancer
• Endometriosis	• Increased Risk of Endometrial Cancer
• Infertility	• Restraint of Osteoclast Function (bone loss)
• Interference with Thyroid Function	• Reduced Oxygen in All Cells (Foggy Brain)
• Loss of Libido (Sex Drive)	

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.

Traditional Treatments
Traditional treatments have included tranquilizers, diuretics, dietary changes, thyroid supplements, herbs, vitamins, exercise, acupuncture and psychiatric counseling. While these may provide some easing of symptoms, the underlying causes remain.

• Successful Treatments


Hot Flashes


Heart Health


Premature Birth


Dietary Consideration

- 20 -

Complaint

LAVINIA AND NATURAL PROGESTERONE .. PROGESTERONE.COM ..

Page 2 of 4

- Suggested Use
- Where Can I Find a Quality Natural Progesterone Cream

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#) |

© 1995 - 2007 Health Science Research, NY, NY, U.S.A.

Complaint

Are All Progesterone Creams the Same? :: Progesterone.COM ::

Page 1 of 4

[Index of Diseases](#)
[The Experts](#)
[Product Information](#)
[Shop Online](#)
[Contact Us](#)

[Home](#) | [Sign In](#)

The Informed Woman
[Overview](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More
[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic Progesterone](#)
[Tissue Cleansing](#)

Are All "Progesterone" Creams The Same?

The task of selecting an effective "progesterone" cream can be a challenging one.

Women are bombarded by a constant supply of new companies selling "progesterone" creams, often times started by those who have no nutritional or health care experience. In a desperate attempt to generate income many of these companies will use marketing techniques that emphasize fantastic commission checks to their distributors, who, in their heightened state of about to be realized "financial independence", will tell the consumer almost anything.

Further, Many "popular creams" sold today contain little or no Progesterone USP, or contain inconsistent levels:

- Each 2 oz (57 g) pot of Pro-Gest® Cream (Emerita™) contains 200 mg of progesterone..
- This assay was done on tubes of Pro-Gest® cream purchased by mail over a period of 5 months! *The Lancet Medical Journal, (Volume 351, Number 9111, 25 April 1998)

Complicating matters is the fact that, at one time, one of the components of Yam (*Dioscorea villosa*), diosgenin, was believed to be converted in the female body to progesterone. In fact, in his first book, Dr. John Lee of California, U.S.A., states that diosgenin is probably converted to Progesterone. However, that has since been proven to be unsubstantiated and, in fact, in his current book, "What Your Dr. May Not Tell You About Menopause" on page 270, Dr. Lee states "...there is no evidence that the human body converts diosgenin to hormones."

Dr. David Zava, (PhD in Bio Endocrinology whose focus has been progesterone and estrogen receptor activity) is the laboratory director of Aeron Life Cycles, one of the foremost hormone testing facilities in the world. Dr. Zava has tested progesterone levels for many thousands of women and responded with the following: "In response to your question about wild yam steroids - do they convert into progesterone? The answer is no, there are no enzymes in the human body that will convert diosgenin, the active component of wild yams, into progesterone. This does not mean diosgenin is without activity in the body as it has been used by phytotherapists for centuries as an adaptogen."

So, when selecting a progesterone cream for the purpose of raising bio-available progesterone levels, the first criteria that must be met is that the cream must contain sufficient levels of USP Natural Progesterone and be a Certified Potency Cream! The cream must also be properly formulated. Second and equally as important, the consumer benefits by the selection of a company that is adequately staffed or owned by Health Care Consultants who are trained in natural, side-effect free approaches to optimal health.

Considering the normal healthy monthly female cycle, we observe, in response to ovulation, that progesterone levels increase from 2-3 mg. per day to 22-25 mg. per day for 12 to 14 days just prior to menstruation. Because there are many cream companies promoting a product that contains only a few milligrams of progesterone per ounce or none, those formulations are unable to have a positive effect on biologically available levels of progesterone.

Consequently, the typical response from women using a "yam cream" or a cream that does not have a certified potency has been:

- It seems to have helped a little, but it is not what I really need."

Conversely, women who use a properly formulated certified potency progesterone cream





Complaint

JAN 14 10 50 AM '08 WWW.FTC.COM

Page 2 of 2

and have applied the supplemental suggestions from a qualified Health Care Consultant, have stated:

- I have finally achieved relief from the symptoms I have endured for many years and I now experience a sense of well-being that I have not enjoyed since

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. Used in conjunction with known Dietary-Lifestyle modifications, many thousands of women around the world (114 countries) have regained their health and control of their lives.

| [Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#) |

© 1995 - 2007 Health Science Research, NY, NY, U.S.A.

Complaint

Price Information and Cream Comparison - Progestone.com ..

Page 1 of 1

Index of Diseases The Experts Product Information Shop Online Contact Us	
Home Sign In	
The Informed Woman Overview Breast Cancer Depression Estrogen Dominance Fertility Hot Flashes Insomnia Libido Menopause Migraines Osteoporosis Ovarian Cancer PMS	Serenity Products All Products Products by Category
Price Information & Cream Comparison	
Learn More Brain Function & Aging Diet/Lifestyle Fluoride Toxicity And Osteoporosis Infertility Intestinal Health Microwave Hazards Synthetic-Progesterone Tissue Cleansing	Many "popular creams" sold today contain little or no Progesterone USP, or at best, have inconsistent levels of progesterone. "Each 2 oz (57 g) pot of Pro-Gest® cream (Emerita™) contains 200 mg of progesterone..." * (This assay was done on tubes of Pro-Gest® cream purchased by mail over a period of 5 months) *The Lancet Medical Journal, (Volume 351, Number 9111, 25 April 1998). Additionally, most creams, including those that claim to be "progesterone" creams are formulated with petrochemicals. 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 Other Products
  	
Sign In Literature Request Contact Us Site Map Privacy & Security Copyright	
© 1995 - 2007 Health Science Research, NY, NY, U.S.A.	

Complaint

Hysterectomy Prevention .. PROGESTERONE.COM ..

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Index of Diseases The Experts Product Information Shop Online Contact Us		
Home Sign In		
The Informed Woman Overview Breast Cancer Depression Estrogen Dominance Fertility Hot Flashes Insomnia Libido Menopause Migraines Osteoporosis Ovarian Cancer PMS Learn More Brain Function & Aging Diet/Lifestyle Fluoride Toxicity And Osteoporosis Infertility Intestinal Health Microwave Hazards Synthetic-Progesterone Tissue Cleansing	Hysterectomy Prevention (A Letter from Sheila Simons) 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. I would have had an unnecessary operation if I had not investigated and took charge of my own health. And by the way, I always put my situations in God's hands and this was an answer to my prayers. Thank-you Sheila Simons Van Nuys, California, USA	  
Sign In Literature Request Contact Us Site Map Privacy & Security Copyright		
© 1995 - 2007 Health Science Research, NY, NY, U.S.A.		

Complaint

Ovarian Cancer .. Progesterone.COM ..

Page 1 of 4

[Index of Diseases](#)
[The Experts](#)
[Product Information](#)
[Shop Online](#)
[Contact Us](#)

[Home](#) | [Sign In](#)

The Informed Woman
[OverView](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Ovarian,Cancer





Typically, lower fertilization rates are found in women who have polycystic ovaries rather than those with tubal disease or endometriosis. Increased levels of estrogen stimulate increased levels of testosterone and androgen (increased body hair). Increased androgen (hyper-androgenism) has been shown to be critical in the pathogenesis or development of polycystic ovaries and ovarian cancer.

Mechanisms by which androgens induce cyst formation, however, have not yet been elucidated. It has been hypothesized that ovarian androgen excess produces larger follicles and increased apoptosis, resulting in cyst formation and follicular atresia (death and regression of an ovarian follicle).

Hyper-androgenism, therefore, produces larger follicles and increased apoptosis. Apoptosis is the process by which a cell runs its life course and actively "commits suicide".

It is now well recognized that apoptosis is essential in many aspects of normal development and is required for maintaining tissue homeostasis. Failure to properly regulate apoptosis can have catastrophic consequences. Cancer and many diseases (AIDS, Alzheimer's disease, Parkinson's disease, heart attack, stroke, etc.) are thought to arise from deregulation of apoptosis.

The basic roles, therefore, performed by estrogen and progesterone are

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. Insufficient estrogen levels or fluctuations of estrogen can lead to hot flushes, vaginal dryness, rapid skin aging, urinary problems, excessive bone loss and possible acceleration of dementia. An excess of estrogen, relative to testosterone, is thought to play a role in the development of prostate problems in men. 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, which includes Polycystic Ovaries. Natural Progesterone also helps regulate apoptosis. Progesterone also helps create a balance of all other steroids. It also has intrinsic calming and diuretic properties. Progesterone is the "Pro-Gestational" hormone and is the single most important hormone for conception and full-term pregnancy. It is important in women, but it's importance in men for the maintenance of prostate health is only now being appreciated.

So, whether a woman conceives through traditional "natural pregnancy" or IVF Fertility Treatment, it is critically important that she maintain optimal levels of progesterone throughout pregnancy. A drop in progesterone levels or a blockade of progesterone receptors during the first 11 or 12 weeks of pregnancy will often result in loss of the embryo.

Dr. Catherine Dalton has suggested that pregnant women use a properly formulated natural progesterone cream until the start of the third tri-mester when the placenta takes over progesterone production. She further states that women who maintain high progesterone levels during pregnancy produce healthier and more intelligent children.

Polycystic Ovaries

A 29 year old woman in the United States presented with excessive facial/body

- 26 -

Complaint

Ovarian Cancer .. Progesterone.Com ..

Page 2 of 2

hair growth, acne, and weight gain about the waist. She had suffered with these problems since puberty and had been on several of the popular low fat/high carbohydrate diets, which helped with weight temporarily, but resulted in rebound weight gain. Menstrual periods were also irregular. Saliva testing during the second half of the menstrual cycle (luteal phase) indicated high-normal estradiol, low progesterone, and high androgens-both DHEAS and testosterone. Further examination by her doctor revealed cystic ovaries. Dietary modification (removal of simple, refined carbohydrates-pastas, chips, pastries, sodas etc.) and use of natural progesterone has helped restore normal menstrual cycles, resolve the cystic ovaries and reduce the risk for ovarian cancer.

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.

| [Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#) |

© 1995 - 2007 Health Science Research, NY, NY, U.S.A.

Complaint

Menopause, Estrogen and Your Health - Health-Science.COM

Page 1 of 2

| Home | Sign In

[Index of Diseases](#)
[The Experts](#)
[Product Information](#)
[Shop Online](#)
[Contact Us](#)
The Informed Woman:

[Overview](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility & Progesterone](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Natural Progesterone](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More:

[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic-Progesterone](#)
[Tissue Cleansing](#)

Menopause, Estrogen & Your Health**Menopause Overview**

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.

Significantly, the common thread weaving its way through all of these conditions is estrogen dominance, secondary to an insufficiency of progesterone. However, after menopause or a hysterectomy, estrogen production decreases by about 40% to 60%. In other words the female body still produces estrogen at about 40% to 60% of pre-menopause levels.

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.

By establishing a balance of these hormones through proper Diet, Stress Management and Natural Progesterone supplementation, fluctuations of estrogen and progesterone, the resultant hot flashes, night sweats and other symptoms of menopause are either significantly alleviated or completely eliminated.

Persistent Symptoms

For those women for whom hot flashes, night sweats and/or vaginal dryness still persist they have found that 400 I.U. of natural vitamin E three times per day (1200 I.U./day), essential oil supplementation (primrose oil, omega III) and four to six tablespoons of whole psyllium seed husks in juice daily has been effective in ameliorating these persistent symptoms.

In cases where Estrogen Replacement Therapy is elected to control hot flashes, vaginal dryness or night sweats, natural estriol cream is recommended usually for several months or, in some cases a year. This is a safe, non-cancer promoting form of phyto-estrogen available here.

In most cases, however, estriol is not needed when a sufficient amount of Natural Progesterone is available, as it is the precursor (raw material) for other adrenal hormones, including all three forms of natural estrogen and cortisone.

Safety of Natural Hormones

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

Risks of HRT

This is in contrast to the standard medical protocol of HRT.

Studies have shown that women taking replacement estrogen have a 2 to 8 times higher risk of developing breast cancer, ovarian cancer and endometrial cancer than women who do not take estrogen. The risk increases after 2 to 4 years of estrogen use and seems to be greatest when large doses (>1 mg./day) are taken or when the estrogens are used for long periods of time (>4 years). This risk factor increases sharply in women who smoke cigarettes.

Sleuthing a Thyroid Mystery
by Dr. Stephen Langer



Premature Birth



Osteoporosis



Infertility

Complaint

Health & Science Research, New York, NY, U.S.A.

Page 2 of 2

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

Serenity For Women Info .. HEALTH-SCIENCE.COM ..

Page 1 of 2

[Home](#) | [Sign In](#)[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)**The Informed Woman:**

[Overview](#)
[Breast Cancer](#)
[Depression](#)
[Estrogen Dominance](#)
[Fertility & Progesterone](#)
[Hot Flashes](#)
[Insomnia](#)
[Libido](#)
[Menopause](#)
[Migraines](#)
[Natural Progesterone](#)
[Osteoporosis](#)
[Ovarian Cancer](#)
[PMS](#)

Learn More:

[Brain Function & Aging](#)
[Diet/Lifestyle](#)
[Fluoride Toxicity](#)
[And Osteoporosis](#)
[Infertility](#)
[Intestinal Health](#)
[Microwave Hazards](#)
[Synthetic-Progesterone](#)
[Tissue Cleansing](#)

Serenity For Women Info**Product Description**

Serenity for Women is The Finest Quality Moisturizing Cream that contains not less than 1,260 mg. of USP Natural Progesterone (converted from plant sources) per 2.1 ounce (60 gram) jar (Why a Jar? Isn't a tube better) This is the optimal progesterone level for a proper cream formulation. (Fragrance Free & HYPO-ALLERGENIC)

Ingredients

Purified Water, Organic Aloe Vera Gel 200:1 Concentrate (Aloe Barbadensis), Vegetable Glycerin, Natural Progesterone USP (2.1%), Vespene (Complex, Stabilized Vegetable Oil), Natural Vitamin E, Glyceryl Stearate (from plant), Stearic Acid (from plant), Cetyl Alcohol (from plant), PEG-20 Methyl Glucose Sesquisteate (from plant), Methyl Glucose Sesquisteate (from plant), Hyaluronic Acid (Natural Skin Moisturizer), NaPCA (Natural Skin Humectant), Xanthan Gum, Citrus Seed Extract (a natural preservative).

- Serenity for Women is formulated with the most advanced delivery system for maximum absorption (97-100% assimilated) and is light & non-oily.
- The process involves No Animal Testing, No Animal Cruelty and No Animal by-products.
- A 60-gram jar normally lasts six to twelve weeks, depending on the severity of symptoms and beginning progesterone levels.
- No Petroleum Derivatives or by-products are used in the manufacturing of Serenity for Women.
- Serenity for Women does not contain Keratin!

Suggested Use

Please see the Suggested Use Page

Precautions

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.

A few women may temporarily experience an increase in the symptoms caused by too much estrogen. This is not an adverse reaction to progesterone or to the cream, but an increase in the activity of estrogen. This is often referred to as the "healing crisis" and can be alleviated by strict adherence to the dietary/lifestyle pages.

Note: If you are using thyroid medication your health care professional should monitor thyroid function as progesterone may support normal thyroid function and thyroid medication may over stimulate the thyroid gland.

Any persistent problems should always be checked by a qualified health care professional.

Related Links

Free Dr. Lee book with purchase of three Serenity!



Premature Birth



Osteoporosis



Infertility

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [FDA Disclaimer](#) | [Copyright Information](#)

© 1995 - 2007 Health & Science Research, New York, NY, U.S.A.

Complaint

... FEDERAL TRADE COMMISSION ...

Page 2 of 2

Complaint

hysterectomy :: progesterone.com ::

Page 1 of 1

[Index of Diseases](#) [The Experts](#) [Product Information](#) [Shop Online](#) [Contact Us](#)

[Home](#) | [Sign In](#)

The Informed Woman
Overview
Breast Cancer
Depression
Estrogen Dominance
Fertility
Hot Flashes
Insomnia
Libido
Menopause
Migraines
Osteoporosis
Ovarian Cancer
PMS
Learn More
Brain Function & Aging
Diet/Lifestyle
Fluoride Toxicity
And Osteoporosis
Infertility
Intestinal Health
Microwave Hazards
Synthetic-Progesterone
Tissue Cleansing

Hysterectomy

A hysterectomy causes the female body to become immediately menopausal.

According to Dr. Stanley West, Chief Endocrinologists 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.

The standard medical decision, however, is to perform a hysterectomy and to give women estrogen replacement therapy, in spite of the fact that 75% of patients still make sufficient amounts of estrogen. This can be verified by a saliva hormone test which measures available levels of estrogen and is more meaningful than a blood test.

After surgery hormone production does not cease, as estrogen and progesterone should still be made by the adrenals & fat cells. The importance of proper balance of these two hormones is more critical at this time due to the fact that progesterone plays a critical supportive role in bone building (Osteoblast Cells), stroke prevention and a health heart.

Since the female body makes natural estrogen from natural progesterone, most women need only supplement with a properly formulated natural progesterone cream. Some women, however, do not readily make this conversion and may temporarily need supplemental estrogen or may implement a diet that is rich in phyto-estrogens and contains sufficient amounts of fiber.

For the women who need supplemental estrogen due to continued hot flashes, night sweats, and vaginal dryness, a natural estriol cream is a safe and effective treatment.

So, for menopause, whether surgically induced or not, Dr. Lee states in his book, "Adding progesterone will actively increase bone mass and density and can reverse osteoporosis."

Natural progesterone offers many other benefits for women who have had a hysterectomy and they are listed Here.


Heart Health

Weight Loss

Premature Birth

Dietary Consideration

[Sign In](#) | [Literature Request](#) | [Contact Us](#) | [Site Map](#) | [Privacy & Security](#) | [Copyright](#)

© 1995 - 2007 Health Science Research, NY, NY, U.S.A.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act; and

The Respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the Respondents that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Health Science International, Inc. is a Florida corporation with its principal office or place of business is at 1648 Taylor Road, Suite 118, Port Orange, Florida 32128.

Decision and Order

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. His principal office or place of business is the same as that of Health Science International, Inc.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “Respondents” shall mean:
 - a. Health Science International, Inc., a corporation, and its successors and assigns and its officers; and
 - b. David Martin, individually and as an officer of Health Science International, Inc.
2. “Competent and reliable scientific evidence” shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or synthetic), including but not limited to progesterone (whether produced by the human body or produced outside

Decision and Order

the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Serenity for Women Natural Progesterone Cream.

4. "Food," shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.
5. "Drug" shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. "Device" shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Decision and Order

7. “Covered product or service” shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.
9. “Endorsement” shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

- A. That such product or service is effective in preventing, treating, or curing osteoporosis;

Decision and Order

- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user's risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user's risk of developing breast cancer;
- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

Decision and Order

IT IS FURTHER ORDERED that:

- A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration;
- B. Nothing in this order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and
- C. Nothing in this order shall prohibit Respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict,

Decision and Order

qualify, or call into question the representation or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

V.

IT IS FURTHER ORDERED that Respondents shall delivery a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of the order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change with regard to Health Science International, Inc. or any business entity that any Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. *Provided, however*, that, with respect to any proposed change about which Respondents learn less than thirty (30) days prior to the date such action is to take place, Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by

Decision and Order

certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondents, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment; or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IX.

This order will terminate on November 13, 2027, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

Analysis to Aid Public Comment

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a Respondent in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that this order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

**ANALYSIS OF PROPOSED CONSENT ORDER
TO AID PUBLIC COMMENT**

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Health Science International, Inc., a corporation, and David Martin, individually and as an officer of Health Science International (together, "respondents").

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons.

Analysis to Aid Public Comment

Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of Serenity for Women Natural Progesterone Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that Serenity for Women Natural Progesterone Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) 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. The complaint alleges that respondents failed to have substantiation for these claims. The complaint also alleges that respondents misrepresented that clinical testing proved that Serenity for Women Natural Progesterone is effective in preventing, treating, or curing osteoporosis. The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Analysis to Aid Public Comment

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration (“FDA”) standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

SHELLY BLACK,
TRADING AND DOING BUSINESS AS
PROGESTERONE ADVOCATES NETWORK

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4206; File No. 072 3146

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order addresses Progesterone Advocates Network's advertising and promotion of Nature's Precise Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. The complaint alleges that the respondents represented that Nature's Precise Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) 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. The consent order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Participants

For the Commission: Gregory A. Ashe, Laura DeMartino, Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the Respondents: Not represented by counsel.