

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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

)	
In the Matter of)	
)	
LAWRENCE A. JORDAN,)	
an individual trading and doing business)	DOCKET NO. C-4203
as SPRINGBOARD and PRO HEALTH)	
LABS, and)	
)	
STEPHANIE L. JORDAN,)	
an individual trading and doing business)	
as SPRINGBOARD and PRO HEALTH)	
LABS.)	
)	

COMPLAINT

The Federal Trade Commission, having reason to believe that Lawrence A. Jordan and Stephanie L. Jordan, individuals trading and doing business as Springboard and Pro Health Labs (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Lawrence A. Jordan is an individual trading and doing business as Springboard and Pro Health Labs with his principal office or place of business at 3115 Stoney Oak Drive, Spring Valley, California 91978. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Springboard and Pro Health Labs, including the acts and practices alleged in this complaint.

2. Respondent Stephanie L. Jordan is an individual trading and doing business as Springboard and Pro Health Labs with her principal office or place of business at 3115 Stoney Oak Drive, Spring Valley, California 91978. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Springboard and Pro Health Labs, including the acts and practices alleged in this complaint.

3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman’s risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman’s risk of developing breast cancer.

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including ProBalance™ and ProBalance Plus™. Respondents primarily advertise and offer the products for sale through the Internet sites www.springboard4health.com and www.sb3.com.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, ProBalance™ and ProBalance Plus™ are “drugs” as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. ProBalance™ is a drug labeled as containing Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube) and other ingredients. A two fluid ounce tube costs \$19.95 plus shipping and handling. ProBalance Plus™ is a drug labeled as containing Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube), Estriol (900 mcg per 1/4 measuring teaspoon), Estradiol (100 mcg per 1/4 measuring teaspoon), and other ingredients. A two fluid ounce tube costs \$27.00 plus shipping and handling. ProBalance™ and ProBalance Plus™ are applied transdermally.

8. To induce consumers to purchase ProBalance™ and ProBalance Plus™, Respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondents’ websites:

A. All Progesterone creams are not created equal!

Natural Progesterone

ProBalance reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects often associated with synthetic hormone replacement therapy.

* * *

Natural Progesterone With a Blend of Phytoestrogens

ProBalance Plus™ is a safe and natural menopause alternative for women over 45 without the side effects often associated with HRT.

* * *

USP Pharmaceutical grade progesterone. Non-greasy. Absorbs quickly. No carcinogens or unnecessary ingredients. We have yet to find a doctor who has been recommending ProBalance to his/her patients switch to any other brand of progesterone cream. The saliva test results prove the effectiveness, and the feel makes applying it a pleasure.

(Exhibit A at 1.)

B. Breaking News - On Health

Switching to Natural Hormones Now That HRT Is No Longer Every Woman's Answer

The recent headlines about the risks of synthetic hormone replacement (HRT) have forced women to scramble to find ways to balance their hormones naturally. Natural, bio-identical hormones are the safe alternative to HRT and hundreds of thousands of women are already using them. The following information from John R. Lee, M.D., one of the leading experts on the subject of natural hormones, are offered here to answer questions you may have about switching from synthetic HRT to natural.

While the abrupt cancellation of The Women's Health Initiative (WHI) made headline news around the country, it did not surprise those who have kept up with all the studies over the last decade which warned of the risks of HRT. The WHI analyzed the health of 16,000 women aged 50 to 79 years over five years of using HRT in the form of Premarin, Provera or PremPro. The researchers found an increased incidence of just about every major disease the hormones were supposed to be preventing! The data showed:

- A 41 percent increase in strokes
- A 29 percent increase in heart attacks
- A 26 percent increase in breast cancer
- A 22 percent increase in total cardiovascular disease

— A doubling of the rate of blood clots.

* * *

Stretch these numbers out over a decade, and nearly 40,000 women will have been harmed by taking these drugs, not counting all the women who have suffered the dismal side effects of this form of HRT — weight gain, fatigue, depression, irritability, headaches, insomnia, bloating, low thyroid, low libido, and gallbladder disease. That is an epidemic. If we dare to multiply 40,000 women harmed times three — the number of decades women have been using synthetic HRT— we are talking about an epidemic of the worst proportions.

* * *

And so it has gone, until the Women's Health Initiative, expecting to document the lifesaving benefits of HRT, found life threatening risk instead. The study was stopped in its tracks – three years short of its scheduled end.

To readers of the works of Dr. John Lee, Dr. David Zava and other pioneers of the natural hormone movement, the risks and side effects of conventional HRT are not news. The evidence of harm has been showing up in the scientific research for at least a decade. This particular study was finally large enough and prestigious enough that conventional medicine was forced to pay attention. The challenge now for doctors is to inform themselves and their patients about the efficacy, use and prescribing of natural hormones.

Questions and Answers About Natural Hormone Replacement Therapy with Dr. John Lee

(Provided with permission of Dr. John Lee, author of WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT MENOPAUSE and co-author with Dr. David Zava of WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT BREAST CANCER)

Do the results of the WHI apply to using natural estrogen and progesterone as you recommend?

Not at all.

* * *

Looking at this another way, from puberty until menopause, a healthy woman's body is making its own natural hormones in synchrony and balance, without

giving her cancer, heart disease or strokes. What I recommend is attempting to regain or mimic this natural balance as closely as possible.

Conventional HRT not only fails to measure hormones and use physiologic doses, it uses synthetic, not-found-in-nature hormones that are foreign to the human body and cause a long list of unwanted side effects.

* * *

My doctor says that I cannot use estrogen and progesterone cream, because progesterone cream will not protect my uterus the way the progestins do.

Progesterone cream protects the uterus just fine. Not only did I not have any problems in my hundreds of menopausal patients before I retired from practice, I am in touch with dozens of physicians who have thousands of patients between them, who have never had a problem. Some of them have been doing this for over a decade.

* * *

What are bio-identical hormones and can you explain the difference between natural progesterone and the synthetic version?

Bio-identical hormones (BHRT) are synthesized from natural substances and are identical in structure and function to those our bodies produced naturally, pre-menopause. When production drops below normal levels at perimenopause and menopause, BHRT is the best and safest way for women to supplement. Bio-identical hormones are available by prescription through compounding pharmacists. Natural progesterone is a bio-identical hormone as opposed to progestin which is the synthetic version (the “pro” in Prempro). Natural progesterone is just like the progesterone your ovaries made and is available in a topical form over-the-counter and by prescription (when compounded with natural estrogens and other hormones).

* * *

(Exhibit A at 3-6.)

- C. ProBalance Natural Progesterone Cream
Natural progesterone reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects associated with synthetic hormone replacement therapy.

* * *

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

* * *

(Exhibit A at 7.)

D. More on ProBalance Natural Progesterone

* * *

Apparently, nature intended that estrogen and progesterone be balanced. Progesterone counters every undesirable effect of excess estrogen. Progesterone stimulates bone growth. It protects against reproductive organ and breast cancer, it helps the body to use fat for energy, it is a natural diuretic, it normalizes blood clotting, it aids thyroid hormone action, it helps to normalize blood sugar levels, it restores libido, and it is a natural antidepressant. Progesterone has also been found to be effective in treating PMS, ovarian cysts, breast fibrocysts, endometriosis, pelvic disorders, and uterine fibroid tumors.

* * *

Progestins such as Provera ® , are synthetic progesterones, synthesized from natural progesterone, but because the structure is altered, there is a long list of side effects including mental depression, insomnia, cervical erosion, edema, acne and pulmonary embolism. When taken in combination with estrogens, a woman may experience nervousness, dizziness, hair loss, fatigue, or hypertension, to name a few. Although many doctors believe that there is no difference between synthetic and natural progesterone, some synthetic progesterones can produce masculinizing effects in women whereas natural progesterone does not cause masculinization.

Transdermal absorption of natural progesterone has been established as an effective and safe delivery method. Rubbed into thin-skinned areas such as the palms of the hands, face, neck, breasts, inner arms, or soles of the feet, the progesterone is absorbed into the skin and stored in the fatty tissues. It is then taken into the bloodstream where it circulates to receptor sites throughout the body.

* * *

(Exhibit A at 9-11.)

- E. Osteoporosis is often caused by a lack of progesterone. Very rarely is it a lack of calcium. New bone is formed by osteoblasts, and old bone is removed by osteoclasts. When the osteoclast activity goes faster than the osteoblast activity bone loss occurs. Progesterone is the key factor in osteoblast or building of new bone. Dr. John R. Lee checked this out with 63 women over a 3 year period, doing bone mineral density tests every six months. At the end of a 3 year test on these women using progesterone cream, the average increase in bone density was 15.4%. These were all postmenopausal women who would normally expect to have a 1/5% bone loss per year, or a total bone loss for 3 years of 4.5%. There was a 19.9% difference between the expected loss and the real increase that occurred. This is very exciting, as medicine has been saying that you can't reverse osteoporosis; you can only slow it down. Estrogen does not reverse it. It only slows down bone loss for the two to three years of menopause, then has no further effect.

Dr. Lee tells of a woman 72 years old who had over 40% bone loss and was in pain because of a stress fracture in her lower spine. In spite of opposition from 5 doctors involved in her case, she decided to follow Dr. Lee's advice, and in only 16 months experienced a 23% increase in her bone density. All but one of the doctors wrote Dr. Lee telling him that they would not have believed it had they not seen it with their own eyes. This lady is now 80 years old, and is continuing to use the progesterone cream. Her total increase in bone density is up 38%. When Dr. Lee was asked how long she should continue using it, he responded: "Keep using it until you are 95, and then we'll reevaluate."

(Exhibit A at 14-15.)

- F. ProBalance Plus - Natural Progesterone Cream with Phytoestrogens
ProBalance Plus™ is the safe and natural menopause treatment alternative for women over 45 without the side effects associated with synthetic hormone replacement therapy.

(Exhibit A at 16.)

- G. More On ProBalance Plus

Natural Progesterone Cream
ProBalancePlus

* * *

In the years following menopause, the risk of cardiovascular disease, osteoporosis, and cognitive decline increases dramatically. A growing number of research studies have linked some of these risks to the relative absence of estrogens and progesterone. For decades, physicians prescribed synthetic estrogen, such as

Premarin®, without other accompanying hormones. When it was discovered that the risk of developing endometrial cancer due to unopposed estrogen replacement could be reduced by adding progesterone, physicians began prescribing progestins (synthetic progesterone which could be patented) such as Provera®. According to some estimates, standard hormone replacement therapy using synthetic hormones like Premarin® and Provera® may increase a woman's risk of breast cancer by as much as 30 percent. Many doctors think that the lower risks of heart disease and osteoporosis attributable to estrogen replacement make the odds acceptable. On the other hand, a majority of these doctors aren't women!

For women who find these odds unacceptable, considering natural hormone replacement is a "no brainer." The benefits include those of synthetic HRT plus a few more including:

- Prevention of osteoporosis and increase of bone density

* * *

- Reduced risk of endometrial cancer and breast cancer

* * *

The benefits of progesterone are amazing. According to John R. Lee, M.D., the well-known proponent of supplemental progesterone, transdermal progesterone can:

- Promote bone building and protect against osteoporosis
- Help protect against breast cancer
- Protect against endometrial cancer

* * *

(Exhibit A at 18-19.)

H. **Breast Cancer and Natural Progesterone**

* * *

Progesterone Upregulates the Gene that Causes Cancer Cells to Die Estrogen Upregulates the Gene that Cause Cancer Cells to Not Die

* * *

What do we have? The BCL2 stimulates the risk of cancer. Gene P53 decreases the risk of cancer. Estradiol upregulates BCL2. Progesterone upregulates P53.

Therefore progesterone decreases cancer. Unopposed estradiol causes the cancer.
Simple.

(Exhibit A at 31.)

I. **Breast Cancer & Natural Progesterone**

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It is Dr. John Lee's contention that progesterone prevents breast cancer, and if you already have breast cancer progesterone protects you against reoccurrence or late metastases. In his medical practice he treated many women who had mastectomies. In the 20 years since he started recommending the use of progesterone, not one of the hundreds of women he treated has died of breast cancer. Think about what the odds are on that number when you compare it to normal post mastectomy figures.

(Exhibit A at 34.)

J. **Osteoporosis**

Excerpts from a talk by John. R. Lee, M.D.

Bone is living tissue and hormones have an effect on bone. Estrogen causes bone resorption while progesterone and testosterone cause new bone to be made.

* * *

So what I stumbled on to is that progesterone causes new bone formation.

* * *

What I learned is that progesterone turns on the processes which lead to new bone formation.

* * *

When I retired from practice nine years ago I asked my nurse to pick out 100 records of women on **progesterone**. Out of the 100 I took only those who had at least three years of bone mineral density tests every six months. I was left with 62 patients. The average increase in bone density in these postmenopausal women over three years was 15.4% versus a normal expected loss during that period of time of 4.5%. That is almost a 20% average difference between what normally happens and what happens when women are using **progesterone**. Estrogen only

slows down bone loss for the period of menopause, and after menopause it doesn't even do that. **Progesterone**, however, causes new bone growth even in postmenopausal women.

* * *

Examples from my practice of how progesterone increased bone density

This first chart was in 1982. The lady was 72 years old and had very poor bones. She had broken her forearm lifting her sick husband. She went to her doctor who told her that she had such poor bones that she had to take fluoride treatment. She told him that was a bad idea because she had taken Dr. Lee's class at College of Marin on Opti-mal Health, and he said fluoride was a bad thing for bones. So he told her to go see Dr. Lee. I put her on **progesterone** and she had a 24% improvement in bone density over the next 30 months. Her bone density went from .669 to .865. Given her height and weight this is a perfectly fine bone mineral density.

* * *

The woman stuck with my thinking and told her husband she was going to try **progesterone** cream despite his objection. Finally her husband gave in saying, "Then in six months we're going to make you get another bone mineral density test." In six months she went from .446 up to .516. That's over 14% in six months! Another test was done ten months later and her bone density was still increasing.

* * *

There are things in life that do not need a double blind, placebo-controlled study. . . . If they say that after age 65 osteoporosis cannot be reversed, and you reverse it in 62 women using just progesterone, you don't need a double blind study! I'm not against someone doing a double blind study, but they know that no one will pay for it. Progesterone is a real hormone and since it's not a patentable synthetic, there is no money to be made so no one is going to ante up the \$500,000 to \$1,000,000 to do a study.

(Exhibit A at 40-46.)

9. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that:
 - A. ProBalance™ and ProBalance Plus™ are effective in preventing, treating, or curing osteoporosis;

- B. ProBalance™ and ProBalance Plus™ are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and
- C. ProBalance™ and ProBalance Plus™ do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 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 the ProBalance™ and ProBalance Plus™ are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer and breast cancer.

13. In truth and in fact, clinical testing does not prove that ProBalance™ and ProBalance Plus™ are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer and breast cancer. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

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

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

By the Commission.

Donald S. Clark
Secretary

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