Good, Better, Best:

**How Do I Buy A Progesterone Cream?** 



**John Tice** 

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Marcus Laux, ND, author of *Natural Woman*, *Natural Menopause*, became a friend and supporter of Kokoro and Women's Balance Creme.

Raquel Martin and Judi Gerstung, DC, authors of *The Estrogen Alternative: Natural Hormone Therapy With Botanical Progesterone*, have shared ideas and spoken at Kokoro-sponsored women's seminars.

Cheri Schatz, Dorothy Gibson, Debra Andrews, Rosalyn Rogers, Win Chambers, Norma Fouquet, Debi Smith, and Marlene Salazar are among many who have been instrumental in our successes.

I thank these individuals as well as my family and my personal "inner circle" who continue to inspire me.

John Tice Santa Ana, California May 2003

#### Addendum:

Since the initial writing of this book, our good and mentor, John Lee, died in October 2003. Dr. Lee brought the importance of hormonal balance to the forefront of American conciousness and was a strong advocate for women's (and men's) health.



Down-to-earth and practical, I remember his sense of humor about health and balance in all things. In January 1998, Dr. Lee was speaking to a group of women in Columbus, Georgia about the impact of genetics on health. He told us how his father, grandfather, and uncle died of heart-related problems before reaching their mid-fifties. He said that since he was 70, he was "either adopted or doing something right." John, we're glad you had an extra twenty years to share with us and to help improve the quality of life for thousands of people. We'll miss you.

John Tice Santa Ana, California August 2004

# **REVISIONS**

# **Background**

Like any work, this book is subject to changes and updates. One of the advantages of electronic publishing is the ability to rapidly update our information. I will make updates as I become aware of new information or mis-information. If you have suggestions or comments, please let me know for future revisions. Listed below are the updates and where to find them:

# Introduction

#### Who Needs This Book?

If you are confused about which company is "best"—you need this information.

If you don't know whether yam derived progesterone is "better" than soy derived progesterone—you need this information.

If you've heard that "USP 2% Progesterone" is recommended by experts"—you need this information.

If you are looking for "Dr. Lee's cream"—you need this information.

If you want a cream with no chemicals"—you need this information.

If you want a cream with only organic ingredients"—you need this information.

In short"—you need this information.

### **Background**

Over the years we have been asked a number of questions about progesterone, progesterone cream, ingredients, etc. This book is designed to assist you with some of the answers. It is not all-inclusive. While we have tried to tone down our own biases and stick to the facts, they will appear – we're in the progesterone business and we are passionate about our products.

In terms of "progesterone cream history," we're old-timers—we've been in business over fourteen years. From the first day of business our philosophy has been simple: make the best product we can without skimping on quality to save money, offer good customer service, and provide honest accurate information. We believe too much is riding on not taking this approach—your health!

As the author of this book, let me be clear about two things: I am not a medical professional and I am not a chemist. I've learned everything the hard way—by a lot of study and much trial and error. I've spent nearly nine years speaking publicly on to topic of progesterone and health to audiences as few as two to as many as 1,000. I've talked with thousands of women and hundreds of men. I know all of the major authors and authorities on the topic and have spent countless hours learning from them. I don't claim to have all of the answers—I don't even know the questions!

The sections below offer advice (and opinions) about many facets of progesterone cream, progesterone levels, companies, and ingredients. We solicit your feedback on this project – it is an evolving work.

Most writers will put their cautions and caveats at the end of their writing we're putting it up front and in bold letters.

This information is not intended to diagnose any medical condition and is not intended to replace competent advice from your health care professional. None of the information contained in this report has been evaluated by any regulatory agency. While we have taken every step to ensure that we are offering accurate information some errors may occur, we urge you to seek additional information if you have any questions on our information.

# CHAPTER ONE: CHOOSING A CREAM

ITH DOZENS OF NATURAL PROGESTERONE CREAMS on the market today, many women wonder which cream is "best." Ask any manufacturer of these creams and they will tell you their cream is the best on the market. (If they didn't believe that, they should be in another business.) Many of these companies make medical claims about their product, some will claim to use "Dr. Lee's formula," have "Dr. Lee's cream," or have the "cream as seen on Oprah!," and many make inaccurate claims about the ingredients in their product.

#### Medical Claims

Much has been written about the benefits of progesterone for women (and men). By law, what progesterone companies are selling is legally classified as a cosmetic—it is not a supplement. Any company or web site that declares that progesterone will "cure" health problems or "eliminate" symptoms is in violation of U.S. laws; we suggest you avoid doing business with these companies.

Rather than relying upon information touted by companies selling progesterone, we strongly encourage you to read and study to find out what progesterone will do (or not do) for you. A reading list at the end of this book will provide you with a starting point to learn more.

## Which Company Should I Trust?

When Kokoro, LLC first started business in 1996, there were approximately 18 companies offering a progesterone cream to the public, today this number is, by our count, in excess of 50! The spectrum of companies range from quality, well intended, and honest to the "fast buck, deal-of-the-month" operator.

We know of sellers who will not stand behind the products they sell and that, "No product may be returned for refund or exchanged." This is allegedly under the assumption that this is for the consumer's protection. Personally, I wouldn't do business with a company that wouldn't take a product back for any reason. Companies and resellers should stand 100% behind whatever they sell, period.

Many of the nationally recognized authors such as John R. Lee, MD, Marcus Laux, ND, Raquel Martin, Judi Gerstung, DC, Sherrill Sellman, Uzzi Reis, MD, and others have organized listings of companies that they believe to offer a product that meets minimum recommended levels of progesterone. To our knowledge, none of these authorities have any personal financial interest in any cream manufacturer. None of these authorities have formulated any product. What they are recommending is companies who have levels of progesterone in a cream that is suggested by the authors. We have not seen any of these authorities address the ingredients that make up these creams.

#### "Dr. Lee's Cream"

In checking out the market, we have found companies that tout "Dr. Lee's Formula" or "As Approved by Dr. Lee" or "As recommended by Oprah Winfrey." While we can't speak for Oprah, we have spoken with Dr. Lee on this topic directly: he is emphatic in stating that he does NOT endorse products, receives no fees or compensation from any cream manufacturer (other than speaking fees), nor does he have a "cream formula." Companies stating or implying and endorsement by Dr. Lee is trying to capitalize on Dr. Lee's work without compensating him. He is adamant in requesting companies to NOT make these statements.

If Oprah were to endorse a cream, you would readily expect such an endorsement to be announced from every media source in the U.S.? Our opinion of companies that use these misleading and deceptive practices is not good. In fact, we suggest you buy your cream from someone (anyone!) else.

# Chapter Two: How Much Progesterone Should Be In My Cream?

OHN R. Lee, MD, popularized the notion of using approximately 20mg of progesterone per day. 20mg equates to approximately 480-500mg of progesterone per ounce of cream. Christianne Northrup, MD, used 2% as the level of cream she recommended on the Oprah Winfrey Show. This is equal to approximately 600mg of progesterone per ounce. Her suggestion has lead a number of companies claiming to offer "progesterone (USP 2%)" or "USP 2% progesterone" in their cream. This is a "nonsense" assertion that is akin to labeling milk as "Milk (FDA Grade: 2 Gallon)." More on this is discussed below.

There is a wide range of levels of progesterone in moisturizing creams designed for female use. In determining the amount of progesterone you feel is optimal in a two-ounce jar of cream, it is important to bear in mind a number of points.

- First, decide whether your usage plan has a physiological or a pharmacological goal in mind. Physiological programs are designed to replicate the level of progesterone that your body produces on a normal basis. The normal range of progesterone production is between 20 and 30 milligrams per day during the progesterone phase of the menstrual cycle.<sup>1</sup>
- Pharmacological, or drug, dosages are significantly higher than physiological dosages. Extreme care should be taken when using levels that are too high. Dr. Lee points out that these high levels of hormone dosages can lead to normal hormone production suppression or to actions that are different from those intended. For example, he points out that too much progesterone can lead to suppression of sex drive while lower levels can stimulate sex drive.<sup>2</sup>

Dr. Lee recommends creams that contain between 400 and 500 milligrams of progesterone USP per ounce.<sup>3</sup> When you look at the labels of the products on the market you will notice that some creams give no information, some state the level of progesterone in milligrams and others state the level as a percentage. One of the easy ways to find a cream with enough progesterone is to choose one from the list of creams printed in one of the books on the topic.<sup>4</sup>

# Determining Progesterone Levels

If a cream states its level of progesterone as a percentage, you can determine the number of milligrams of progesterone by simply multiplying the number of milligrams of cream in the jar by the percentage stated. For example, assume a cream's label stated that there is "1.8% progesterone USP" in the jar. You would perform the following calculation: multiply the percentage by 60,000 (the approximate number of milligrams in two ounces of cream). In the above example, 1.8% times 60,000 equal 1,080 milligrams.

To calculate the number of milligrams per ½ teaspoon, you would divide the total milligrams in the two-ounce jar by 48 (the number of ¼ teaspoons in a two-ounce jar). Using the above example, the answer is 22.50 (1,080 divided by 48). This number then tells you that there is approximately 21 milligrams of progesterone per ¼ teaspoon of cream. To get the amount of progesterone in ½ teaspoon, simply double the answer you just calculated.<sup>5</sup>

The table below will give you an idea of the levels of progesterone contained in a two ounce jars as well as the amount of progesterone per ¼ and ½ teaspoons.

What do the numbers in the chart mean? Simply this: If your cream label lists 1.8% progesterone USP, you know that it will contain approximately 510 mg per one-ounce or 1,019 mg per two-ounces. You also know that you are applying 21 mg of progesterone per ¼ teaspoon of cream applied.

One of the comments we have heard many times is, "how does a woman (or man) know how much progesterone is actually being applied?" Using the chart above you will now have a reasonable answer to that question.

If you are looking for a cream with the levels of progesterone suggested by the experts, you can use the chart below to aid you in your search.

Table 1: Progesterone Levels Reference Chart

Percentage	Progesterone per 2-oz	Progesterone per 1/4 Teaspoon	Progesterone per 1/2 Teaspoon
1.0%	600 mg	12.5 mg	25 mg
1.2%	720 mg	15.0 mg	30 mg
1.4%	840 mg	17.5 mg	35 mg
1.6%	960 mg	20.0 mg	40 mg
1.8%	1,080 mg	22.5 mg	45 mg
2.0%	1,200 mg	25.0 mg	50 mg
2.4%	1,440 mg	30.0 mg	60 mg
3.0%	1,800 mg	37.5 mg	75 mg

(Footnotes)

<sup>&</sup>lt;sup>1</sup> Lee, John R., What Your Doctor May Not Tell You About Menopause, Warner Books, New York, p. 69.

<sup>&</sup>lt;sup>2</sup> Lee, p. 78.

<sup>&</sup>lt;sup>3</sup> Lee, p. 271 and personal conversation with Dr. Lee, December 1997.

<sup>&</sup>lt;sup>4</sup> Lee, p. 271.

<sup>&</sup>lt;sup>5</sup> Calculating the exact amount of progesterone and the bioavailability of that amount is beyond the scope of this book.

# Chapter Three: Are All Creams Created Equally?

ERTAINLY EVERY MANUFACTURER would tell you the answer is no. We are no exception. There are others who would tell you that there is really not much difference from one cream to the next as long as you have high enough levels of progesterone. We have heard scientific explanations to adequately argue both sides of this question. We think the easiest way for you to know is to try different brands and then make a decision.

What formula do we prefer? Our personal preference is towards creams that have a strong bias towards natural ingredients or are derived from natural ingredients. We prefer to stay away from creams that contain ingredients that have a petrochemical derivation or use animal products or by-products. In addition to the progesterone USP, we like creams that make use of wild yam extract. In our personal experience we have found that a cream with wild yam extract is both stronger and more effective than one without wild yam extract. This opinion is based upon the personal experiences of women who have reported the difference back to us.<sup>1</sup>

Which cream should you use? If you are comfortable with the level of progesterone in one or more different choices, then choose the one that feels best on your skin. Everyone is different and any one cream will most likely not be the answer for everyone.

#### "Dr. Lee says wild yam is a scam." What gives?

One frequent question we receive concerns the inclusion of wild yam extract in Kokoro Women's Balance Creme. From the onset, it is critical to understand that Balance Creme contains progesterone USP in levels recommended by Dr. John R. Lee and every other important authority on the topic. In fact, Balance Creme has been on Dr. Lee's recommended list of creams for over six years (as well as several other nationally recognized recommended lists).

While Dr. Lee is clear in both his desire to differentiate progesterone and wild yam and his statement that he does not know the specific effects of wild yam on the body, there is some confusion about the benefits that are known. Unfortunately, many women assume that the inclusion of wild yam, for any reason, is something to be avoided.

On the surface it would be easy to simply buckle under and remove the wild yam from our cream. However, thousands of women now rely on the Balance Creme formula as it has been developed. Our commitment as a company is to provide the finest product possible.

Practical experience has shown us that Balance Creme performed better with the inclusion of the wild yam. Kokoro has never given the impression that wild yam changes hormone levels. It does not! Master herbalists tell us that wild yam is known as an adaptogen herb. It would be like using fertilizer on a garden. If the plants need it they use it. On a simplistic level, this is how this herb performs its job. If we find a scientific reason to remove wild yam from Balance Creme, we will do so. In the absence of any evidence to support that, consider the following:

• Wild yam has been used in female-related herbal formulations for years. A recent search of several herbal books on women's health revealed wild yam used in many formulas for pregnancy, nursing, menopause, and other female-specific issues.

• While there are some questions on whether pregnant women should use wild yam, we find herbal literature that supports its use. Further, we have had many women report positive experiences while using Kokoro Women's Balance Creme prior to, during, and after pregnancy.

#### Outlined below are a number of references on this topic.

A Woman's Book of Herbs, The Healing Power of Natural Remedies, Soule, Deb, Carol Publishing Group, 1995. Wild yam is listed as an ingredient in many of the pregnancy-related formulas.

The Little Herb Encyclopedia, The Handbook of Natures Remedies for a Healthier Life, Ritchason, Jack, ND, PhD, and Master Herbalist. Woodland Health Books, 1995, pp 248-9, 369. There are several recommended uses in pregnancy. "This herb is beneficial during pregnancy..." (page 249) "We are providing a list of herbs that can be used safely during pregnancy. ... Wild Yam: for pregnancy pain, nausea or cramping and will lessen miscarriage." (page 369).

The Scientific Validation of Herbal Medicine, Mowrey, Daniel B., PhD, Keats Publishing, 1986, p. 111-112. Recommended uses include: during pregnancy, delivery, and miscarriage.

Today's Herbal Health, Third Edition, Tenney, Louise, MH, Woodland Books, 1992, pp 145-6. Recommended uses include: morning sickness, miscarriage prevention, uterine cramping.

If you will read each of Dr Lee's books carefully, you will see that the scam is when a cream maker claims wild yam will turn into progesterone or some other hormone in the body. For example, in his book What Your Doctor May Not Tell You About Premenopause (WPM), Dr. Lee states, "Those who sell diosgenin or diosgenin disguised as 'extract of wild yam' or Dioscorea (the Latin name for the Mexican wild yam) in creams or capsules AND CLAIM THAT IT HAS THE SAME EFFECT AS PROGESTERONE ARE NOT SPEAKING THE TRUTH." (WPM, page 38-39) [Emphasis added]. The current edition of What Your Doctor May Not Tell You About Menopause (WYD), on pages 269-272, discusses this same topic.

The point here is that it is not the fact that a cream contains wild yam extract; it is what the manufacturer is claiming the extract will do. Our claim with respect to wild yam extract is simple: IT WILL NOT TURN INTO ANY HORMONE IN YOUR BODY. There is no scientific evidence to the contrary. We include it in our cream because we believe there is a synergistic benefit by the yam extract being in the cream.

# Why do you list "wild yam extract" as an ingredient?

Simple. The law requires manufacturers to list ingredients in their products in descending order. We have nothing to hide. If you look carefully at our ingredients, you will also see progesterone USP listed as an ingredient.

## So are you a real progesterone cream with just the words wild yam extract on the label?

Are we a "real progesterone cream?" Not only is the answer, "Yes," but many other experts also feel the same way. We have been on many recommended lists since our inception in 1996. Some of these include:

- What You Doctor May Not Tell You About Menopause, John R. Lee, MD
- What You Doctor May Not Tell You About Premenopause, John R. Lee, MD
- What You Doctor May Not Tell You About Breast Cancer, John R. Lee, MD
- The John R Lee, MD, Newsletter, John R. Lee, MD
- Natural Woman, Natural Menopause, Marcus Laux, ND
- The Estrogen Alternative, Natural Hormone Therapy with Botanical Progesterone, Raquel Martin and Judi Gerstung, DC
- Hormone Heresy, Sherrill Sellman

The list goes on. The point is simply this: these experts only recommend "real progesterone creams" that meet their specifications.

<sup>(</sup>Footnotes)

<sup>&</sup>lt;sup>1</sup> Some women noted a distinct difference in managing hot flashes when the cream formula changed from "standardized yam extract" to a non-standardized, highly concentrated wild yam extract.

# Chapter Four: Ingredients

## Chemicals in My Cream and Long Chemical Names

Over the years customers have told us that they are looking for (or they use) a cream with no chemicals. Simply stated, this is NOT possible – water is a chemical and water makes up to 90% of all creams!

Most likely, what are really objected to are long, chemical names on labels. We don't like them either. There is only one problem – the law. Manufacturers are required by law to label ingredients in a certain manner. If you find a cream (or any product) that does not use correct names, they are in violation of the law. It's that simple.

## "No Synthetic Chemicals"

Unfortunately "non-science," marketing "babble," and consumer ignorance and fears play into the hands of many companies anxious to differentiate their product from a crowded field. Untruths, inaccuracies, and implied claims about synthetic versus natural ingredients are an ongoing debate.

We see statements such as, "Stay away from ingredients with which neither you nor your retailer are familiar" that play into these fears. Consider this: there are over 1 million words in the English language and the law requires the use of specific names for ingredients (for example, Vitamin B-5 is "dexpanthenol"—sounds "synthetic and dangerous, doesn't it?). Unless you take the time to study or carry an ingredients dictionary around with you, neither you NOR your store clerk (who, in reality probably knows LESS than you) will know what you're reading.

For example, we see Sodium Laureth Sulfate (SLS) listed as a "natural" ingredient, often with the notation "from coconut oil." SLS is a foaming agent that has been linked to cancer and is in nearly every shampoo and toothpaste today. Arsenic is natural—I wouldn't want it in any of my products. Just because it's natural doesn't mean it's good and just because it's synthetic, or has a "long name" doesn't mean it's bad.

# Besides progesterone, are there ingredients to look for, or to avoid?

While some of your customers will express concern about wild yam in Women's Balance Creme, we wonder how many know about the potential problems of other ingredients found in many cosmetics, cremes, and lotions.

The Safe Shopper's Bible, A Consumer's Guide to Nontoxic Household, Products, Cosmetics, and Food (Steinman, David & Epstein, Samuel S., MD) points out the potential carcinogenic impact of many common ingredients. For example, unless certified to be 1,4-dioxane contaminant-free, the following ingredients should be avoided: any ingredient that includes the word, prefix, or syllable PEG, Polyethylene, Polyethylene Glycol, Polyoxyethylene, eth (as in sodium laureth sulfate), or oxynol.<sup>1</sup>

Both Polysorbate 60 and Polysorbate 80 may also be contaminated with 1,4-dioxane.

Some preservatives contain formaldehyde, may release formaldehyde, or may break down into formaldehyde. These include: Diazolidinyl urea, DMDM Hydantoin, Imidazolidinyl urea. They should be avoided when possible.

The parabens (butyl, ethyl, methyl, and propyl) do not contain formaldehyde but have a higher than normal potential for allergic reactions. One study has shown that the paraben-class preservatives have a xenoestrogenic properties (compounds that have estrogenic effects on the body).

The following preservatives tend to be gentler and do not promote formaldehyde: Grapefruit seed extract, Phenoxyethanol, Potassium sorbate, Sorbic Acid, Tocopherol (Vitamin E), Retinyl (Vitamin A), Ascorbic Acid (Vitamin C) and Silver Chloride.

#### Other Ingredients to Watch

We know of one site, owned and run by a nurse, who states: "...for your safety, strict...quality control..." In spite of this claim her top recommended contains:

Stearal Konium Chloride

Stearalkonium Chloride is a Quaternary Ammonium Compound ("QAC"). QACs are synthetic derivatives of ammonium chloride. All QAC's "can be toxic..." (Source: Consumer's Ingredients of Cosmetic Ingredients, Fourth Edition.)

(This same cream lists no preservatives on its label.)

#### Is yam- or soy-based progesterone better?

Russell Marker, PhD, developed a process (now known as Marker Degradation) around 1943 to find a way to produce progesterone at an economically feasible price (then priced at \$80,000 per kilogram (!) to less than \$800 per kg within 10 years).

In 1941, researchers isolated a sapogenin, which was named diosgenin. Marker discovered this was best suited for his process and found that the Mexican Wild Yam contained the highest levels of this substance. Today, virtually all progesterone is derived from either wild yam or soy.

The final product is progesterone USP, which is indistinguishable from human progesterone. The final product has no relationship to its source plant. When any company or sales rep states that yam derived progesterone is better than soy derived progesterone (or vice versa), they don't know what they're talking about.

We have frequently heard, "I need yam derived progesterone because I'm allergic to soy [or the opposite combination]." We again assert that both forms of progesterone are identical—that's why it's labeled "USP."

## Phytoestrogens and Pixie Dust

Many creams on the market today contain phytoestrogens, which are plants that have estrogenic-like effects on the body. Many of these plants are very effective in addressing various symptoms women experience, such as hot flashes, menstrual cramps, feelings of depression, etc. While these plants offer solid benefits to their users, we have philosophical problems with the use of phytoestrogens in progesterone creams:

- 1. Most women begin to use progesterone because of symptoms relating to estrogen dominance. Does it make any sense to add more estrogenic effects to your body when you are trying to eliminate estrogen-based problems? We think not.
- 2. Look at the labels of many of these creams and you will see a cornucopia of herbs listed on the label. Many consumers will, at first (uneducated) glance, think, "Wow! I'm really covered with all of these great sounding herbs!"

Table 2: Herbal Ingredients Chart

Herb	Use/Function
Black Cohosh	Control hot flashes Decreases LH Induces labor
Blue Cohosh	Eliminates/reduces labor
Burdock Root	Prevents water retention
Chaste Tree	Increases LH
Damiana	Helps with menopause Strengthening reproductive system Hot flashes
Dong Quai	Blood tonic Stimulates uterus and stops pain Sedative
Irish Moss	Varicose veins Weight reduction
Lemon Balm	Helps with menstruation
Nettles	Reduces menstrual flow
Passion Flower	Hot flashes Hysteria
Red Raspberry	Aids in preventing cramps Good for pregnancy Strengthens uterus and entire reproductive system
Siberian Ginseng	Excellent adaptagen Hormonal balancing Stress
Squaw Vine	Most functions dealing with child bearing Strengthen uterus Used for painful menstruation and miscarriage threat
St. John's Wort Oil	Chronic fatigue Menopause Uterine Cramps
Tansy	Causes uterine contractions
Uva Ursi	Causes uterine contractions Good for post partum conditions
Yellow Dock	Aids in iron assimilation

(Source: The Little Herb Encyclopedia, Third Edition, Jack Ritchason, N.D., Woodland Health Books, 1995; and, Natural Hormone Replacement For Women Over 45, Jonathan V. Wright, M.D. & John Morgenthaler, Smart Publications, 1997.)

- 3. For example, one cream lists the following: 400 mg (per ounce) of Black Cohosh, "....Extracts of Red Raspberry, Nettles, Chaste Tree, Dong Quai, Blue Cohosh, Damiana, Irish Moss, Siberian Ginseng, Burdock Root, Uva Ursi, Passion Flower, Lemon Balm, Squaw Vine, Yellow Dock, and Tansy; St. John's Wort Oil;...." The table above illustrates the common uses of these plants.
- 4. A reading of the table above quickly illustrates that many of these plants are, in fact, used for contrasting purposes. See this, why would all of these "cross-purpose" plants be in the same product?
- 5. Is there any scientific evidence that any (or all) of these plants are effective when used in a skin cream? Just because progesterone can be used in a skin cream does not mean that all ingredients or all hormones can be used transdermally, e.g. the estrogen, estriol, is not readily absorbed through the skin because of the molecule size (it can be used more effectively intra-vaginally).

"Pixie Dust" is a term I coined to mean ingredients that are put into products in minute, ineffective levels—there is just enough to legally say it is in the cream. In fact, we know of companies that will buy a blend of many herbs and then put just enough of the blend into the cream to legally state the inclusion of the blend on the label. What they don't say is that their product contains 1/10 of 1% of a blend of the listed herbs. But the consumer believes that each herb is included at a level that is effective. This is misleading and deceptive.

Take the case of the cream ingredients listed above. If each plant listed were at a level that was efficacious, you would have a product that is nearly impossible to formulate as a cream, it would be unpleasant and unappealing from an aesthetic sense and it would be too expensive to market to the public.

## Conflicting Ingredients

You will note above that some of these herbs are used to induced cramping (contractions) and others are used to relieve cramping. Again, you can see conflicting desired effects. Now consider this: progesterone is a natural relaxant. Why would you put cramping ingredients into a product that, by its nature, helps fight cramping? If this seeming lack of knowledge/care is exhibited with the inclusion of "cross purpose" ingredients, why would you trust anything else about this product or its manufacturer?

# Miscellaneous Ingredient Questions

Occasionally we receive questions about ingredients that are not covered in one of the above sub-sections.

"[progesterone cream] contains various types of oils. I was told that oils affect the absorption of the progesterone because they form a barrier between the progesterone and the skin."

Each ingredient in a cream (or any other product) acts synergistically with each other—some good, some not so good. Progesterone is fat soluble; it is not water soluble, therefore some form of oil is needed. What John Lee, MD, and other experts write about is petroleum-based oils such as mineral oil and petrolatum which slow down the ability of progesterone absorption by forming an occlusive barrier on the skin. Bees wax, a popular cosmetic ingredient also inhibits progesterone. Other oils can either improve, have no effect, or also slow down the absorption of progesterone.

#### (Footnotes)

<sup>1</sup> Steinman, David & Epstein, Samuel, S., M.D., The Safe Shopper's Bible, MacMillan, 1995, pp. 189-95.

# Chapter Five: Filter The Nonsense

TE FREQUENTLY SEE NONSENSE published and somehow many of us believe that if it is in print or "online," it must be accurate. Virtually all statements and claims are made for the purpose of sales (including this report!). Take time to think about what is being said and why. Ask yourself if what you see or hear even sounds logical. When in doubt, get another opinion.

Here are a few "gems" we've found:

#### "Contains a combination of ingredients...

that may benefit women of all ages, formulated with whole wild yam root, rich in black cohosh, and 20 mg (2%) Progesterone USP." — "20 mg (2%) Progesterone USP" really means nothing. 20mg ... per ounce, per 1/4 teaspoon, per what? There is no such thing as (2%) Progesterone USP. Further, we checked their web site and could not find any listing of product ingredients. What else is in their product? "... formulated with whole wild yam root, rich in black cohosh,..." wild yam root is not rich in black cohosh – they are two different ingredients.

#### "One full press of this 4 oz 'pump dispenser'

delivers the recommended 20mg (2%) of natural progesterone. "— Have they, or anyone else selling cream in a pump, certified this claim? Again 20mg (2%) is both meaningless and inaccurate. 20mg progesterone per 1/4 teaspoon is approximately 1.6% by volume of one ounce of cream. 20mg is 0.02% of one gram. These claims are misleading to women who are trying to find quality solutions to their problems.

#### "Their GMP laboratory uses only the highest quality

ingredients from trusted sources to ensure the consistency and reliability of their premium product." — This "unbiased product reviewer" stated the above. Do you really know this to be true? For example, some of the claims on the reviewed site stated:

#### "Progesterone: (USP 2%) Pharmaceutical Grade

(550 mg. per oz. 1650 mg per tube)." — As I stated earlier, there is no such thing as "Progesterone USP 2%.

#### "Lecithin, Evening Primrose Oil and Sesame Oil:

These special oils are very high in Omega 3 and Omega 6 factors which are necessary for transdermal liposome delivery. "— This is a "nonsense" statement. But assuming it is accurate, do they offer any substantiation for this claim? In fact, parts of the wording from this site came from some of our original product information and ingredients used in an early generation of Women's Balance Creme.

#### "Silver Chloride: A full spectrum natural preservative

which eliminates the need for any of the paraffin waxes that are used in many other products, which can hinder delivery of progesterone." — Silver chloride does not eliminate the need for paraffin waxes. The two are not related. We were the first company to use Silver Chloride. The company making this claim knows nothing about the preservative, or so it would seem from this statement.

#### "Vitamin A Palmitate, Allantoin, Xanthan Gum,

Arnica and Panthenol (Vitamin B-5): Aid in the delivery and stabilization of our cream. The special Vitamin B-5 is used to open the capillaries for quick absorption into the skin." — Panthenol, actually dex-Pathenol, is not used to open capillaries. If it is, where is the substantiation? Also, each of these ingredients were first used in Women's Balance Creme and to date, we have <u>only</u> seen these ingredients in "knock-offs" of our earlier formulations.

#### And one of the biggest offenders of all:

"All our ingredients are organic ...." — Water is a major component of all creams. Have you ever seen, or heard of "organic water"? Not only are these claims <u>untrue</u>, they are deceptive.

Simply look at the ingredient list of any product making such a claim and ask yourself if the names cited on the ingredient list even appear to be organic. Further, ask the company for their documentation to prove it—they won't have any. In our early days we were sold an ingredient as "organic." We asked the supplier to document the claim; he could not. We changed suppliers.

#### Food Grade Progesterone?!

Just when you'd thought you'd seen it all, here is one claim that is laughable, frightening, and just plain stupid: [Name left out intentionally] "is the only Food Grade Progesterone on the market." Imagine! Now you don't have to rub it in, you can eat it! There is no such thing as "food grade progesterone."

What's frightening about this claim is that it is made by the owners of a health food store. The same class of people that many shoppers rely (ill-advisedly) upon for information about health and nutritional supplements.

# Chapter Six: Packaging

## Should I buy progesterone cream in a jar, tube, or a pump?

#### Jars

This is a personal choice question more than anything else. In his books, Dr. Lee writes that he prefers a tube. In private conversations, he has stated he likes jars. The issue of oxidation of the progesterone is important only if the cream is not used within three months. If it is not, then a tube or pump is better. By the same token, if you do not use 2 ounces within three months, you are probably not using enough.

We often hear: "Jars are not a sanitary way of dispensing cream." The critics are right if you use your cream after changing the oil in your car or digging in your garden. Our experience is most women use the cream with clean hands. Our creams are preserved to the point that ordinary usage is not a problem.

We know of one web site that states that they will not sell "jar" container products because, in their words, "hormone products absorb every contaminant instantly and easily. ...the product is contaminated after the first use." This is mis-leading nonsense. Any product that is properly manufactured and tested for spoilage is not "contaminated after the first use" when used properly.

#### Tubes

Tubes are another matter. Those selling progesterone in a pump will tell you: "It is convenient"—we agree. But there is one drawback: any tube will produce 3–5% of waste. We think it is easier to use a jar rather than cutting a tube open to get the "very last drop."

#### Pumps

We commonly hear: "Each pump will deliver exactly 20 mg of progesterone per each pump – exactly what a woman needs."

We strongly disagree with this assertion on a number of grounds:

- We don't know, and neither do they, that "each pump delivers 20 mgs of progesterone."
- If the statement is, in fact, correct, then another problem arises, the manufacturer has created a drug out of the product. Over-the-counter natural progesterone creams are legally sold as cosmetics—not drugs.
- The pump concept also falls under the "daddy knows best" idea and that each woman needs exactly the same amount of progesterone and she is not smart enough to determine her own needs. We reject this notion.

There are two solid cases for using a airless vacuum pump:

- Convenience—who can argue with the notion that a small pump is not convenient?
- You don't have to put your finger in a jar with a pump. True, but you'll still have to touch the cream to rub it in.

# Chapter Seven: General Usage & Common Questions



T THIS POINT WE WANT TO MAKE A COMMENT based on years of working with women: *if you choose to use progesterone creams, be committed and be consistent.* 

#### Do all women experience the same results?

Although many women experience positive results quickly, many women may need to commit to several months before they have achieved their desired results. Bear in mind, you didn't get to the point where progesterone supplementation is needed in a matter of hours, days, or even months. Your present needs most likely have developed over many years.

#### If some is good, is more better?

Another consideration is to use common sense. Often, it is tempting to think that if a little is good then a lot would be better. This is not the case. You are working with important substances within your body and many times small, subtle changes are the most effective.

Finally, get competent advice.

#### How much cream is applied?

Normal usage is between 1/8 and 1/4 teaspoon, applied twice a day, to areas of the body high in capillary concentration such as face, chest, throat, breasts, palms of hands and soles of feet, rotating the application area as desired.

#### Premenopausal women:

If you count the beginning of your period as day 1, start application on day 12 and continue until day 26. If your cycle is longer, you may want to continue until day 28. If bleeding starts before day 26, or before it normally would, stop using the cream and begin counting up to day 12 and then start using it again.

#### Menopausal women not receiving estrogen:

You have a wider choice in your timing. You might want to base your use on the calendar month and apply the creme three weeks out of four, then discontinue until the next month. If your symptoms are severe, you may safely increase the amount of creme applied for a couple of months and then gradually decrease.

#### Menopausal women taking an estrogen supplement:

Dr. Lee recommended that estrogen supplements should be reduced by one-half when starting progesterone. He said that if you do not, you may experience an increase in the sensitivity of your estrogen receptors. Your negative symptoms may actually increase for a short time but this is only temporary. If you quit using estrogen abruptly, you may experience vaginal dryness and/or hot flashes. This can be prevented by gradually reducing estrogen and use progesterone creme.

Women may choose to establish a goal of eliminating synthetic estrogen entirely. Dr. Lee suggests doing this over a three to six month period.

If you are taking a progestin, such as Provera, he recommended that you should stop taking it immediately when you start using the creme. We strongly recommend you see your health care

professional before ceasing any prescribed medication.

## Does progesterone play a role in osteoporosis?

Dr. Lee has written that "the presence or absence of estrogen supplements had no discernible effect on osteoporosis benefits [and that] *progesterone deficiency* [emphasis added] is a major factor ... in menopausal osteoporosis." Some of Dr. Lee's patients achieved bone density increases by as much as 35% with the use of natural progesterone. We have experienced many positive reports over the last six-plus years.

#### Patience

Be patient. Every woman's body chemistry is different. It may take some personal adjustments to reach levels that are beneficial. Many women notice results within a very short period of time, however it can take up to three months to be effective.

# CHAPTER EIGHT: LEGISLATION, ETC.

## Drug, Supplement, or Cosmetic?

Many comments are made about natural progesterone creams being (1) a drug, (2) an over-the-counter drug, (3) a supplement, or (4) a cosmetic. So, what is it?

The answer, while seemingly simple, is not. It could be any of the above, depending on how and who is selling it. We are often asked, "Why don't you tell women what progesterone will do?" Answer: because if we do, then we create a drug or and over-the-counter drug out of a product that is legally sold as a cosmetic.

We try to avoid making any medical or medical-relate claim. There is enough literature available for the general consumer to learn what progesterone does, does not, and whether it is appropriate for his or her use. There are many companies on (and off) the internet that make medical claims (both accurate and as we've pointed out in this book, inaccurate). Our advice is straightforward: find credible third party sources of information and read.

#### Proposition 65

California has a law on the books, the Safe Drinking Water and Toxic Enforcement Act of 1986, which is populary known as "Prop 65." Prop 65 contains a list of chemicals or substances "known to the state of California to cause cancer, birth defects, or other reproductive harm, and to inform citizens about exposures to such chemicals."

Progesterone is one of over 700 substances on the list in spite of scientific evidence to the contrary. As of this writing (August 2004), a new summary of reproductive information (from old literature) has been published with the intent of having a public meeting in November 2004 which will probably establish "recognized safe levels of progesterone usage." The link for this document is: <a href="http://www.oehha.ca.gov/prop65/hazard\_ident/pdf\_zip/progeshid5.pdf">http://www.oehha.ca.gov/prop65/hazard\_ident/pdf\_zip/progeshid5.pdf</a>.

Companies with more than nine employees are required by the law to post a "Prop 65" label warning that states: "This product contains ingredients known to the state of California to cause cancer, birth defects, or other reproductive harm."

## Is progesterone as dangerous as "Prop 65" would lead you to believe?

That's a hotly debated question. While it is interesting to note that medically prescribed synthetics have all of the above listed dangers, they are exempt from Prop 65 warnings because they are (1) prescribed by licensed professionals, and (2) they are to include similar warnings required by the FDA. (Have you ever tried to read and FDA warning?)

Once again, we encourage you to read current, and accurate literature on the topic. If you do, we believe that you will not be inhibited from using natural progesterone.

# CHAPTER NINE: CONCLUSION

At this point we hope you have determined a number of things:

- This book is not all-inclusive. We expect you to read and study.
- This book is not unbiased. We are in the business of selling progesterone cream. We have endeavored to be open and honest in our opinions and observations. If there are inaccuracies in this book, let us know; show us the substantiation for your comments. If you're correct, we'll make changes—and thank you for the assistance.
- If you are not using progesterone, we think you should. You owe it to yourself and your family to learn more about why.
- While we would like you to try Kokoro® Women's Balance Creme, it is more important that you use any quality progesterone cream.

Many times in life we often ask ourselves if what we do really makes a difference to anyone. We had been in business for only a few months when I received a phone call from a woman in Arkansas who told me that our cream saved her life and her marriage. I was uncomfortable with this assertion and I thanked her. She repeated her comment twice more and at the third repetition, she began to cry—I started to cry. We talked for two and one-half hours. When she hung up I knew the answer to the question. I've never looked back. We at Kokoro are committed to providing you the best we can offer. We wish you well on your journey of discovery and health.

If you have comments or questions, email us at: <a href="mailto:info@kokorohealth.com">info@kokorohealth.com</a> or you can find us on the internet at <a href="http://www.kokorohealth.com">http://www.kokorohealth.com</a>.

# Chapter Ten: Reading List

Here are a number of books that we have found to be helpful:

Estrogen Alternative, The, 3<sup>rd</sup> Edition, Natural Hormone Therapy with Botanical Progesterone, Raquel Martin and Judi Gerstung, DC

Hormone Heresy, Sherrill Sellman

John R Lee, MD, Newsletter, The, Lee, John R, MD and Hopkins, Virginia.

Little Herb Encyclopedia, The Handbook of Natures Remedies for a Healthier Life, The, Ritchason, Jack, ND, PhD, and Master Herbalist. Woodland Health Books, 1995.

Natural Hormone Balance for Women, Reiss, Uzzi, MD, Pocket Books.

Natural Woman, Natural Menopause, Marcus Laux, ND, Harper Collins.

Safe Shopper's Bible, The, A Consumer's Guide to Nontoxic Household, Products, Cosmetics, and Food, Steinman, David & Epstein, Samuel S., MD, MacMillan Press.

Scientific Validation of Herbal Medicine, The, Mowrey, Daniel B., PhD, Keats Publishing, 1986.

Today's Herbal Health, Third Edition, Tenney, Louise, MH, Woodland Books, 1992.

What Your Doctor May Not Tell You About Breast Cancer, Lee, John R, MD, Zava, David, PhD, and Hopkins, Virginia, Warner Books.

What Your Doctor May Not Tell You About Menopause, Lee, John R, MD and Hopkins, Virginia, Warner Books.

What Your Doctor May Not Tell You About Premenopause, Lee, John R, MD and Hopkins, Virginia, Warner Books.

Woman's Book of Herbs, The Healing Power of Natural Remedies, A, Soule, Deb, Carol Publishing Group, 1995.