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AN EXCELLENT NEW STUDY ON PROGESTERONE CREAM

A well-designed new study of women using progesterone cream has added greatly to the mounting evidence that natural hormones work as advertised.

Nearly every day we receive e-mails from women who ask what to tell their doctor when he or she demands studies proving that natural hormones are safe and effective. Granted, using natural hormones as recommended by Dr. Lee mimics closely what the body would do naturally, and granted there are hundreds of physicians happily using natural hormones safely and effectively, but it's always good to have studies to point to.

We do have the studies of Helene Leonetti, M.D. showing that progesterone cream reduces hot flashes, and that it protects the uterus from the effects of estrogen. In Issue 4 of the Hopkins Health Watch, I told you about what's being called the "Bassett Healthcare Study," led by researcher Anne Hermann, M.D., which showed beyond a shadow of a doubt that progesterone cream is very well absorbed and utilized by the body. Ironically, this study is now being used as a justification for making progesterone cream a prescription item because (surprise surprise) it really works!

Now we have a newly published study from researchers at the College of Nursing and Health Sciences at The University of Texas at Tyler, led by Kenna Stephenson, M.D., which clearly shows that 30 women using 20 mg of progesterone daily, in a cream, had relief of their menopausal symptoms and didn't have the side effects associated with the progestins such as Provera. The study was published in the November issue of *Blood: The Journal of The American Society of Hematology*.

According to a press release published on www.womeninbalance.org, Dr. Stephenson said, "In our study, we tested progesterone cream for safety, efficacy and any short term benefits or harmful effects, by looking at biomarkers. Biomarkers will show up right away as an indication of such serious diseases as cancer, heart disease, infections and dementia. With natural progesterone cream, we found no markers for inflammation or clotting—indicators for most of the serious diseases related to use of traditional hormone replacement therapy, like Provera and Prempro."

Specific Biomarkers Look Good

Stephenson added that in women with higher than normal cortisol levels, there was a marked decline in the level of cortisol to normal range while they were using the progesterone cream as compared to placebo. Stress activates cortisol, and an abnormal cortisol pattern has been associated with an increased risk of heart attacks, cancer, obesity and other diseases.

The study specifically looked at night cortisol levels, and found that these decreased with the use of progesterone. Those of you who have read our interviews with Dr. David Zava of ZRT Lab will remember that high night cortisol is one of the risk factors for breast cancer.

Because PremPro and Provera have been shown to increase the risk of strokes and heart attacks, Stephenson and her team also looked specifically at blood factors that would predispose women to clotting (strokes, heart attacks), and to blood vessel spasm (heart attack). They found that these parameters remained normal in the women using progesterone cream.

“The results of the study are encouraging ,” Dr. Stephenson said, “because it is clinical evidence of the viable option of bioidentical progesterone cream for menopausal women in their search to relieve menopause symptoms.”

The Abstract of the Stephenson Study

Stephenson, Kenna, Price Carol, Kurdowska Anna et al , “Topical Progesterone Cream Does Not Increase Thrombotic and Inflammatory Factors in Postmenopausal Women,” *Blood* , Volume 104, issue 11, November 16, 2004 .

Postmenopausal women have an increased risk of cardiovascular disease, and heart disease is the leading cause of death in postmenopausal American women. Conventional hormone replacement therapy has been shown to result in an increase in thrombotic events in large prospective clinical trials including HERS I, and the recently halted Women's Health Initiative.

One possible mechanism for this observed increase is the unfavorable net effects of conjugated equine estrogens and medroxyprogesterone acetate on the hemostatic balance and inflammatory factors. An estimated 50 million American women are peri or postmenopausal and clinical therapies for menopausal symptoms remain a significant challenge in light of the known thrombotic risks.

In this prospective blinded study, we examined the short-term effect of topical progesterone cream on menopausal symptom relief in 30 healthy postmenopausal women. Potential adverse effects of topical progesterone on hemostatic and inflammatory factors and cortisol levels were also examined. Subjects were randomized

to first receive either 20 mg of topical progesterone cream or placebo cream for 4 weeks.

Following a subsequent 4-week washout period, subjects were crossed over to either placebo cream or active drug for an additional 4-week period. In each case, progesterone and cortisol levels were monitored by salivary sampling. Baseline values, 4-week follow-up values and end-of-study values were also obtained for the Greene Climacteric Scale, total factor VII:C, factor VIIa, factor V, fibrinogen, antithrombin, PAI-1, CRP, TNF α , and IL-6.

For subjects receiving 20 mg of topical progesterone cream for 4 weeks, Greene Climacteric Scale scores were consistently and significantly improved (decreased) over baseline, demonstrating significant relief from menopausal symptoms.

In addition, in a subpopulation of hypercortisolemic women, topical progesterone was associated with a favorable decrease in nocturnal cortisol. Surprisingly, and in sharp contrast to earlier studies with conventional hormone replacement therapy, topical progesterone had no effect on any of the hemostatic components examined: total factor VII:C, factor VIIa, factor V, fibrinogen, antithrombin, and PAI-1 levels were all unchanged. Levels of CRP, TNF α and IL-6 also remained unchanged.

From this study we conclude that administration of topical progesterone cream at a daily dose of 20 mg significantly relieves menopausal symptoms in postmenopausal women without adversely altering prothrombotic potential. Since the thrombotic complications that are typically observed with conventional hormone replacement therapy do not seem to occur with topical progesterone, this treatment should be seriously considered as an effective and safe alternative clinical therapy for women suffering from menopausal symptoms.

PCCA CONFERENCE GIVES THE LATEST SCOOP ON NATURAL HORMONES, THYROID, ADRENAL FATIGUE AND MORE...

Cutting edge research on using thyroid supplements, wonderful insights on diagnosing and treating adrenal fatigue, and some tips on managing stress and balancing hormones were all part of a recent "Functional Endocrinology Symposium" in Houston sponsored by the Professional Compounding Centers of America (PCCA), a group that supports compounding pharmacists. A compounding pharmacist is one who, in addition to dispensing standard prescription medications, also makes custom medications. This is particularly important when it comes to natural hormones. Remember, the ideal process for achieving hormone balance includes an assessment of hormone balance that includes looking at symptoms plus a saliva hormone level test, followed by replacing the deficient hormones in the dosage and timing that's optimal for each person. A compounding pharmacist can work with a doctor and patient to create the best possible hormone combination for the individual, and can change it at any time if symptoms of excess or deficiency occur.

Help in Finding a Doctor who Uses Natural Hormones

Something I discovered at this conference, is that because PCCA members have stayed current on the best ways to use natural hormones, doctors often depend on them to work one-on-one with their patients to maintain hormone balance over the months and years. Conversely, compounding pharmacists are a great resource for finding doctors who prescribe natural hormones. In other words, if you're looking for a doctor who uses natural hormones, one of the first things you can do is check your yellow pages or go to www.iacprx.org, the website of the International Academy of Compounding Pharmacists, to find a compounding pharmacist in your area. You can then call the compounding pharmacist to get the names of doctors who are using natural hormones.

The Latest Scoop on Treating Low Thyroid

The PCCA symposium was a great way to get the latest scoop on what health care professionals are learning about hormone balance, as well as some fascinating factoids from experts in the field. For example, Ridha Areem, M.D., author of the book *The Thyroid Solution*, pointed out that while T4 is the most abundant thyroid hormone, what's more important is its conversion to T3, which is a much more active thyroid hormone. Furthermore, only 20% of T4 is converted to T3 in the thyroid gland—80% is made in other glands and organs, particularly the liver. This means that good liver function is closely tied to good thyroid function. Areem also emphasized that thyroid hormone levels can fluctuate when you're ill, sleep deprived or stressed, and that these factors should be taken into account when testing thyroid hormones.

Another speaker on the subject of thyroid was John M. Lee, M.D. (I kid you not!), a doctor from Australia who has made the work of John R. Lee, M.D. instrumental in his practice. This Dr. Lee has delved deeply into the subject of thyroid imbalance and has a unique approach to treating patients with low thyroid function. He believes that conservatively, 40% of women in the U.S. have measurably low thyroid and as a result are suffering from fatigue, depression, cold hands and feet, dry skin and hair and many other symptoms associated with hypothyroidism (low thyroid).

He pointed out how misguided it is to prescribe T4 or a combination of T4 and T3 to hypothyroid patients when in fact there are no T4 receptors in the body! T4 has to be converted to T3, which is a very complex process and is followed by an equally complex process of getting it into the cells. And yet, when we supplement with thyroid, it's with either T4 alone (Synthroid/thyroxine) or with a combination of T3 and T4—Thyrolar or Armour.

The conventional medical wisdom on this approach is that because T3 is used up very rapidly, when you take it orally it creates a steep peak and then a steep drop, which can result in a rapid heartbeat and other *hyperthyroid* (high thyroid) symptoms. The other is fear of bone loss. To get around this problem, Dr. Lee has developed a slow-release T3 which he has used very successfully with his patients. If you're interested in trying a

slow-release T3, your doctor can call the Central Ohio Compounding Pharmacy at (614) 847-0109, or e-mail them at cocp@compuserve.com.

Dr. (John M.) Lee points out that any thyroid function problem should be examined in the larger context of adrenal fatigue, hormone imbalances such as estrogen dominance, nutritional deficiencies, liver dysfunction, and digestion and absorption problems. For example, it takes the help of a long list of vitamins, minerals and amino acids to make the conversion from T4 to T3, and to get the T3 into the cells. Just a simple deficiency of the trace mineral selenium can interfere with the conversion of T4 to T3. I'm sure we'll be hearing more from the Australian Dr. Lee in the future.

If you're interested in what your thyroid hormone levels are, you can do a simple blood spot test at home, without a prescription. Here's where to find it: [Thyroid Blood Spot Test Kit](#).

The Latest Scoop on Adrenal Fatigue

One of the more interesting speakers at the PCCA symposium was Dr. James L. Wilson, a naturopath and chiropractor who wrote an excellent book called *Adrenal Fatigue: The 21 st Century Stress Syndrome*. He has used his extensive clinical experience to pinpoint the signs and symptoms of adrenal fatigue, and to zero in on the best methods of treating it. As Dr. Lee has pointed out in all of his books, it's impossible to achieve real hormone balance if you have tired adrenal glands.

And guess what Dr. Wilson's bottom line, basic treatment recommendations include? You guessed it: wholesome food, plenty of sleep, regular moderate exercise, stress management and balanced hormones. Sound familiar? However, there are lots of specific dietary recommendations in Dr. Wilson's book, and he has developed an excellent line of supplements specifically for those with adrenal fatigue, which you can find at his website, www.adrenalfatigue.org.

The Latest Scoop on Progesterone is that More is Not Better

George Gillson, M.D., gave two talks, one on insulin and metabolic syndrome (see Issue 5 of the Hopkins Health Watch), and one on the "Hormone Symphony" (Dr. Lee's original metaphor for the complex interplay of hormones). Dr. Gillson pointed out—along with other speakers at the symposium—that the proper response when natural hormones aren't working, or are causing side effects, isn't to raise the dose, but to *lower* it. I was gratified to hear this emphasized, as it was a point that Dr. Lee was constantly trying to drive home. Both conventional physicians and compounding pharmacists seem to have a tendency towards overdosing with hormones—it's the old, "if a little is good, more must be better," approach, which is pretty much guaranteed to backfire when it comes to hormones.

My good friend Dr. David Zava of ZRT Lab gave two talks, one on detecting hormone imbalance by saliva and blood spot testing, and the other on the hormone link to breast

cancer. You can find these details in our book, [What Your Doctor May Not Tell You About Breast Cancer](#).

The Stress Connection

Every speaker at this symposium emphasized the role of stress in illness and in hormone imbalances. There's just no way around it: if you're constantly stressed it's going to affect every cell of your body in a negative way, and over time it's sure to create illness. Poor diet, lack of sleep and not enough exercise are forms of stress on the body, but the most harmful type of stress is the mental/emotional kind caused by rushing around all day, financial worries, relationship issues, and all that goes along with trying to maintain our new millennium zoom zoom lifestyles. There's a lot to be said for slowing down and simplifying; for introspection and contemplation designed to balance the mind/emotions; and for having a spiritual perspective on life that can help remind us what our real priorities are.

FLU SHOT REDUX

A lot of you must have noticed by now that every fall there's a flu scare—it's the wrong strain of flu in the vaccination, or it's a new, more virulent flu, or this year it was a shortage of the flu vaccine. The media eats up the scare value and panicky people stand in line for hours to get their shots.

First, let's put flu vaccinations in perspective. What's the worst that could happen if you get the flu? You could die. However, the chances of a healthy, middle-aged adult dying from the flu are astronomically small. There were only 272 flu/pneumonia-related deaths among people ages 5 to 49 between late 1990 and early 1998. During that same time period, about three times more people were struck by lightning. Furthermore, a healthy adult who is vaccinated still has about a 50-50 chance of getting the flu.

The Centers for Disease Control (CDC) lumps together mortality (death) statistics for the flu and pneumonia, but even at that, more than 90 percent of flu and pneumonia-related deaths occur in people over the age of 65. Your risk of dying from illness related to the flu rises dramatically as you age—but this is complicated by the fact that most people that age have other underlying conditions, such as diabetes, heart and circulatory diseases, and significantly decreased immune function. Even at that, the estimated number of people over the age of 50 who die from flu-related illness and/or pneumonia each year is around 58, and over the age of 65 the number is about 915. A flu shot reduces the risk of getting the flu in the elderly by 10 to 30 percent, depending on which study you read.

How about kids? Among children in the U.S. age less than one year (the flu shot is not recommended for children under six months) to four years old, there were an estimated 38 pneumonia/influenza-caused deaths reported between late 1990 and early 1998. That's an average of 4.75 deaths a year.

The very young, the very old and those with compromised immune systems, who supposedly need the flu vaccination the most, are the ones least likely to be able to mount a strong enough antibody response to fight off the flu. In other words, the flu shot is least effective in the populations who need it most.

Now that we can safely assume that your chances of dying of the flu are very small unless you're among the frail elderly (and even then the flu shot protects you only 10 to 30 percent of the time), what's really at issue is getting sick. That's unpleasant and it's a nuisance. Get lots of herbal tea, lots of kleenex, and hunker down. If you want to play the Pollyanna game and find something good in the flu, according to Philip Incao, M.D. there's nothing like a few days of fever to cleanse the body and upgrade and reinvigorate the immune system.

And by the way, flu season is just getting underway, but so far the CDC reports a "very low" incidence of flu outbreaks.

THE BEST OF JOHN R. LEE, M.D.

In the last issue of the *John R. Lee, M.D. Medical Letter* in October 2003, Dr. Lee wrote about the new contraceptive, Seasonale, designed to both provide birth control and reduce menstrual periods to four times a year. He pointed out all the reasons why this is not a smart or safe idea. Slick TV ads for Seasonale have recently appeared, which means millions of women will be debating its merits. Yes, it's FDA approved, but so were DES, estrogen-only HRT, PremPro, Vioxx and a long list of other unsafe drugs. Are there any long-term studies for Seasonale? Nope. It might be the next best thing since sliced bread, but then again, it might not. Buyer beware.

Here's an excerpt from the October 2003 article:

A BIRTH CONTROL PILL THAT ALSO STOPS MENSTRUAL PERIODS

Conventional medicine continues to peddle unproven drugs that will harm women.

By John R. Lee, M.D.

Just when you think that perhaps conventional medicine has learned its lesson about women's hormones, something else happens that tells us not much has changed. The latest craziness is an oral contraceptive named Seasonale which is designed to limit a woman's menstrual periods to four times a year (once a season). The primary justifications for this new drug are that periods are inconvenient and messy, and that women with PMS will get some relief.

Let's review the facts about oral contraceptives and see whether it's smart to have fewer menstrual periods and continuous use of synthetic hormones.

Are Periods Really Necessary?

Menstrual periods are only important if you have a uterus, want to have children, and want to avoid the possible complications of having extended tissue buildup in the uterus. Each month, over the course of a normal menstrual cycle the uterus builds up a layer of tissue (the endometrium) in preparation for the possibility of receiving and nurturing a fertilized egg. When the egg doesn't appear, hormone levels drop and the tissue is expelled in menstruation. The blood-rich endometrium that is built up is also rich in hormones and other biochemical signals that say, "Grow, grow, grow!" Shedding the endometrium each month is one of Mother Nature's strategies for protecting a woman from too much growth in the uterus, or uncontrolled growth, which can result in cancer or fibroids (benign tumors in the uterus). So yes, menstrual periods are important if you have high enough hormone levels to create a menstrual cycle.

Do Women Need the Monthly Ebb and Flow of Hormones?

Some will argue that contraceptive hormones block the production of one's own hormones and substitute the synthetic hormones present in the contraceptive, which don't create as much endometrial buildup. This may be true of some of the contraceptives, but what is the price of shutting down a woman's ovaries and thus blocking her own hormone production?

What happens when the production of a woman's own progesterone is blocked? None of the progestins in contraceptives fully duplicate progesterone's beneficial effects, including bone building; protection against estrogen dominance; a balanced libido; a calming influence on the brain; efficient fat burning; normal fluid levels; and the normalizing of blood sugar, thyroid levels, blood clotting, blood vessel tone, and cell oxygen levels.

The normal production of estrogen by the ovaries is also blocked by contraceptives. Natural estrogen in normal amounts promotes normal female development; plays a role in cognitive function and memory; contributes to healthy vaginal and cervical mucus; contributes to healthy bladder function; promotes healthy sleep patterns; contributes to healthy skin and good wound healing; and keeps progesterone receptors active. The ovaries also produce testosterone, which contributes to bone building; healthy libido; healthy skin and wound healing; muscle development; faster metabolism; and brain function.

The Pressure to Be on the Pill

I know very well from having a family practice for 30 years that there is enormous pressure to help younger women avoid pregnancy, and the risks inherent in unwanted pregnancy. Thus, taking contraceptive drugs becomes what is known as a risk-benefit equation. In most doctor's minds, and in many women's minds, the positive of avoiding pregnancy outweighs the negative of contraceptive side effects, so nobody really wants to talk about the side effects. Although I prefer that women not use contraceptive

hormones, I do understand that their use can be justified. However, I do not see any justification for using Seasonale.

There aren't any long-term studies on Seasonale—the research that led to its approval lasted for only a year, and there was no placebo group. In other words, Seasonale was only tested against other contraceptive drugs. (Anderson and Hait, *Contraception* 2003; 68: 89-96.) The consequences of suppressing menstruation and exposing the body to continuous, long-term synthetic hormones is primarily going to show up in the long run. This means that once again, women are being treated as guinea pigs. How many years will it be this time, and how many women will have to get sick and/or die before this drug is pulled from the market?

So much for evidence-based medicine. It's a good bet that the consequences of suppressing menstrual cycles and taking synthetic hormones continuously will include increased bone loss, a greater risk of endometrial cancer, infertility, blood sugar problems, and chronic hormone imbalances later in life that we can only speculate on now. And that doesn't include a magnification of the risks we already know about. Let's examine those risks...

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