



**Total Health**  
 PHARMACY  
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 Your Compounding Specialty Pharmacy

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## LETTER FROM THE EDITOR

Dear Friend,

This document is a collection of information which will provide you with extensive details on Bio-Identical Hormone Replacement Therapy (BHRT). The packet includes a discussion of the following topics.

- Hormone Replacement Therapy in light of the Women's Health Initiative Study - including information on safety and health benefits
- Bio-Identical Hormones - their source and information on available dosage forms to meet your individual needs
- Saliva Hormone Testing - highlighting which hormones can be tested and advantages of testing.
- A Confidential Hormone Replacement Evaluation Form - containing questions about your medical history, symptoms you may be experiencing of deficiency or excess hormone, and your hormone replacement goals. Completed forms may be returned to Total Health Pharmacy or Dr. Wojcicki, an internal medicine specialist with expertise in BHRT, to begin developing a BHRT therapy that is right for you.

Thank you for allowing Total Health Pharmacy to assist you in your evaluation of BHRT. We hope you find this information useful. Please contact us any time if you have any additional questions or if we can assist you in any other way.

Best regards,

*Miranda*

Miranda Tawfik, Pharmacist/Owner



*Having your hormone levels checked provides you and your healthcare providers with an invaluable picture of your body's hormonal status. With your hormone level results, a more accurate and individualized therapy can be designed for you.*

## THE WOMEN'S HEALTH INITIATIVE STUDY AND HORMONE REPLACEMENT THERAPY

In light of the July 2002 Women's Health Initiative (WHI) study by the National Institutes of Health, we want to address women's most common questions and concerns about hormone replacement therapy (HRT). We hope this piece will provide you with the answers you need to decide whether HRT is right for you.

### What are the specific risks about HRT that were uncovered by the WHI study?

The study found no difference in death rates between the group on hormone replacement therapy and placebo. However, specific risks in several areas were identified.

**Heart Disease:** In the first year, the study showed a small, but statistically significant increased risk for heart-related events such as non-fatal heart attacks.

- 37 per 10,000 women on HRT
- 30 per 10,000 women on placebo

**Breast Cancer:** The study showed a statistically significant increase in risk of breast cancer after 4 years

- 38 per 10,000 women on HRT
- 30 per 10,000 women on placebo

The risk for the HRT group appears to be cumulative (increases over time) and also increases with the placebo group too, as advancing age also increases one's risk for breast cancer. As an individual, your risk, taking the exact HRT regimen studied, would be increased less than one tenth of one percent per year.

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## WOMEN'S HEALTH INITIATIVE (CONTINUED)

**Stroke:** There was a 41% increased risk of stroke for the HRT group

- 29 cases per year per 10,000 women on HRT
- 21 cases per year per 10,000 women on placebo

**Blood Clots:** The HRT group had a greater rate of blood clots than the placebo group

- 34 cases per year per 10,000 women on HRT
- 16 cases per year per 10,000 women on placebo

**Were there benefits associated with HRT in the WHI study?**

Yes, there were benefits to the HRT regimen studied. The benefits noted during the study are as follows:

**Colon Cancer:** The risk of colon cancer was reduced by 37%. The benefit appeared after 3 years of use and became more significant over time.

**Bone Fractures:** The HRT group had a 24% reduction in total fractures, and a 34% reduction in hip fractures.

**Vasomotor symptoms:** Beyond the study, it is commonly accepted that HRT is the most effective treatment for the relief of vasomotor symptoms such as hot flashes and night sweats as well as sleep disturbances, which can affect both physical and mental health. HRT is also effective in treating symptoms such as vaginal dryness and sexual discomfort.

**How do I apply the conflicting risks to my own situation?**

Knowing how to apply the risks uncovered by the WHI study is complex for both you and for your physician. When considering any HRT regimen, one must closely review the following with your physician:

- What are your GOALS for taking HRT
- What are your expected personal BENEFITS gained through HRT use?
- Weigh your own personal RISKS, taking into account your individual and family history for conditions such as heart disease and breast cancer.

Since the percentage of women in the WHI study who actually had adverse effects from the HRT was small, the size of the risk for each individual on HRT was also small. What the study's authors had decided was that since this drug is taken by millions of women over many years, the risks can translate into a large number of women with adverse effects (heart disease, stroke, or breast cancer). As such, it cannot be recommended for everyone.

Speak to your doctor about your individual risks and benefits.

**What is the bottom line for women trying to make a decision about taking HRT?**

The bottom line is that HRT is still an acceptable option for the treatment of menopausal symptoms. The American College of Obstetricians and Gynecologists recommend some guidelines on the use of HRT in women:

- HRT should be taken for the shortest possible time that works for you
- The smallest effective dose of HRT should be taken
- Consult your physician regularly (at least once a year) to reevaluate your HRT
- Screen for breast cancer regularly



*It must be noted that the WHI study only looked at one hormone replacement therapy regimen. This regimen was the 0.625 mg conjugated equine estrogen and 2.5 mg medroxyprogesterone acetate (Prempro®), a synthetic progestin given once daily. It cannot be assumed other hormone regimens are safer or more dangerous until more conclusive data is gathered on each option.*



**More Questions? Contact us.**

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## BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

Have you ever wondered if bio-identical hormone therapy (BHRT) is right for you? Read below to find some answers.

### What are bio-identical hormones?

Bio-identical hormones are hormones that are identical in their molecular structure to the hormones found in your body. Your body recognizes them as “self”, not as a foreign substance.

Your body can utilize the BHRT hormones more efficiently because they fit your cell's hormone receptors perfectly. Your body also has methods to remove used and/or excess hormones from your body (hormone metabolism). These metabolism mechanisms already exist for the bio-identical hormones, while they do not for the synthetic hormones.

### Where do bio-identical hormones come from?

Bio-identical hormones, also known as “natural” hormones are not human in origin, but are actually derived from a plant oil called diosgenin. Diosgenin is extracted from soybeans and certain wild yams. Diosgenin is very similar in its chemical structure to the human steroid hormone cholesterol. Once extracted it is chemically altered to exactly match our human hormones. Allergenicity to these plants is believed to be removed during this conversion process, so individuals with a soy or yam allergy should still be able to use BHRT.

### How do I know which hormones I need in my BHRT?

You will need to work with your physician, examining both physical findings (lab results from blood tests, saliva tests, etc.) and your clinical picture (symptoms - your list of health complaints).

Upon analyzing your whole health picture, your physician should begin to see a trend which would indicate whether a hormone imbalance is the source of your health problems. Common hormone imbalances are progesterone deficiency with estrogen dominance, progesterone and estrogen insufficiency, testosterone deficiency, dehydroepiandrosterone (DHEA) and cortisol imbalance.



### What advantages does compounded BHRT have over commercially available HRT?

Compounded bio-identical hormones have several distinct advantages:

1. Bio-identical Hormones are identical to human hormone. By supplementing hormone deficiencies with hormones identical to your own hormones you avoid certain adverse effects of synthetic estrogens and progestins. BHRT allows your body's hormone receptors and hormone metabolism to function the same as with your own hormones!
2. Customized dosing: Total Health Pharmacy can customize your dose so that you are getting the exact dose that meets your individual needs.
3. Custom hormone combinations. Total Health Pharmacy can combine multiple bio-identical hormones into one dose. This makes being compliant to your regimen much easier than trying to take multiple medications.
4. Multiple dosage forms available. Compounding pharmacists can help you pick a dosage form that best meets your needs and preferences. The more we tailor your BHRT to your wants and needs, the more likely you will experience successful results.

BIO-IDENTICAL HORMONES ARE AVAILABLE IN A WIDE VARIETY OF DOSAGE FORMS TO MEET THE INDIVIDUAL NEEDS OF EACH PATIENT:

- TRANSDERMAL CREAMS
- VAGINAL CREAMS
- VAGINAL SUPPOSITORIES
- CAPSULES, OR
- TROCHES

### Do I need a prescription for BHRT?

Yes, you must have a prescription for BHRT. If your physician is not familiar with BHRT, fill out the Physician Information Packet Request Form. Total Health Pharmacy will inform your physician you are interested in BHRT and will provide them with detailed information on BHRT so that they may evaluate this therapy option and help you make the proper decision for your individual healthcare needs.



## SALIVA HORMONE TESTING

Understanding the role of each hormone in the body will help us to understand what can go wrong if there is an excess or deficiency of hormone present. The hormones we test in saliva include estrogens (estradiol, estrone, and estriol), progesterone, androgens (testosterone and dehydroepiandrosterone (DHEA), and cortisol.

### Estrogens

Estrogens (estradiol, estrone, and estriol) are predominately female hormones, which are important for maintaining the health of the reproductive tissues, breasts, bone, skin, and brain. Excessive estrogens or “estrogen dominance” can cause unwanted symptoms such as fluid retention, weight gain, and migraines as well as over-stimulation of the breasts, ovaries, and uterus, which can lead to cancer. Insufficient estrogen levels can lead to hot flashes, vaginal dryness, rapid skin aging, urinary problems, excessive bone loss, and possible acceleration of dementia. In men an excess of estrogen, relative to testosterone, is thought to play a role in the development of prostate problems.

Replacement of estrogen with bio-identical estrogens can help reduce or eliminate:

- hot flashes & night sweats
- vaginal dryness
- skin problems
- memory loss

### Progesterone

Progesterone can be thought of as a balancing hormone. It enhances the beneficial effects of estrogens while preventing the problems associated with estrogen excess. Progesterone also helps to create a balance of all other steroids, and has intrinsic calming and diuretic properties. It is important in women, but its importance in men for the maintenance of prostate health is only now being appreciated.

Replacement of progesterone with bio-identical progesterone can help with the following symptoms:

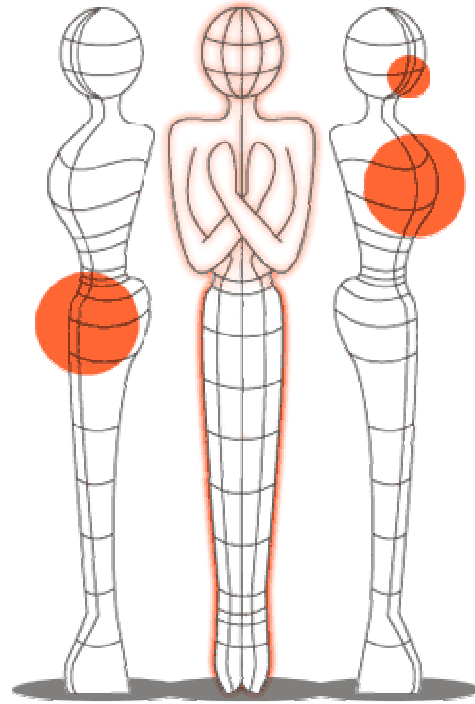
- mood swings
- breast tenderness
- decreased bone density
- bloating
- sleep disturbances

### Androgens (Testosterone and DHEA)

Testosterone and DHEA play an important role for men and women in maintaining the structural integrity of skin, bones, and muscles.

DHEA is the principal androgen in both men and women. DHEA levels decline with age, and in some cases, supplementation with DHEA can restore energy, improve immune function, lift depression, and improve mental function.

Testosterone is involved in maintenance of lean body mass, bone density, skin elasticity, sex drive, and



cardiovascular health in both sexes. Although men make more of this hormone, testosterone is vital to optimal health and well-being in both men and women.

Replacement of bio-identical testosterone can help to:

- increase libido (sex drive)
- enhance bone building by increasing calcium retention
- improve energy levels

### Cortisol

Cortisol is produced by the adrenal glands in response to emotional and physical stressors. Cortisol plays an essential role in immune function, mobilizing the body's defenses against viral or bacterial infection, and fighting inflammation; however, chronic elevated cortisol levels suppress the immune system and predispose to frequent infections. Cortisol levels are highest first thing in the morning, to combat the stress of overnight fasting and to animate the body for daily activities. Levels steadily decrease over the course of the day, falling to their lowest point at night in preparation for sleep. High cortisol, particularly when chronic and elevated at night has been closely associated with many of the diseases of aging (insulin resistance, diabetes, osteoporosis, cardiovascular disease and breast cancer). On the other hand, chronically low cortisol levels portend excessive fatigue, thyroid dysfunction, and allergies caused by a compromised immune system. Either high or low cortisol levels are a warning sign of adrenal imbalance which can accelerate the aging process and have devastating effects on health.



## THE TECHNOLOGY OF SALIVA TESTING

In the past 20-30 years a number of research studies have validated saliva as a diagnostic medium to measure the unbound, biologically-active fraction of steroid hormones in the bloodstream. Saliva is a natural ultra-filtrate of blood, and unbound steroids in the blood freely diffuse into saliva. The majority (90-99%) of steroid hormones in the blood are bound tightly to carrier proteins (cortisol-binding globulin, sex hormone binding globulin, albumin) rendering them unavailable to target tissues. Steroids are very small lipophilic (fat-loving) molecules that, when released from the binding proteins and red blood cells in the blood, freely diffuse into tissues, which include the salivary gland and saliva. The steroid hormones most extensively studied in saliva are: estrogens (estradiol, estrone, and estriol), progesterone, androgens (DHEAs, testosterone) and cortisol (for assessment of adrenal function).



MOST COMMON HORMONE TESTS ORDERED FOR	
FFMΔI FS	MΔI FS
ESTRADIOL	TESTOSTERONE DHEA
PROGESTERONE	
TESTOSTERONE	
DHEA	
CORTISOL (MORNING)	

### Advantages of Saliva Testing

- Saliva measures the free, "bioavailable" fraction of steroid hormones that have moved out of the bloodstream (blood and urine measure total levels) and into the tissue.
- Saliva is the most reliable measurement of tissue uptake with topical hormone supplementation.
- Painless, noninvasive and needle-free (stress of conventional blood draw can alter test results).
- Private (home collection) and convenient for both patient and doctor allows for optimal collection time.
- Hormones are stable in saliva at room temperature for weeks allowing for worldwide shipment.
- Transport of saliva samples to laboratory requires no special handling.
- Ease of collection allows for routine monitoring and adjustment of hormone supplementation as needed.

Saliva Testing is used to help health care providers:

- Identify hidden hormonal imbalances (deficiency or excess) associated with patient symptoms of menopause and andropause as well as reproductive disorders, chronic illness and diseases of aging.
- Link clinical symptoms to specific hormone imbalance(s).
- Maintain health and prevent disease through early detection of hormonal imbalance(s).
- Restore hormonal balance and patient quality of life using test results as a rational basis for treatment.
- Monitor patient hormone levels for "individualized" hormone replacement.
- Track patient progress with comparative history reports provided with follow-up testing.

## THE FINAL WORD ON BHRT

Consult with your physician regarding the role of balanced BHRT in your life. Research the information beforehand and approach your physician prepared with questions to ask. Books on the subject of hormones and hormone therapy are available at bookstores and the library (call us for some recommended titles). Beware when researching information on the Internet, not all web sites are accurate. Try to find web sites that are endorsed by a reputable organization. Please feel free to contact Dr. Wojcicki (contact info below) or myself, Miranda with any further questions.



For a Hormone Evaluation Consultation and To Order Your Saliva Test Kit Today, contact:

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