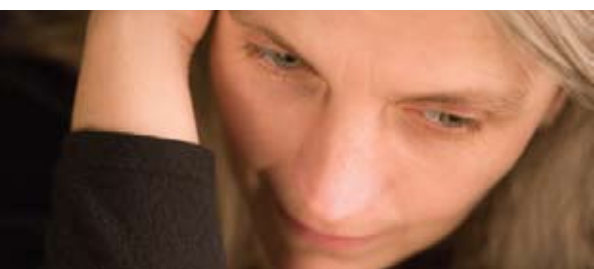


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## Bioidentical Hormone Replacement Therapy

### Facts About Bioidentical Hormone Replacement Therapy

Lloyd V. Allen, Jr., PhD, RPh

*International Journal of Pharmaceutical Compounding*  
Edmond, Oklahoma

The following facts are often overlooked or simply unknown when considering bioidentical hormone replacement therapy (BHRT). These facts should be considered by the physician, the pharmacist, and the patient so that a woman's access to alternatives of manufactured synthetic hormone products is not restricted.

- BHRT differs only from hormone replacement therapy (HRT) in that only those hormones that occur naturally in the body are used for therapy.
- HRT also includes conjugated estrogens and progestins that do not occur naturally in the body but may have some similar effects; however, they may also have additional unintended side effects.
- BHRT hormones include the following:
  - Estradiol
  - Estriol
  - Estrone
  - Progesterone
  - Testosterone
- The term "natural" may have two different meanings when applied to BHRT: (1) they occur naturally in the body; (2) many of them are derived from plant (soy and yam) materials initially and then synthesized into the pure chemical *United States Pharmacopeia* drug substance.
- Some of these BHRT hormones are commercially manufactured by drug companies and are available on prescription; all are commercially available by major drug companies in countries throughout the world.
- All of these BHRT hormones are available for compounding for your patients so you can individualize the therapy of each patient to meet their needs.
- All of these BHRT hormones have *United States Pharmacopeia* monographs and purity standards.
- To enable greater patient compliance, numerous dosage forms can be compounded including capsules, topical creams and gels, sublingual drops, troches/lozenges, minitroches/minilozenges, Pluronic lecithin organogels, vaginal creams and gels, injections, and others.

### Conclusion of Bioidentical Hormone Replacement Therapy Status Paper

Holtorf K. The bioidentical hormone debate: Are bioidentical hormones (estradiol, estriol, and progesterone) safer or more efficacious than commonly used synthetic versions in hormone replacement therapy? *Postgrad Med* 2009; 121(1): 73-85.

Dr. Kent Holtorf comments: "A thorough review of the medical literature supports the claim that bioidentical hormones have some distinctly different, often opposite, physiological effects to those of their synthetic counterparts. With respect to the risk for breast cancer, heart disease, heart attack, and stroke, substantial scientific and medical evidence demonstrates that bioidentical hormones are safer and more efficacious forms of HRT than commonly used synthetic versions. More randomized control trials of substantial size and length will be needed to further delineate these differences." (196 references)

## The Role of Bioidentical Hormones in Quality of Life and Wellness

**Jim Paoletti, RPh, FAARFM**

ZRT Laboratory  
Beaverton, Oregon

In the scientific evidence-based medical approach, the goal is to use the best choices in therapy based on the available scientific evidence to provide treatments. In the area of hormone replacement, bioidentical hormones are the obvious choice based on the evidence available.

### Why Hormone Replacement Therapy?

When hormones are not replaced, it can result in negative outcomes. Risk of cardiovascular events increase 9 to 10 fold, and complications from incidents related to bone loss increase dramatically. Brain function and memory decline. Cancer risk increases. Quality-of-life issues increase. If resolution of these issues could be obtained while decreasing the inherent risks associated with hormone decline, it would be not only logical to replace hormones as they decline with age, it could be considered negligence not to inform patients of potential therapeutic choices supported by the scientific literature.

There remains confusion and controversy as to whether benefits exceed risks with hormone replacement, who should receive hormones, and for how long they should be given. Based on the evidence, the controversy applies only to the use of synthetic hormone substitutes and/or supraphysiologic dosing of any hormone replacement. Physiologic doses of balanced bioidentical hormones have been shown in the literature to be both safe and effective for the general population, without increased risks.

### Why Bioidentical Hormone Restoration?

The evidence is very clear. Replacing declining hormones treats the symptoms of menopause and andropause that affect patients' quality of life. Using synthetic substitutes for hormones or excessive doses of hormones increase certain risks including the risk of breast cancer. Restoring hormones to balanced physiologic levels with bioidentical hormones provides the best patient outcomes with least risk.

One of the greatest fears for female patients considering hormone replacement is the possibility of breast cancer. The increased risk of breast cancer has been shown to be correlated with a lack of progesterone in the nonsupplemented patient. Breast cancer risk also increases with the use of estrogen-only therapy, with most forms of estrogen.<sup>1-7</sup> The exception is estriol. At least in part due to its ability to preferentially bind to the ER $\beta$  and decrease proliferation, estriol has been shown to be protective against breast cancer at physiologic doses.<sup>2,5,8-13</sup>

The greatest increase in the risk of breast cancer is seen with the use of synthetic progestins. While all synthetic progestins significantly increase the risk of breast cancer,<sup>2,14-43</sup> all studies with physiological bioidentical progesterone have shown that it has not increased or decreased the risk of breast cancer.<sup>44-56</sup> This alone is enough strong evidence that progesterone should always be the first choice of therapy, and not just for the women who have a uterus. Progesterone protects against breast cancer, stimulates bones growth,<sup>57-60</sup> helps with cardiovascular protection, and balances the effects of estrogen in general. Why should the woman who has had her uterus surgically removed not be offered protection of her other systems and organs, especially her breasts?

Cardiovascular events kill more women than does breast cancer. It has been shown that while almost all estrogens have certain beneficial effects on the cardiovascular system, such as vasodilation and maintenance of the lipid profile, conjugated equine estrogens significantly increase the risk for venous thromboembolism (VTE) and stroke<sup>17,19, 61-65</sup> and fails to show benefits on clinical events or progression of atherosclerosis.<sup>66,67</sup> Of the choices of estrogen therapies, bioidentical estradiol provides the best cardiovascular protection, and does so best at physiologic amounts. When a synthetic progestin is added to any estrogen, it completely negates all benefits on the lipid profile and protection from a cardiovascular event.<sup>17,19,68-94</sup> Medroxyprogesterone acetate has been shown to significantly increase the incidence of coronary heart disease, stroke, and VTE.<sup>17</sup> However, when bioidentical progesterone is added to estrogen therapy, it helps to maintain the lipid profile, and it acts synergistically with estradiol to provide a significantly



### COMPOUNDED FORMULATIONS FOR BIOIDENTICAL HORMONE REPLACEMENT THERAPY

**Rx**

**Progesterone 50-mg/mL Topical Gel**

**Rx**

**Progesterone Vaginal Cream (5%)**

**Rx**

**Progesterone Troches (100-mg, Soft)**

**Rx**

**Testosterone 10-mg/0.1-mL Sublingual Drops**

**Rx**

**Estradiol 2.5-mg, Progesterone 50-mg, and Testosterone 1-mg Capsules**

**Rx**

**Estradiol 1-mg/g and Progesterone 50-mg/g Topical Cream**

greater protection from cardiovascular events.<sup>68-70, 73,75,77,82,85,87,93,95-100</sup> The Writers for the PEPI study, the largest study on hormones at the time of publication, concluded that "we should be giving women natural progesterone." Based on the scientific evidence for hormones and associated cardiovascular protection, the obvious evidence-based choice is balanced physiologic bioidentical estrogen and progesterone.

Women seek a practitioners help with hormones not because of a fear of increased cardiovascular risk or higher risk of breast cancer without hormones, but because they feel terrible. They suffer from the many symptoms of imbalanced and deficient hormones including fatigue, weight gain, irritability, sleep disturbances, loss of memory, and other quality-of-life issues. While conventional hormone replacement therapies temporarily address some of these symptoms, they lack long-term effectiveness.<sup>101</sup> Although there are reported problems and increased risks with estrogen-only therapies<sup>102</sup> and no scientific literature that supports the use of any estrogen-only therapy, estrogen-only therapy is often given to women without a uterus. Based on the scientific evidence, the safest and most effective choice is physiologic estrogen therapy, and we should never give any woman estrogen therapy without balancing it with bioidentical progesterone.

Synthetic progestins cause numerous side effects and increase risks significantly.<sup>103-111</sup> Bioidentical progesterone, when compared to medroxyprogesterone acetate, causes significantly less side effects and is preferred by patients.<sup>106,112-114</sup> Considering the strong evidence that bioidentical progesterone decreases the risks for cardiovascular events and breast cancer, two of the leading killers of women, it should be given to every woman as their progesterone levels decline during peri-menopause.

Evidence-based medicine is not: listening to expert opinion; waiting for a large double-blind placebo controlled trial to prove a point; ignoring qualified studies that exist; or ignoring a therapeutic choice until it becomes more widely used. Instead, it is the use of the latest and best scientific evidence to make the wisest choice for the patient's welfare. The use of bioidentical hormone restoration therapy is obviously the best choice for evidence-based hormone therapy. The opponents of bioidentical hormones that claim there is no evidence to support any greater efficacy or safety with BHRT have failed to acknowledge the large body of evidence which opposes their view. They have also failed to show any scientific evidence which supports overall the use of conventional therapies. Physiologic bioidentical hormone restoration has been shown in the literature to be the safest and most effective choice for hormone replacement therapy,<sup>115,116</sup> and is the choice of practitioners utilizing evidence-based medical principles to provide improved quality of life for their patients.

*References available upon request.*