



# What You Should Know About Bioidentical Hormone Therapy

## *True or False*

**C**onfusion and false claims surround compounded “bioidentical hormone therapy” for relief of menopausal symptoms, such as hot flashes. Claims include promoting weight loss, preventing Alzheimer’s disease and breast cancer, and controlling the aging process. Instead, women are being exposed to impurities and unregulated doses. So what’s the truth about these compounded products?

**Claim:** Bioidentical hormone therapy is safer than commercial products.

**Truth:** The term “bioidentical hormone therapy” (BHT) usually refers to custom-made formulas compounded for an individual woman according to her health care provider’s prescription. But some of the hormones are not approved or monitored (estriol) and may contain nonhormonal ingredients (dyes, preservatives) that cannot be tolerated by all women. It is not known how many of the hormones are imported from other countries.

Custom-compounded formulations are not tested in clinical trials. They are not approved by the Food and Drug Administration (FDA), and these products often do not warn patients about the increased risks of stroke, breast cancer, and blood clots as FDA-approved estrogen and progestogen products are required to do.

**Claim:** Bioidentical hormones are identical to those made by the ovaries.

**Truth:** Compounded BHT is generally made from soy and yams, but the plant product needs to be chemically altered to become a therapeutic agent, such as estradiol or progesterone, for human use. Claims by compounding pharmacies that BHT is “natural” and “identical” to the hormones made in the body are not true. There are, however, many approved products that are chemically identical to hormones made in the ovaries.

**Claim:** Bioidentical hormone therapy complies with quality control regulations.

**Truth:** Because compounding pharmacies are not regulated by any government agency nor are their products tested for quality, purity, and potency, BHT preparations can vary substantially from batch to batch. Because women cannot rely on the effectiveness of a given prescription, they could overdose or underdose. As well, users could be exposed to unidentified risks.

**Claim:** Saliva testing accurately evaluates a midlife woman’s hormone levels.

**Truth:** Many proponents of compounded BHT rely on testing of estrogen levels in a woman’s saliva in order to prescribe an individualized remedy. According to the FDA, however, there is no scientific basis for using saliva testing because a midlife woman’s body changes from day to day depending on diet, time of day, and the specific hormone being tested. This test is neither accurate nor recommended. It is not necessary to test hormone levels to treat menopausal symptoms.

**Claim:** All compounding pharmacies should be closed down.

**Truth:** This statement is not true. The FDA has no interest in eliminating appropriate pharmacy compounding. It focuses instead on those inappropriate compounders who make unfounded claims of efficacy and safety that mislead the public. The government and The North American Menopause Society advocate that BHT products include patient information about proven benefits and risks identical to that required for FDA-approved, clinically proven products.

### The Good News

For most women suffering from menopause-related symptoms, commercially available and approved hormone therapy will provide appropriate therapy without the risks of custom preparations. Many of these approved products are considered bioidentical to the hormones produced by women. Go to The North American Menopause Society at [www.menopause.org/bioidenticalcharts.pdf](http://www.menopause.org/bioidenticalcharts.pdf) for a complete list of FDA-approved BHT products.