

# The Truth about Bioidentical Hormones

## **Myth: Bioidentical hormone replacement therapy (BHRT) is unregulated.**

*Fact:* Bioidentical hormones – like all compounded medications – are made from FDA- and USP-registered materials – the same used by pharmaceutical manufacturers – and their preparation is well regulated by state boards of pharmacy that have responsibility for overseeing all pharmacy practice in each state. Pharmacies that compound medications, including bioidentical hormones, are regulated by state pharmacy boards – similar to the relationship doctors have with state medical boards. In addition, there are also national standards and guidelines for compounded medications. The ingredients and their suppliers are regulated at the federal level by the FDA, with additional oversight provided by the U.S. Pharmacopeia.

## **Myth: Compounded bioidentical hormones are unsafe because they aren't FDA-approved.**

*Fact:* Compounded medications are regulated by state boards of pharmacy and are not subject to federal laws designed to regulate mass-produced drugs. This is because they are customized to meet the unique needs of patients based on the specific orders of a physician. The FDA approval process is designed for mass-produced manufactured drugs; it is universally recognized that holding compounded medications to these standards would completely eliminate their availability.

Compounded medications are in a similar position as manufactured products prescribed for off-label use, which constitutes about a fifth of all prescriptions. They are not approved by the FDA for such use, and yet it is well accepted that physicians should be able to use their discretion to prescribe medications for off-label use.

## **Myth: Bioidentical hormones are just as risky as manufactured products like Premarin and Prempro.**

*Fact:* There are no studies comparing the two types of therapies, so we cannot make any direct comparisons.

The Women's Health Initiative study examined only Premarin and Prempro, which do not use the same ingredients that are used to compound bio-identical hormones. To date there have been no studies that show a

link between BHRT and cancer/strokes/heart attack, however the pharmacy community supports and funds

studies to better determine the risk profile of BHRT.

A physician is trained and licensed to diagnose disease and to determine appropriate therapy for patients. A

physician uses clinical expertise to determine appropriate therapies for patients. Premarin and Prempro may be

appropriate for some patients. Bio-identical hormones may be appropriate for others. It is up to doctors to make

that determination.

## **Myth: Pharmacists are recklessly promoting BHRT as safe and effective.**

*Fact:* Compounded medicines are a lot like off-label prescriptions: they are not subject to FDA approval and, as

a result, cannot be marketed as safe or effective. In fact, the FTC Act, 15 U.S.C. § 41 et seq., prohibits unfair or

deceptive acts and practices, including false and unsubstantiated advertising claims. It is already illegal for a

pharmacy to make claims without substantiation or to overstate the health benefits of the products they promote.

**Myth: “Bioidentical” is a misleading term.**

*Fact:* The chemical structures of bioidentical hormones are identical to those produced by the human body.

Because the chemical structure is identical, these hormones are often referred to as “bioidentical.”

*The Truth about Bioidentical Hormones (cont’d)*

**Myth: BHRT is not necessary.**

*Fact:* Doctors often prescribe manufactured synthetic hormone products such as Premarin and Prempro. When

they determine those products are inappropriate, doctors sometimes prescribe bioidentical hormones tailored to

meet each patient’s unique needs.

For many patients, manufactured synthetic products are effective, but for some they are not.

○ That may be because the manufactured drugs simply don’t relieve the symptoms of menopause.

It may also be because doctors determine that their patients need a lower dose than what is available commercially.

○ Other times, doctors find that changing combinations of hormones – progesterone, estradiol, estriol and estrone – in ways that are not commercially available may best alleviate their patients’ symptoms.

○ Or doctors find that different delivery forms – creams, liquids, pills, troches – are more effective for an individual patient.

○ Or a patient experiences severe side effects from manufactured drug products which can sometimes be relieved by switching to compounded alternatives.

○ One manufactured bioidentical medication, Prometrium is made with peanut oil, a common allergen. Many patients are allergic to peanut oil and need progesterone – the active ingredient in Prometrium – to be compounded without it.

○ When compounded hormones are prescribed, it is because doctors determine that their patients have needs for medications that are significantly different from what is manufactured.

**Myth: Bioidentical hormones need a black-box warning.**

*Fact:* Black-box warnings are required for FDA-approved drugs and include information that is derived from the

approval process. Requiring that level of information for compounded medications would create an impossible

requirement that could be used to broadly restrict patients’ access to BHRT. As policymakers consider labels

for compounded products, it is important that they not unintentionally create onerous requirements.

Simply

applying manufacturers’ requirements to compounders may seem like an easy solution but it likely leads to

restrictions, since the requirements for manufacturers are designed for them and not for compounders, who

operate under a regulatory structure specific to pharmacy practice.

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**Congressional Offices may also contact Jim Rock at (202) 547-4000.**