

the Buzz on
Bioidenticals
THE FACTS ABOUT HORMONE THERAPY

Developed by *The Female Patient*[®] magazine,
the Red Hot Mamas[®], and Elizabeth Lee Vliet, MD.

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Elizabeth Lee Vliet, MD

women's health physician,
hormone therapy expert,
author, and radio show host

www.HerPlace.com

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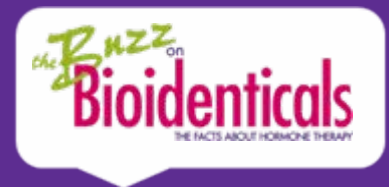
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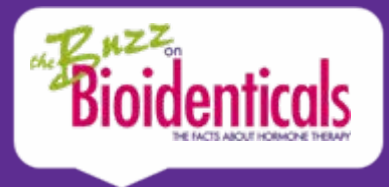
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What Are Bioidentical Hormones?

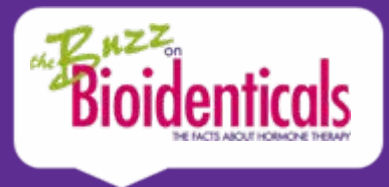
- Bioidentical means an exact copy of a hormone produced by the body.
- Usually refers to hormone medications containing estradiol (or progesterone)



MYTHS About Bioidenticals

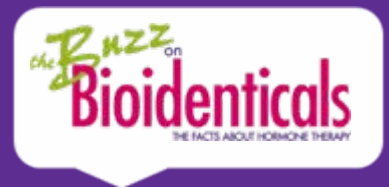
MYTH #1: You can only get bioidentical hormones from compounding pharmacies.

FACT: There are many FDA-approved bioidentical hormone products.



FDA-Approved Bioidenticals

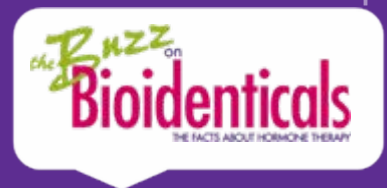
- FDA-approved bioidentical hormones available in US since 1975
- Products in use longer have more studies and safety monitoring
- EstroGel was approved in France in 1974; it was FDA-approved in the United States in 2004
- EstroGel one of first bioidenticals in the world
- Now in use in more than 70 countries
- One of longest track records of safety data



FDA-Approved Bioidenticals

ORAL	TRANSDERMAL Gels, lotion, spray	TRANSDERMAL Patches	VAGINAL
Estrace, 1975	EstroGel gel, 2004	Estraderm, 1985	Estrace cream, 1984
Estradiol generic, 1997	Estrasorb lotion, 2006	Vivelle, 1994	Estring ring, 1996
Prometrium,* 1998	Divigel gel, 2007	Climara, 1995	Prochieve 4% gel,* 1997
	Elestrin gel, 2008	Vivelle Dot, 1998	Vagifem tablets, 1998
	Evamist spray, 2008		Femring ring, 2003

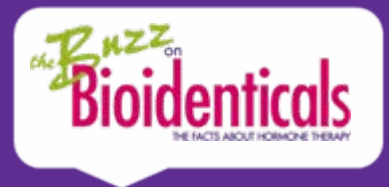
Note: All brands contain the hormone estradiol except those with an asterisk (*), which contain the hormone progesterone.



MYTHS About Bioidenticals

MYTH #2: Hormone therapy prescribed by traditional physicians is not bioidentical.

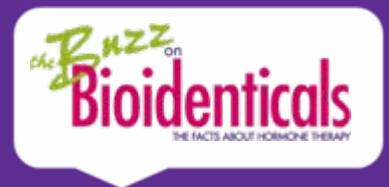
FACT: Your physician can prescribe FDA-approved bioidentical hormones, and they are usually covered on your health insurance.



MYTHS About Bioidenticals

MYTH #3: Bioidentical hormone therapy obtained from a compounding pharmacy is natural.

FACT: Compounded hormones are no more “natural” than FDA-approved bioidentical products.



MYTHS About Bioidenticals

MYTH #4: Bioidentical hormone therapy obtained from a compounding pharmacy is safer than FDA-approved hormone therapy products.

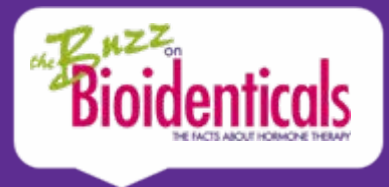
FACT: Compounded products are less reliable, and can vary greatly in doses, potency, and stability compared to FDA-approved hormones.



MYTHS About Bioidenticals

MYTH #5: Saliva testing is the best way to check hormone levels to determine doses of hormones.

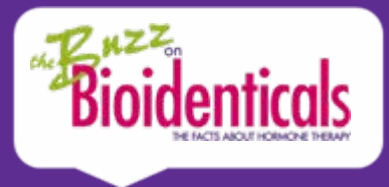
FACT: Blood tests done by your regular doctor are the most reliable way to test hormone levels.



Choosing Wisely: FDA-Approved Hormones Versus Compounded Drugs

2 main reasons why FDA-approved hormones are better than compounded drugs:

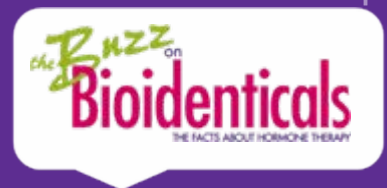
1. FDA-approved products have safety and efficacy data from many clinical studies. Compounded hormones do not undergo clinical trials.
2. FDA-approved products are held to strict manufacturing standards. The FDA has no oversight of compounding pharmacies.



FDA-Approved Bioidenticals

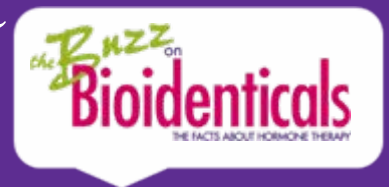
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Note: All brands contain the hormone estradiol except those with an asterisk (*), which contain the hormone progesterone.



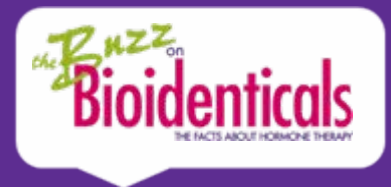
What you should know about the Women's Health Initiative (WHI)

- The WHI study used only oral pills (Premarin and PremPro).
- Premarin is a mixture of estrogens from **pregnant mare** (horse) **urine**.
- PremPro contains horse-derived estrogens plus medroxyprogesterone, a synthetic progestin.
- These hormone pills are not bioidentical because they are chemically different from estradiol and progesterone.



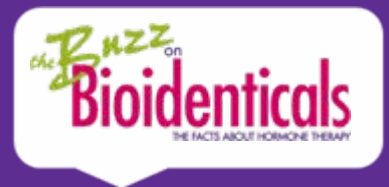
What you should know about the WHI

- WHI linked oral estrogen with a small but significant increase in risk of heart attack and stroke.
- Combined estrogen-progestin therapy with PremPro slightly increased the risk of breast cancer.
- WHI studied only hormone pills, did not study bioidentical transdermal hormones.



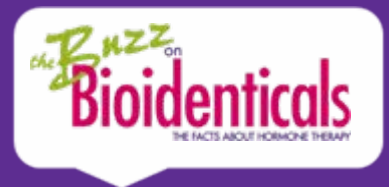
Pills Versus Transdermals (Gel, Patch, Lotion, Spray)

- Pills are not the only option for taking hormones. FDA-approved hormones can be taken by
 - Transdermal patch
 - Transdermal gel
 - Transdermal lotion
 - Transdermal spray
 - Vaginal preparation
- Transdermal hormones delivered through the skin have lower risks than hormone pills.
- Many transdermal products, and one pill, are bioidentical.



Pills Versus Transdermal Hormones

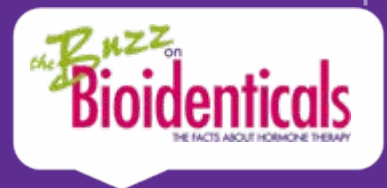
- Pills go through a first step in the liver that changes the hormones before they reach the body.
- This means pills (a) use higher doses since some hormones are lost in the stomach and intestines, (b) cause “ups and downs” in hormone blood levels.
- Transdermals **AVOID** first step in liver, are absorbed directly into bloodstream, and maintain more “even” or consistent blood levels of hormones.
- Transdermals use lower doses because of direct absorption into bloodstream.



FDA-Approved Bioidenticals

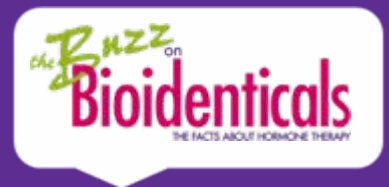
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Why haven't you heard about FDA-approved transdermal hormones?

- Transdermal hormones have been the most popular form of hormone therapy in Europe for decades.
- The French ESTHER study showed many benefits of transdermal estradiol hormones.
 - ESTHER found that transdermals have a lower risk of blood clots and that pills have a 4-fold higher risk of clots because of the first pass in the liver.
- Women in the US have not had much information on benefits of FDA-approved bioidentical transdermals. Until now!



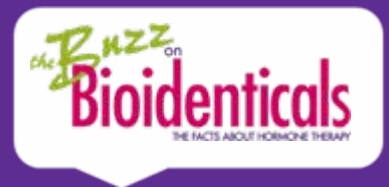
3 Primary Human Estrogens

- **E1 = Estrone:** Primary “reservoir” of estrogen, and dominant estrogen remaining **AFTER** menopause. Produced in ovaries, body fat, breasts.
- **E2 = Estradiol:** Primary active estrogen **BEFORE** menopause. **LOST** at menopause when follicles are gone. Produced in ovaries; some made from testosterone in the brain, breast, muscles.
- **E3 = Estriol:** Weak estrogen made by placenta during pregnancy. Not found to a measurable degree in adults.



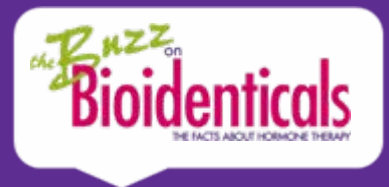
The Importance of Estradiol

- The only estrogen in FDA-approved bioidentical hormones is estradiol.
- Perimenopausal and postmenopausal women do not need the hormones estrone and estriol.



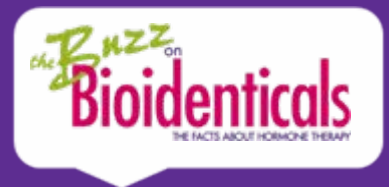
The Problem With Estriol

- Estriol-E3 often used by compounding pharmacies
- No drug with estriol has been approved by FDA.
- Pharmacies may not compound drugs containing estriol unless they have an investigational new drug (IND) application with FDA.
- Doctors are not allowed to prescribe estriol unless they have filed an IND with FDA.
- Many compounding pharmacies violate FDA regulations and add estriol to their products.



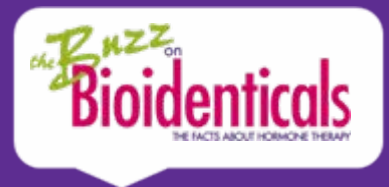
The Facts About Compounded Hormones

- Compounding pharmacies prepare custom-mixed drugs prescribed by a physician for each patient.
- Medical uses for compounding are to:
 - Change form of a drug, ie, from a pill to a liquid
 - Eliminate an ingredient causing allergies
 - Increase/decrease dosage for individual patients
- FDA issues safety warnings on Rx; compounders not required to issue same type of warnings.
- FDA will not approve any compounded products because not standardized.



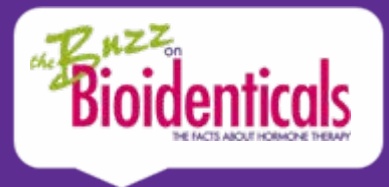
Who Regulates Compounding Pharmacies?

- FDA does not regulate compounding pharmacies—states do.
- Compounding pharmacies are licensed and regulated in the 50 states and D.C. by state boards of pharmacy.
- Each state has different regulations.
- This can result in significant variations and problems with consistency in oversight.



What Is In Compounded Hormones?

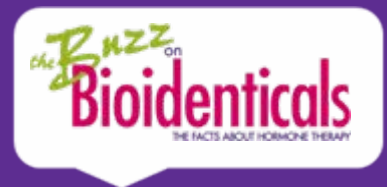
- Estradiol, progesterone, and testosterone USP raw powder come from SAME suppliers for compounded and FDA-approved bioidentical hormone products.
- Each compounding pharmacy uses formulas with **different ingredients and doses**, but hormones have the **same name** at each pharmacy!
- Batch differences in dose, potency, and duration lead to variations in symptom relief, side effects.
- Difficult for your health care professional to know what you are taking!



Some Compounding Pharmacies Use Misleading Advertising

They may say their “bioidentical” hormones...

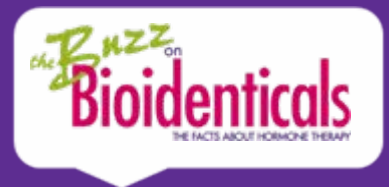
- Are a natural, safer alternative to dangerous prescription drugs
- Can help you lose weight by reducing hormonal imbalances
- May prevent breast cancer and Alzheimer disease
- Improve maintenance of muscle mass and strength.
- These claims are FALSE.
- Some compounding pharmacies have been issued warnings by the FDA.



The Facts About Compounded Hormones

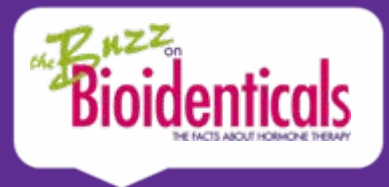
Saliva Testing

- Many compounding pharmacies advertise saliva testing to “individualize” hormone therapy.
- Hormone levels in saliva vary widely, do not correlate well with blood levels.
- **Plastic tubes for saliva alter hormone levels.**
- Studies show saliva testing is not a reliable measure of hormone levels.



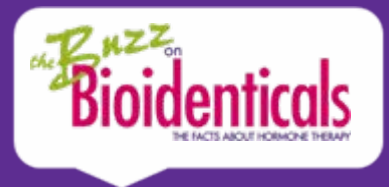
The Facts About Progesterone

- Women hear misleading information about progesterone.
- Progesterone is a hormone made by the body that prepares a woman for pregnancy.
- It helps store fat for pregnancy; it can lead to weight gain.
- Progesterone is often added to compounded hormones.



The Facts About Progesterone

- Progesterone is not safer than other hormones.
SHOULD NOT BE USED IF UTERUS REMOVED
- Studies show progesterone does NOT prevent bone loss OR breast cancer.
- Progesterone may **increase** risk of breast cancer.
- “Wild Yam” creams often contain progesterone, which should not be in over-the-counter products, and is often present in high doses.
- Progesterone absorbed through the skin is unreliable to protect the uterus.

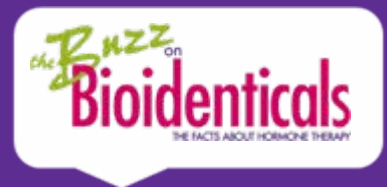


Example: Real Patient With Problems From Compounded Hormones

- A compounding pharmacy gave Sandra, a 40-year-old-mother:
 - Daily progesterone
 - Testosterone high-dose cream
 - T3 (thyroid hormone) (compounded)
 - Cortisone (compounded)
- Problems she is having: muscle pain, headaches, mood swings, fatigue, middle body weight gain, no sex drive

Quote:

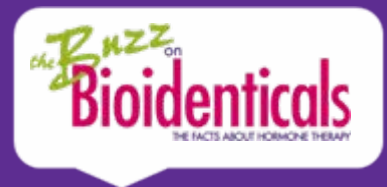
“I have two little children who need me, I feel like I am 80, like I am old before my time, I am in pain all the time. I am too young to feel this old! There has to be a better combination for me than this, I’ve got to feel better!”



From My Practice: Side Effects of Many Compounded Hormones

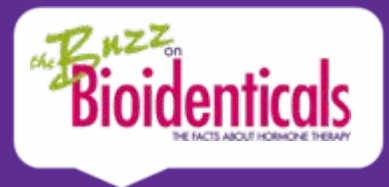
- **Brain:** Headaches, mood swings, depression, anxiety, insomnia
- **Body:** Breast enlargement, middle-body weight gain, swelling of hands and feet, palpitations, brownish skin discolorations, dry skin, “doughy” body fat changes. **Excess testosterone:** acne, oily skin, scalp hair loss, excess facial and body hair, clitoral enlargement, irritability, anger outbursts, insomnia
- **Metabolic:**
 - Excess progesterone: insulin resistance and weight gain
 - Excess testosterone: elevated cholesterol, elevated triglycerides
 - Excess estrone: high cholesterol and triglycerides

There are many others - these are most common



Who Would You Rather Trust With Your Health?

- The Endocrine Society, ACOG, and NAMS are **NONPROFIT** medical organizations.
- ACOG, NAMS, and the Endocrine Society have published warnings about compounded hormones.
- Compounding pharmacies are **FOR-PROFIT** businesses.
- Go to these Web sites for more information:
 - www.acog.org
 - www.menopause.org
 - www.endo-society.org



Why You Should Choose FDA-Approved Hormones Over Compounded Drugs

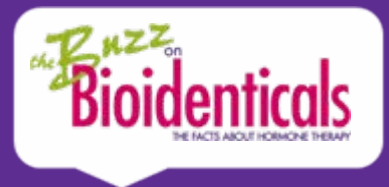
FDA survey on quality control of compounded drugs

- FDA analyzed 29 compounded products from 12 compounders for sterility, potency, uniformity
 - 10 of the 29 products (34%) of compounded drugs failed at least one quality test
 - 25% failed potency test: products contained less of the active drug than stated on the label



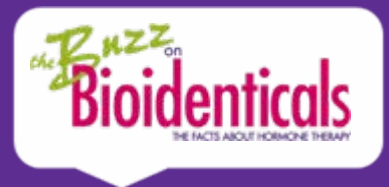
Why You Should Choose FDA-Approved Hormones Over Compounded Drugs

- FDA also tested more than 3,000 FDA-approved drugs. **Less than 2% failed the tests.**
- Survey available online at www.fda.gov.



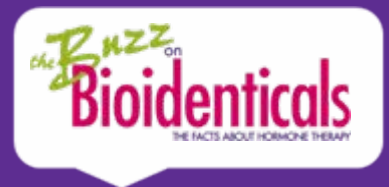
Who Should Take Menopausal Hormone Therapy?

- Transdermal hormones are FDA-approved for:
 - Hot flashes
 - Vaginal dryness
 - Preventing bone loss
- Ask your health care professional if hormones are right for you.
- It is best to start hormones during the “window of opportunity” close to menopause
 - The earlier the better to avoid adverse effects
 - The risks increase the later therapy is started



Risks of Compounded and FDA-Approved Hormones

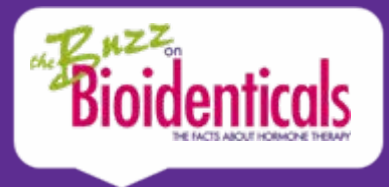
- The risks include, for some women, an increased risk of blood clots, heart attacks, breast cancer, stroke, and gallstones.
- If you have your uterus, taking estrogen alone can increase risk of endometrial cancer unless you add progestin or progesterone.
- If you have had a hysterectomy, you should not take progesterone: risks increase



Who should not take menopausal hormone therapy?

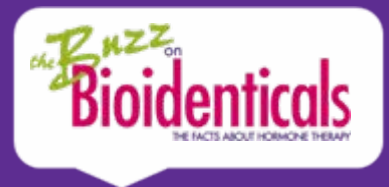
Women who:

- May be pregnant
- Have vaginal bleeding of unknown cause
- Have or have had certain kinds of cancer
- Have had a stroke, heart attack, blood clots, or liver disease.
- NOTE: Transdermal delivery of hormones has **lower risks than oral** hormones and may be an option for women who should not take oral hormones.



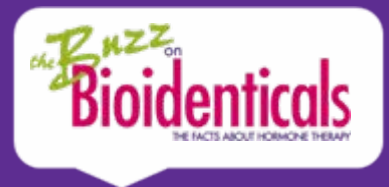
Lifestyle Changes To Reduce Hot Flashes

- Eat a healthy diet
- Limit caffeine and alcohol
- Quit smoking
- Exercise regularly
- Maintain a healthy weight
- Manage stress with meditation, exercise, and yoga.



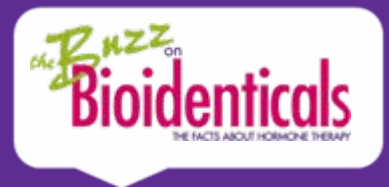
What If You are Taking a Compounded Hormone Now?

- Find out if there are FDA-approved options that are right for you. They may also cost less!
- Doses recommended by compounders are often too high – especially for testosterone and progesterone creams.
- Review the doses you are taking with your health care professional.



What You Have Learned

- You don't need to go to compounding pharmacies to obtain bioidentical hormones.
- Compounding pharmacies and the media may be communicating wrong information.
- There are many FDA-approved bioidentical hormones available from your local pharmacy.
- FDA-approved transdermal hormones are bioidentical and most likely are covered on your health insurance.



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