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UNDERSTANDING THE IMPORTANCE OF BIO-IDENTICAL HORMONES

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What Are Hormones?

Hormones are molecules largely composed of a fatty, steroid backbone made from cholesterol with protein components. Hormones are made in the endocrine glands and released into the blood stream where they then circulate in the body and dock onto receptors on cells in most tissues to influence metabolism, genetic processes, and most functions of the body. Our hormones control processes of temperature, blood pressure, blood sugar, hunger, satiety and many other regulations.

Some examples of the endocrine glands and the hormones they produce:

Pituitary	Thyroid Stimulating Hormone Prolactin Human growth hormone Luteinizing Hormone Follicular Stimulating Hormone Oxytocin
Pancreas	Insulin
Thyroid	T1, T2, T3, T4 (mostly T4)
Adrenal	Cortisol DHEA Aldosterone Oxytocin Glucocorticoids Mineralcorticoids Aldosterone Pregnenolone
Ovaries and Testes	Estrogen Progesterone Testosterone Oxytocin
Skin / Kidneys	Vitamin D
Hypothalamus	Adrenal corticotrophin releasing hormone Growth hormone releasing hormone Gonadotropin releasing hormone Thyrotrophic releasing hormone

For a list of symptoms that occur when hormones are deficient, see the section: an overview of important hormones.

There are several distinctions to be made among the types of prescription and supplemental hormones. Hormones can be classified as bio-identical, non-bio-identical, synthetic, plant or

equine. The term “natural” has also been used but doesn’t adequately describe the properties of the hormone. Let’s discuss the definition of these types of hormones.

“Synthetic Hormones”: *All prescription hormones are synthetic.* This is because no matter what source is used to derive the hormones, they are manipulated in a laboratory to create the final product. Hormones may be derived from natural sources such as wild yam or soy bean, or from synthetic pharmaceutical products. Synthetic hormones may or may not be bio-identical. Often synthetic hormones are **patented** by pharmaceutical companies, but not always. Pharmaceutical companies can patent hormones if they create a hormone with a unique shape, such as in the case of birth control pills, or when hormones are processed in a proprietary process such as the equine hormones in Premarin®. Patented hormones made by pharmaceutical companies are regulated by the FDA and approved by the FDA before they can be placed on the market.

“Bio-identical Hormones” refers to the shape, not source of hormones. They can be derived from natural sources such as wild yam, soy bean, or synthesized from pharmaceutical substrates but are then chemically modified in a laboratory to exactly match the shape, structure and configuration of human hormones. Generally, bio-identical hormones cannot be patented, just as other naturally occurring substances such as vitamins cannot be patented, but the application or formulation of the product can be patented. For example, vitamin formulations can be patented when a company has proprietary rights to a specific combination or formulation of a vitamin mixture. Bio-identical hormones can’t be patented but if it is applied to a patch (Vivelle), or proprietary delivery system such as a cream (Estrace), or prepared in pre-manufactured tablets (Estrace), those applications can be patented.

Compounding pharmacies usually use non-patented (therefore non-FDA regulated), pure forms of hormones provided in bulk which are then prepared into a cream, gel, capsule, or drop. Because they use these non-patented forms of hormones, insurance companies may not cover these products as insurance companies often have “formularies”, lists of allowed drugs that are usually manufactured forms from pharmaceutical companies.

“Equine hormones” are derived from pregnant mares and do not match the structure of human hormones, therefore are not bio-identical. They are only bio-identical if you are a mare! Opponents of equine hormones also claim that the conditions in which the mares are kept to obtain their urine is inhumane.

Equine hormones in the form of Premarin and Provera were used in the Women’s Health Initiative Studies. The first phase was released in 2002 and concluded that women who took Premarin for longer than five years then experienced an increased risk of cancer, dementia, bone loss and heart disease. The study was ended earlier than planned due to the negative findings. Clearly, equine hormones are not safe, especially when used longer than five years.

“Plant hormones” is not a particularly effective term in identifying chemicals found in fruits, vegetables and seeds such as wild yam, soy, and flax seed that have hormone-like properties. The molecules in these plants, such as isoflavones, are not bio-identical hormones. They are instead molecules that can interact with hormone receptors, hormones, or enzyme systems to influence hormone balance in the body. Plant hormones include molecules such as sterols and sterolins which **may act like hormones without raising hormone levels**. They can help modulate hormones, meaning they influence the function and balance of hormones and the body’s ability to metabolize hormones.

“Natural hormones” is a term that inadequately describes hormones or plant chemicals. The only true natural hormones are endogenous hormones, those made naturally in our bodies. Bio-identical hormones can mimic nature.

Based on these definitions prescription hormones are synthetic and can be either bio-identical, or non-bio-identical. Also, they are either patented and manufactured by pharmaceutical companies and therefore regulated by the FDA, or formulated

into creams, gels, drops or capsules by compounding pharmacists who are not FDA regulated.

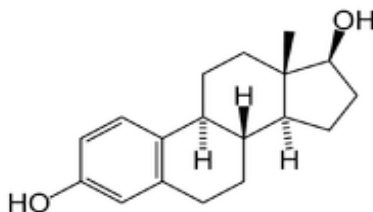
EXAMPLES OF THE TYPES OF HORMONES:

Non-bio-identical, manufactured progesterone is called a "Progestin", or "Progestogen". Progestins will not act quite the same as bio-identical progesterone. Non-bio-identical estrogen is usually in the form of an esterified estrogen, also called Ethinyl-estrogen. Non-bio-identical testosterone is usually Methyl-testosterone.

Non-Bio-identical Progestins	Depo, Provera (methyl progesterone; medroxyprogesterone) Micronor Aygestin (norethindron), Mirena, Norplant (Levonorgestrel) Prempro
Non-Bio-identical Estrogens	Premarin Esterified Estrogens(Ethinylestradiol)
Non-Bio-identical testosterone	Methyl-testosterone; Estratest
Bio-identical Progesterone	USP or Micronized progesterone Crinone 4% or 8% vaginal gel Prometrium capsules
Bio-identical Estrogen	Vivelle, Estraderm, Climera, Estrasorb emulsion, Estrace vaginal gel, Biest, Triest, Estradiol, Estriol
Bio-identical Testosterone	Natural, micronized testosterone
Bio-identical Thyroid (all)	Armour, Levoxyl, levothyroxine, Westhroid, USP thyroid,

COMPARING THE STRUCTURE OF BIO-IDENTICAL AND NON-BIO-IDENTICAL HORMONES:

Biological (bio-identical) estradiol



Non Bio-identical estradiol (Ethinylestradiol)

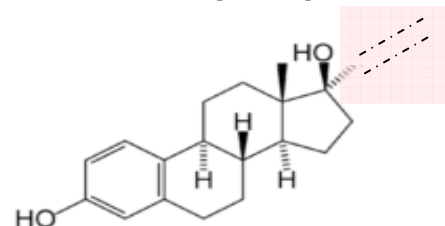
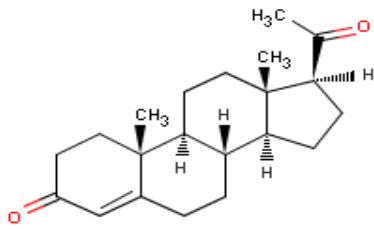


Fig. 1: The molecular structure of bio-identical and non-bio-identical estrogen shares the same steroid frame work, but non-bio-identical estrogen has an added side chain (in pink box) that prevents it from acting exactly like the bio-identical form. It creates more side effects and has other draw backs.

Biological Progesterone



Non-bio-identical Progestin (Norethindrone)

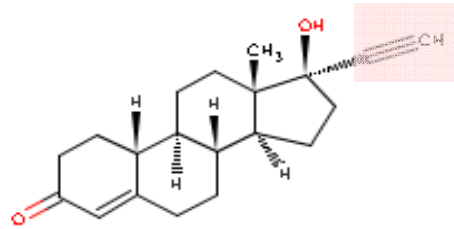


Fig 2: The molecular structure of bio-identical and non-bio-identical progesterone shares the same steroid frame work, but the non-bio-identical progestin has an added side chain (in pink box) that causes it to act differently in the body than the bio-identical form.

BIO-IDENTICAL AND SYNTHETIC HORMONES ACT DIFFERENTLY IN THE BODY

Because non-bio-identical hormones do not share the same molecular structure with bio-identical hormones, they behave somewhat differently in the body. This is especially true in the case of equine estrogens as was demonstrated in the Women Health Initiative (WHI) studies. These studies reported that when women took equine estrogens for five years or more there was an increased risk of cancer, heart disease, dementia and bone loss.

Non-bio-identical hormones have also been reported to induce severe behavioral changes in women. Some women who take non-bio-identical progestins experience increased PMS symptoms, and severe depression. Non-bio-identical progestins also have been shown to block the brain signal that promotes a woman's body to make endogenous (biological) progesterone.

Non-bio-identical progestins also lack the thermogenic (heat producing) effect of biological progesterone which contributes to temperature regulation and feeling warm. They also can interfere with the function of biological progesterone made in the body. Non-bio-identical progestins have also been found to increase the blood clot forming tendency of oral non-bio-identical estrogens.

Non-bio-identical hormones may not go through the normal conversion to other hormones as endogenous, biological hormones do and can cause increased sodium and water retention.

Alternately, bio-identical hormones have been found to be protective against disease formation. Bio-identical hormones do not suppress the body's production of biological hormones, they do have a thermogenic effect, and are converted to other corticosteroids hormones.

In a compelling review by Kent Holtorf, published in January, 2009, he reviewed 196 studies on the use of bio-identical hormones and concluded that bio-identical hormones are safer and more efficacious than non-bio-identical hormones. He states: "Physiological data and clinical outcomes demonstrate that bio-identical hormones are associated with lower risks, including the risk of breast cancer and cardiovascular disease, and are more efficacious than the non-bio-identical synthetic or equine counterparts. Until evidence is found to the contrary, bio-identical hormones remain the preferred method of HRT."

PLANTS CAN CONTAIN HORMONE-LIKE CHEMICALS

Various foods contain “phytonutrients”, chemicals that have physiological effects in the body. These effects include helping with balancing hormonal systems, and at times acting like hormones in the body. These chemicals are also called “phyto-hormones”, although that term may be misleading. Twenty or more phyto-hormones have been identified in over three hundred foods including carrot, soy, flax, potato, wheat, rice, beans, apples, and coffee.

Some chemicals such as the isoflavones in soy or lignans found in flax seeds are called “Phytoestrogens”. Phytoestrogens are weak agonists (bind weakly) to estrogen receptors and compete for binding with biological estrogen made in the body that is trying to bind to the receptor also. This is helpful in both conditions of excess estrogen (estrogen dominance) and estrogen insufficiency (perimenopause or ovarian underfunction). It is helpful when phytoestrogens compete with excess estrogen because when estrogen binds to the receptors it creates stronger reactions. Phytoestrogens inhibit the estrogen from binding, and their binding to the receptor creates a weaker response. Yet this can also be beneficial when there is deficient or insufficient estrogen in the body. In a case of deficiency of estrogen, the weak binding of phytoestrogens to receptors produces enough effect to relieve the symptoms of deficiency.

Phytohormones have been found to have many health benefits such as inhibiting tumor growth and preventing cancers. Yet, it may be possible to consume too many phytohormones, as epidemiological studies show overconsumption of phytohormones is correlated with infertility in animals and irregular menses in women.

Structure and Properties of Phytoestrogens

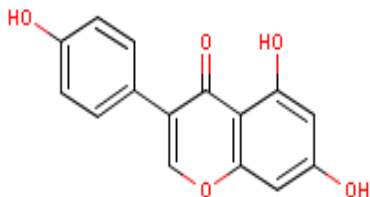


Fig. 3: The steroid structure of “Phyto-hormones” does not match the structure of biological estrogen or progesterone, therefore are not considered bio-identical hormones. These chemicals are not exactly hormones, but have hormone-like effects in the body.

Bio-identical Hormones can be formulated by a credentialed compounding pharmacist into:

- ▶ Tablets or capsules
- ▶ Transdermal creams
- ▶ Patches
- ▶ Gels
- ▶ drops

For most hormones the preferred form is the transdermal cream. Thyroid hormones are mostly delivered by pills or capsules which work well.