Georgia Hormones P.C.

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# **BIO-IDENTICAL HORMONES**

# What are bio-identical hormones?

The ovaries, testicles and the adrenal glands manufacture a series of hormones all derived from cholesterol. These are called the steroid hormones. Since the early 1960s, chemists have been able to synthesize all of these molecules starting either from cholesterol or from plant steroids found in wild yam and soy. Since the manufactured molecules are exact duplicates of the hormones made by the various glands in the body, they are called bio-identical.

Which bioidentical hormones are the most commonly used? There are three estrogens made by the ovaries. They are Estradiol, the strongest of the three, Estrone, of intermediate power, and Estriol, the weakest. The ovary and the placenta make Progesterone. On the male side is Testosterone. The Adrenal gland makes two weaker androgens, DHEA or Dehydroepiandrosterone, and Androstenedione as well as Cortisol. Actually, ovaries, testicles and adrenal glands can all make any of these hormones, although the quantities vary. The Thyroid hormones, T4 and T3 are bioidentical. Synthroid and Levoxyl are T4 and Cytomel is T3. Humalog is a manufactured hormone identical to human insulin. All of these hormones, as well as some others, are available for purchase by a doctor's prescription.

# What kinds of hormones are NOT bioidentical?

Many pharmaceutical companies have developed and manufacture hormones that have been altered with some atoms added or removed. These hormones are different from anything the body naturally makes. They are not identical to anything naturally occurring in a human body.

### Why would a pharmaceutical manufacturer make non bio-identical hormones?

Some of these changes make the hormones better absorbed when taken by mouth. Some changes make the hormones stronger or last longer. Some changes alter the hormones effects. Birth control pills are all synthetic. The estrogens in birth control pills are better absorbed by mouth than natural estrogen. Natural progesterone requires relatively large quantities to work. Most birth control pills use an altered Testosterone, which acts in some ways like Progesterone. The drug companies call these Progestins. They are better absorbed by mouth than real progesterone, are stronger and last longer, so less is needed and the pills are smaller. In addition, a manufacturer can get a patent on a newly created molecule. Natural hormones cannot be patented.

#### Are Bioidentical hormones FDA approved?

Yes. All hormones available at the compounding pharmacist are FDA approved. They require a doctor's prescription with instructions to the pharmacist as to the form of the medication, dosage and how it is to be used.

<u>How is this different from the medicines at a regular pharmacy?</u> For a manufacturer to produce and advertise a medication, they must first prove to the FDA that each particular dosage form, strength and use will perform according to their advertising, be safe and effective. This costs the manufacturer a huge amount of money. They patent their new drugs and hope that they will pass the FDA and sell enough to make back their investment plus a profit. While under patent, no one else can make or sell their drug.

<u>Why don't big pharmaceutical companies make many of the Bioidentical hormones?</u> You can't patent parts of the human body. Once the FDA approves any drug or dosage form, any company can make and sell a generic, unless a patent protects the drug. Without patent protection, it simply does not make business sense for any manufacturer to spend the money getting specific dosage forms through the FDA.

Are there any Bioidentical hormones at regular drug stores? Yes. Estrogen patches, for the most part, use real Estradiol. The manufacturer has patented the patch itself, not the hormones inside. Prometrium is real Progesterone mixed by a patented process with peanut oil. The peanut oil mixture is what is patented. It comes in only two dosages, but is available at any drug store and is covered by most insurance. Synthroid is real T4 and Cytomel is real T3. Thyrolar is a combination T4/T3 in a 4:1 ratio.

# What is the advantage of compounding pharmacies?

Hormones at a compounding pharmacy are real, bioidentical hormones. They can be put into oral capsules or tablets, skin cream, vaginal cream, oral troches, vaginal suppositories, or liquid drops and in any dose the doctor chooses. Different patients have individual needs and preferences. Most manufactured medications like Prometrium, come in one form and only a couple of doses. Forty years ago, before there were big chain drug stores, all pharmacies were compounding pharmacies. Most prescriptions were blends of medications or herbs created by doctors and pharmacists, and prepared by the pharmacist for the individual patient. Since this is time consuming, chain drug stores have chosen to sell only pre-manufactured medications. Since bioidentical hormones are body parts, they cannot be patented. Manufacturers have no financial incentive to get multiple dosages and forms through the FDA, so they cannot be mass-produced and distributed in chain pharmacies. What is the problem with synthetic hormones?

The human body was developed with the ability to regulate, break down and excrete natural hormones. Synthetics do not act in exactly the same way as the natural hormones. Laboratory tests are available to measure levels of the natural hormones. Most synthetics cannot be easily measured. In addition, the normal levels of most real hormones are known. What would be the "normal" levels of synthetic hormones?

#### How are Bioidentical hormones administered?

Prior to starting on hormone therapy, the patient's own hormone levels are measured. Dosage and form of therapy are chosen. Once the patient has been on the therapy for a period of time, levels can be measured again and the dosage adjusted or the route of administration changed, to suit the patient's individual needs. Doctors have been treating thyroid disease, diabetes and electrolyte imbalance in this manner for many years. The object is to get the patient back into balance using bioidentical replacement products and using each patients symptoms and laboratory levels as a guide.