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Bioidentical Hormones

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What are bioidentical hormones?

The ovaries, testicles and adrenal glands manufacture a series of hormones that are all derived from cholesterol. These are known as the steroid hormones. Since the early 1960s, chemists have been able to synthesize molecules that start from either cholesterol or 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 bioidentical.

Which bioidentical hormones are most commonly used?

There are three estrogens made by the ovaries. They are estradiol, the strongest of the three, estrone, an intermediate power, and estriol, which is the weakest. The ovary and the placenta make progesterone. On the male side, testosterone is dominant while the adrenal gland makes two weaker androgens, Dehydroepiandrosterone (DHEA) and androstenedione, as well as cortisol. Ovaries, testicles and adrenal glands can all make these hormones, though 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 with a doctor's prescription.

Which hormones are NOT considered bioidentical?

Many pharmaceutical companies have developed and manufactured hormones that have been altered (*such as adding or removing atoms*). These hormones are different from anything the body naturally makes and not identical to anything that naturally occurs in the human body.

Why would a pharmaceutical company make non-bioidentical hormones?

When taken orally, some of the modifications can make the hormones become better absorbed, stronger and last longer. Some changes alter the effects of the hormones. All birth control pills are synthetic and the estrogen found in birth control pills are better absorbed by mouth than the body's own natural estrogen. To generate enough natural progesterone (to be effective) would require the body to produce relatively large quantities. Most birth control pills contain altered testosterone, which in some ways acts like progesterone. The drug companies call these progestins. Better absorbed by mouth than real progesterone, they are stronger and last longer, making the body require less (*even the pills are smaller!*).

Manufacturers can get a patent on a newly created molecule while natural hormones cannot be patented.

Are bioidentical hormones FDA approved?

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

How is this different from medications found at a regular pharmacy?

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, and be safe and effective. The costs are huge — the manufacturer obtains a patent for the new drug with the hope it will pass FDA requirements and sell enough to make back their investment (plus a profit). While under patent, no one else can make or sell that drug.

Why don't pharmaceutical companies make many of the bioidentical hormones?

You can't patent parts of the human body. Once the FDA approves a drug in any dosage form, other companies can then make and sell a generic brand (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 approved through the FDA.

Are there any bioidentical hormones available 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 drugstore and is covered by most insurance companies. Synthroid is real T4 and Cytomel is genuine T3. Thyrolar is a combination T4/T3 in a 4:1 ratio.

What is the advantage of using a compounding pharmacy?

Hormones offered by a compounding pharmacy are real, bioidentical hormones. They can be put into oral capsules, tablets, skin and vaginal creams, oral troches, vaginal suppositories or liquid drops. Doctors choose varying doses based on individual needs and preferences of the patient. Most manufactured medications such as Prometrium, come in one form with limited dosage choices. **Forty years ago, before big chain drug stores became the norm, all pharmacies were compounding pharmacies.** Most prescriptions contained a blend of medications or herbs (created by the doctor or pharmacist), and prepared by the pharmacist. Producing compounded prescriptions can be time consuming so chain drugstores will only sell pre-manufactured medications. Since bioidentical hormones are body parts, they cannot be patented. Manufacturers do not have any financial incentive to secure multiple dosages and forms through the FDA and ultimately 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, breakdown and excrete natural hormones. Synthetic hormones do not operate exactly the same way as natural hormones. Laboratory tests are available to measure levels of

natural hormones. Most synthetics cannot be easily measured, making it unclear how to determine normal levels for many real hormones.

How are bioidentical hormones administered?

Prior to starting hormone therapy, the patient's hormone levels are first measured — then dosage and form of therapy can be decided. After the patient has been on therapy for a period of time, levels can be reexamined for making dosage adjustments or route of medication administration. For many years, doctors have been treating thyroid disease, diabetes and electrolyte imbalance in this manner. The object is to get the patient back into balance using bioidentical replacement products specifically customized to individual patient symptoms and laboratory levels.