Beauty From The Inside Out
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Bioidentical hormone replacement therapy (BHRT), also known as bioidentical or natural hormone therapy, is a form of alternative medicine that has created a buzz in the anti-aging and aesthetics communities. This new trend is rooted in our human desire to feel and look as physically young as we do mentally and/or emotionally. Historically, much of the anti-aging and aesthetics communities have focused on external youth and preservation. Recently, however, it has expanded into a more holistic approach; that of treating the whole patient – inside and out.

Scott Blyer, MD, FACS who practices in Long Island and in New York, NY notes that “more than ever before, information is more accessible to the general public. This has bred a smarter consumer with regard to all aspects of lifestyle, health, beauty and wellness. This Whole Food movement” has trickled down to medicine and patients who are seeking to look and live better and longer. Bioidentical hormones for anti-aging and weight loss have become an important part of my practice. Simply looking 20 years younger after surgery is not enough. People want to feel 20 years younger and maintain their results for years to come”.

Functional medicine experts agree that a large part of feeling younger is about achieving internal balance – and that often involves replacing hormones. This could be as simple as taking Synthroid® for an underactive thyroid gland or as complex as replacing multiple sex hormones like estrogen and testosterone. This is accomplished by bioidentical hormone replacement therapy (BHRT) or the traditional synthetic hormone replacement therapy (HRT).
BHRT was first introduced to the United States by Jonathan Wright, M.D. in the early 1980s. Dr. Wright developed and introduced the use of comprehensive patterns of bioidentical hormones (including estrogens, progesterone, DHEA and testosterone) after he directed the development of tests to ensure their safe use in 1982.³ Wright’s efforts were a response to what he believed were many symptoms caused by hormone abnormalities. Wright sought to treat patients’ feelings of lethargy, unexplained weight gain, insomnia, mood swings and other complaints that often yielded no explanation other than that of a potential hormone imbalance.

BHRT seeks to replace hormones and restore hormonal imbalances caused as a result of the aging process, environmental factors and genetics. BHRT has been used to treat young women who suffer from PMS, mature women with hot flashes (as a result of menopause) and men who suffer from low testosterone (which may start to decline as earlier as age 25). There are numerous other indications for BHRT including treatment for sexual dysfunction, osteoporosis (bone loss) and other conditions for which they are prescribed.

Bioidentical hormones “have the same exact molecular structure as the hormones produced naturally within the body. The body does not distinguish between supplemental bioidentical hormones and the hormones produced within the body. As a result, bioidentical hormones are properly utilized, and are then able to be naturally metabolized and excreted from the body.” http://www.lef.org/Magazine/2009/10/Bioidentical-Hormones/Page-01

A major benefit to BHRT as opposed to traditional hormone replacement therapy (HRT) is that the therapy is individualized. The medication is then compounded by a pharmacy to be tailored to the exact needs of the patient. No one size fits all approach here.

Another benefit of BHRT over that of commercially available synthetic hormones (used in traditional HRT), is that, they are plant-derived compounds that are found in nature. Therefore, BHRT proponents believe that BHRT is a safer alternative to synthetic hormones. The pharmaceutical industry sees things differently. A portion of the medical community believes pharmaceuticals may have this view based on business. “Bioidentical hormones cannot be patented as they come from plant sources and are identical to the same hormones produced from our body. Our body cannot tell the difference. On the contrary, synthetic hormones are chemically altered to purposely be different than what our body produces allowing them to be patentable and, as a result, a quite lucrative business. When our body metabolizes many of these synthetic hormones, the byproducts are chemicals our body does not recognize. This foreign chemical has lead to concerns such as cancer in the female hormone replacement arena. No such risk exists with bioidentical hormones”, Blyer states.

Indeed, the use of natural plant based products has been proven to be more effective in other areas of aesthetic treatments. The approach is similar to the way hyaluronic acid based fillers are used to fill or replace the collagen that depletes with age. Remember collagen injections? The collagen used for recreating facial form and structure is typically extracted from cow or pig bovine and injected into the dermis. Today, these products are considered archaic and are used very infrequently. Hyaluronic acid fillers like Juvaderm® and Restylane® offer a safer and more compatible alternative because hyaluronic acid is naturally occurring in the body. Cow collagen? Not so much. In fact, most collagen injection manufacturers recommend patch testing a discrete area prior to administering a full treatment. This is not the case with newer filler options.

Yet, like with many alternative or holistic approaches to wellness, BHRT is not without controversy. The Food and Drug Administration (“FDA”) recently issued consumer alerts advising that it has “not approved compounded ‘BHRT’ drugs and cannot assure their safety or effectiveness.”

One of the FDA’s biggest gripes is that the safety of BHRT has not been studied in double-blind placebo-controlled environments. Yet, the biggest reason that BHRT has not been studied is because it is a natural product which cannot be patented, as Blyer states. Drug companies with big budgets, are not likely eager to fund studies that support the efficacy and, possibly, the superiority of bioidenticals versus synthetic, commercially available hormones because they have no vested interest in supporting a competitive medication.

¹ http://www.tahomaclinic.com/dr-jonathan-v-wright/.
BHRT drugs require prescriptions that are compounded in pharmacies based on a patient specific prescription. Traditional compounding involves combining, mixing, or altering ingredients by a pharmacist, according to a prescription from a licensed health care professional, to produce a drug that meets an individual’s special medical needs. The FDA considers traditional compounding to be a valuable service when used appropriately, such as customizing a drug for someone who is allergic to a dye or preservative in an FDA-approved, or commercially available, medicine.” www.fda.gov. However, according to the FDA, “some pharmacies that compound BHRT drugs make unsupported claims that these drugs are more effective and safer than FDA-approved MHT drugs.” www.fda.gov.

As a patient and consumer, erring on the side of caution regarding anything you put into your body, is prudent. Just like the food you eat and water you drink, research on product quality and integrity are critical components to good decision making. As a patient, a big plus is that most doctors prescribing BHRT compounds have chosen who they feel to be reputable and trustworthy compounding partners. Most big box and chain pharmacies do not compound, making relationships between prescribers and pharmacies critical. With the advent of electronic prescription requirements, often a prescriber writes a prescription for a patient’s compounded medication, and submits it directly to the pharmacy, bypassing the patient. Be sure to ask your prescriber who is filling the script and by what credentials and experiences did they choose said pharmacy. http://www.webmd.com/women/news/20090115/oprah-and-bioidentical-hormones-faq?page=2

According to Gopesh Patel, Rph at New Drug Loft Pharmacy in New York, “There are five components that contribute to the validation of a PCAB accredited compounding pharmacy: quality, distinguish, confidence, credibility and safety”. A PCAB accreditation ensures that the pharmacy administers quality in their practice to patients, prescribers and payers. By being PCAB accredited, the pharmacy is distinguished, which gives the PCAB accredited pharmacies an edge compared to non-PCAB accredited pharmacies. Additionally, this accreditation gives the pharmacy confidence because the pharmacy follows national standards, which improves the overall credibility of the pharmacy. Finally, PCAB accreditation ensures the products that are produced by the compounding pharmacy are safe for the patients using the medications.

The good news is that in many cases, hormone replacement therapy, whether bioidentical or synthetic, offers patients choices and may aid in quality of life. Many experts believe that the choice to be well makes this a wonderful time in medicine. It is up to you to become educated on your options and to find a clinician experienced in all types of hormone evaluation and replacement, if necessary, creating harmony and beauty on the inside and outside.

For questions regarding your local, state or FDA regulations on BHRT and compounding, contact Allyson Avila, Esq. at Wilson Elser Moskowitz Edelman & Dicker, LLP at (914) 872-7445 or email at Allyson.avila@wilsonelser.com. For questions regarding how you can incorporate BHRT into your practice, contact Samantha Blakeney at New Drug Loft Pharmacy 212-979-0910 or Samantha@newdrugloft.com.