

Compounded Bioidentical Hormones

Your body produces more than one hundred different types of hormones and, without them, you couldn't live. Hormones are chemical messengers that circulate in your bloodstream and orchestrate the continuous activity in the cells and organs in your body. From the regulation of your heart-beat and breathing, to the control of your blood pressure and metabolism, hormones are involved. They also help fight stress, calm anxiety, soothe pain, and stimulate your immune system. Sex hormones such as estrogens, progesterone, and testosterone play important roles in controlling sex drive, regulating the menstrual cycle, and allowing for pregnancy and birth.

Proper hormone balance is critical to your health, and hormones are the most delicately balanced system in your body. Given the number of hormones that make up this system, and the continual communication between hormones that is necessary to maintain a healthy balance, the literature on hormones is vast. Unfortunately, much of the information available today is inconsistent, and at times misleading, especially with respect to hormone therapy.

Different types of hormone therapy involving various forms of hormones are now prescribed to offset hormonal imbalances, yet the differences between such therapies are not always clear.

The goal of this newsletter is to provide a solid understanding of bioidentical (or biologically identical) hormones, along with their uses and benefits.

What Does "Bioidentical" Mean?

Although bioidentical hormones are created in a lab (not extracted from humans or animals), they have the exact same molecular structure as hormones made in the human body. In other words, they are chemically indistinguishable from one another. Because their chemical structure is identical, bioidentical hormones generate the same physiologic responses in the body as do hormones already produced by the body. When making choices about hormone therapies, bioidentical hormones are an option that makes sense, as they replace and replenish the balance your own hormones naturally provide. One well-known example of a bioidentical hormone therapy is the use of injectable human insulin in the treatment of diabetes.

With bioidentical hormone therapies, each individual's hormone deficiencies or excesses must be evaluated. In determining the optimal hormone therapy for an individual, a practitioner needs to take into consideration

the interactions of the different hormones with one another, as well as the other potential effects of each hormone throughout the body. For example, bioidentical progesterone protects the uterus and, at the same time, has positive effects on mood, memory, and sleep.

The Rest of the Story

We are bombarded with information daily—from television, radio, newspapers, magazines, brochures, and the Internet—and, for many people, these have become the primary sources of information about hormone therapies. However, while it may be helpful, the information disseminated may be only part of the story, or sometimes even biased, based on its sources.

Many studies and media statements discuss hormones in general terms, without making a distinction between bioidentical and non-bioidentical forms of hormones. For example, a clinical study involving medroxyprogesterone (a progestin)—a non-bioidentical form of progesterone—may inaccurately refer to the hormone as "progesterone." Yet medroxyprogesterone and progesterone differ in their molecular structure, their derivation, and—most importantly—their effects on your body. Therefore, the results from such a study reflect only those of

the particular progestin used, and not any other types of progestin, or progesterone itself, which might, in fact, produce different results.

Landmark Studies

The very studies created to test the safety and benefits of hormone therapies are often responsible for creating misinformation. In some cases, study designs have been faulty, and therefore the results misleading and potentially alarming for women taking hormones. The Women's Health Initiative (WHI) is the landmark example of a highly publicized study that suffered from flawed design, as well as inadequate screening of study participants.

The WHI study was developed to study the long-term effects of non-bioidentical estrogens and progestin hormone therapy in postmenopausal women and specifically assess the risk of heart disease, hip and other fractures, and breast cancer. One hormone product used in this study was Premarin®, which some consider “natural estrogens” because it comes from pregnant horse urine. However, Premarin's effects in the human body are different than the effects of bioidentical estrogens. Another hormone product used in the WHI study, Prempro®, contains Premarin and medroxyprogesterone (a progestin).

Of the approximately 16,000 female participants in this trial, none were screened prior to the study to determine whether or not their own hormone levels were adequate. The Prempro portion of the study was stopped early due to an increased risk of breast cancer, heart disease, stroke, and blood clots. Soon after, the Premarin portion of the study was also stopped. These results, and the media attention they received, left women and their practitioners

“In truth, everyone has a unique biochemical thumbprint; we don't all need the same dose of pharmaceuticals, vitamins, or even the same amounts of nutrients in foods.”

alarmed and unsure about what to do. They also raised many questions regarding whether women should continue with their therapy, try alternate therapies, or completely stop their therapy. Furthermore, the publicity implied that these results applied equally to “all” hormones when, in fact, bioidentical hormones were not included in this study.

Another landmark study, the Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial assessed heart disease risk factors in postmenopausal women using hormone therapies. In women, it is believed that high levels of HDL (good cholesterol) protect against coronary heart disease.

This study tested three different hormonal regimens:

1. Premarin and bioidentical progesterone, which produced the most favorable increases of HDL levels.
2. Premarin alone, which also produced favorable increases in HDL levels but significantly increased the occurrence of severe hyperplasia in women who still have a uterus.

3. Premarin and medroxyprogesterone (a progestin), which also led to increased HDL levels although the increases were less significant than those obtained with Premarin alone or Premarin and progesterone.

The PEPI Trial demonstrated a clear distinction between the effects of bioidentical progesterone and non-bioidentical medroxyprogesterone.

Terminology Used

Common terms used when referring to bio-identical hormones include:

- Natural
- Bioidentical
- Biologically Identical
- Human identical
- Plant-based hormones

Many different acronyms are now being used for hormone therapies, including HRT, BHT, BHRT, and NHRT to name a few. HRT is the general acronym for Hormone Replacement Therapy, while BHT stands for Bioidentical Hormone Therapy. BHRT is the same as BHT with the word

Continued on Page 3

“replacement” added. NHRT, which stands for Natural Hormone Replacement Therapy, can be a confusing term because “natural” is also often used when describing herbal remedies, as well as BHT.

Bioidentical hormones can be either manufactured or compounded. Briefly, bioidentical manufactured hormones have the advantage of being FDA approved; however, they are mass produced and are only available in limited dosing strengths and formulations. On the other hand, compounded bioidentical hormones can be prepared for individualized dosages/strengths, and in a number of different formulations.

Why Compound?

Compounding allows healthcare practitioners to prescribe medication specific to their patient’s individual needs.

One of the primary benefits of working with a compounding pharmacy is that a patient is not limited to the commercially available dosages, strengths, and forms; instead, compounded prescriptions can be changed to different formulations that may be more efficient or easier to administer. For example, if a patient has difficulty swallowing pills, the compounding pharmacist can formulate the medication or hormone(s) as a cream or gel. Or, for sensitive patients who require preservative-free or allergen-free prescriptions, a compounding pharmacist can meet these needs by preparing prescriptions accordingly.

Dr. David Brownstein, an advocate of compounded prescriptions, points out in a special report in *Integrative Medicine* that patients need individualized doses of hormones.

“Pharmaceutical companies want us to believe that everybody needs the same dose of all medications,” he writes. “In truth, everyone has a unique biochemical thumbprint; we don’t all need the same dose of pharmaceuticals, vitamins, or even the same amounts of nutrients in foods.”

For optimal hormone treatment, a practitioner can fine-tune or modify the dose or prescription of a compounded BHT as an individual’s hormonal needs change, or match an individual’s

preferences and absorption abilities. Another advantage to compounded BHT is that multiple hormones can be combined in a single dosage form to ensure better patient compliance.

A Bit of History

Until the 20th century, pharmacy was all compounding and involved the use of water and alcohol, for the extraction of substances from plants, animals, and minerals. Going back to the time of Hippocrates (4th century BC),

The Many Uses of Compounded Prescriptions

Compounded prescriptions are essential to the well-being of many individuals; thus, they are used in many facets of healthcare. For example, compounded medication is commonly prescribed in the fields of pediatrics, geriatrics, internal medicine, obstetrics/gynecology, and endocrinology. The veterinary profession is also greatly aided by compounding, as many more species and sizes of animals can be treated individually. In all these specialties, practitioners can address specific needs whether they are dosage forms, dosage strengths, flavors, routes of administration, or combinations of medications.

Practitioners have more options in treating their patients when prescribing compounded medications, especially when it comes to the individual needs of premature infants, babies, children, and the elderly. Infants born prematurely and weighing only a few pounds rely on the compounded prescriptions and smaller dosages of many lifesaving and life-sustaining drugs. For geriatric patients, who often are unable to swallow pills and may need different dosage forms in order to take their medications, compounding is critical. A significant percentage of the needs of home healthcare patients are met by compounded medications as well, such as total parenteral nutrition, which is necessary for the post-operative healing of colon disorders.

End-of-life therapy in hospice or through palliative care also often involves compounding different dosage forms to allow patients to spend the rest of their lives free of pain and discomfort. Compounded prescriptions may be vital for patients who can’t swallow medications or don’t have the muscle mass required to endure daily multiple injections. Many cancer-fighting medications and lifesaving intravenous drugs used in hospitals are compounded. Finally, hormone therapies can be prescribed to suit a patient’s individual hormone needs, thanks to compounding.

the preparation of pills, ointments, oils, and inhalations was commonplace. Over the next two thousand years, pharmacists continued to apply the art and science of pharmacy to the preparation of medication, using the highest standards possible at the time.

In 1820, the U.S. Pharmacopeia was established to promote the standardization of formulas. While compounding was still the most prevalent way of formulating medications well into the 20th century, it became less common as the pharmaceutical industry began providing standard dosage forms.

During the 1980s and 1990s, the number of compounded prescriptions began increasing due to a resurgence of recognition of individual patient needs—something that mass produced drugs are unable to accomplish because many are available only in limited dosage forms and strengths. Today, the demand for prescription compounding makes it a rapidly growing component of pharmacy practice.

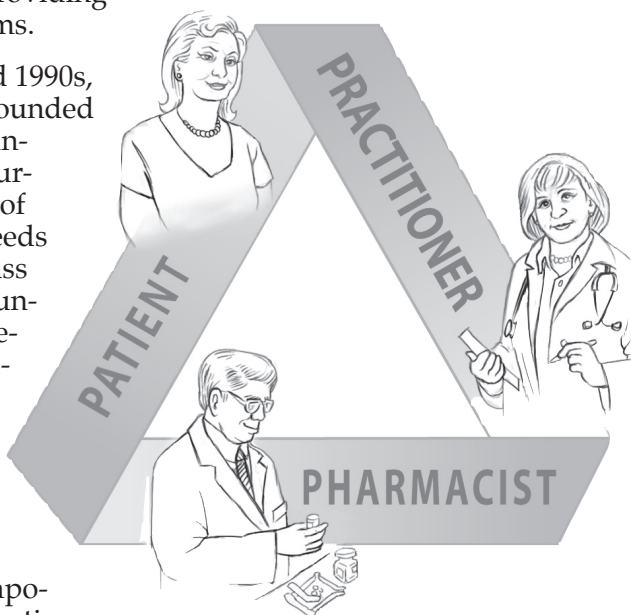
Compounding pharmacists formulate combinations that may include approved FDA and/or pharmaceutical-grade ingredients, as determined by a medical practitioner, into specific dosage forms such as capsules, creams, gels, tablets, lozenges, suppositories, and other forms.

In the pharmacy industry, compounding pharmacists are regulated by their state boards of pharmacy. Standards are set by the U.S. Pharmacopeia and National Association

of Boards of Pharmacy for quality assurance.

The Triad

With compounded hormone prescriptions, it is imperative that the communication lines remain open and free-flowing among the three key players shown in the graphic: the patient, the licensed practitioner, and the licensed pharmacist. All three of these individuals play a critical role in obtaining and maintaining the patient's optimal hormone balance.



The Patient

To achieve hormone balance, the patient needs to pay careful attention to symptoms and communicate this information to the practitioner. Using this information, the practitioner can direct the pharmacist in developing an effective hormone therapy. It is important that patients have good communication with their practitioner and pharmacist with regard to their hormone therapy, and feel comfortable asking questions and requesting information.

The Practitioner

The practitioner examines, evaluates, tests, diagnoses, and prescribes treatment. Once the appropriate hormone therapy is prescribed, the practitioner monitors the effects of the hormone therapy. Compounded bioidentical hormones can be adjusted in their dosing as well as their formulation, under the guidance of the practitioner, to achieve the goal of optimal hormone balance for each of their patients.

The Pharmacist

The pharmacist provides quality assurance for each and every prescription compounded. The compounding pharmacist is available to the practitioner and the patient to provide information and resources about hormone strengths/dosages, formulations, and effects.

Conclusion

Compounded bioidentical hormone therapy has significantly improved the lives of many people who suffer from symptoms due to a hormone imbalance. However, all hormone therapies—whether bioidentical or not—have risks associated with them, even though these risks may be different depending on the kind of hormone therapy. You and your practitioner should discuss the advantages and disadvantages of various hormone therapies, and weigh the risks of therapy against the risks of the potential health issues and discomfort associated with leaving your hormone imbalance untreated.

Awareness, education, and communication are key to optimal hormone balance.

A Note from the President and Pharmacists at Women's International Pharmacy

Compounding pharmacists are valuable resources to practitioners and their patients. Prior to obtaining a compounded bioidentical hormone prescription, be confident that your prescription comes from a highly qualified pharmacy that specializes in compounding. Work with pharmacists who can offer you information about hormone therapies and assist you with your questions while providing high-quality compounded prescriptions.

The pharmacists at Women's International Pharmacy understand the uniqueness of each person and go the extra mile in taking the time and effort to meet the needs of the practitioners and their patients. Call our toll-free number 800-279-5708 and give us the opportunity to provide you with knowledge and guidance regarding bioidentical hormone therapies.

References

- *The Hormone Solution - Stay Younger Longer*, Thierry Hertoghe, MD, Harmony Books; New York, NY; 2002.
- *Natural Hormone Balance for Women*, Uzzi Reiss, MD, Pocket Books; New York, NY; 2001.
- *The Miracle of Natural Hormones*, David Brownstein, MD, Medical Alternatives Press; West Bloomfield, MI; 1998.
- *The Hormone Solution*, Erika Schwartz, MD, Warner Books; New York, NY; 2002.
- "Natural Hormone Replacement Therapy: What It Is And What Consumers Really Want," Dana Reed-Kane, PharmD, *International Journal of Pharmaceutical Compounding*, Volume 5, Number 5, Sept/Oct 2001.
- "Comparison of Regimens Containing Oral Micronized Progesterone or Medroxyprogesterone Acetate on Quality of Life in Postmenopausal Women: A Cross-Sectional Survey," Lorraine A. Fitzpatrick, MD, Cindy Pace, BS, and Brinda Wiira, PhD, *Journal of Women's Health & Gender-Based Medicine*, Volume 9, Number 6, 2000.
- "A Comprehensive Review of the Safety and Efficacy of Bioidentical Hormones for the Management of Menopause and Related Health Risks," Deborah Moskowitz, MD, *Alternative Medicine Review*, Volume 11, Number 3, 2006.
- "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial." The Writing Group for the Women's Health Initiative Investigators. *JAMA*, 2002.
- "Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women: The Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial." The Writing Group for the PEPI Trial. *JAMA*, 1995.
- "Why Compounded Prescriptions Make Sense: An Interview With David Brownstein, MD," Kimberly Lord Stewart, *Integrative Medicine*, Volume 5, Number 5, Oct/Nov 2006.
- "A History of Pharmaceutical Compounding," Loyd V. Allen, Jr., PhD, *Secundum Artem*, Volume 11, Number 3, 2003.
- "Recent Advances in Quality Pharmacy Compounding," Loyd V. Allen, Jr., PhD, *International Journal of Pharmaceutical Compounding*, April 2005.
- "What Do You Know About Pharmacy Compounding?," Loyd V. Allen, Jr., PhD, *International Journal of Pharmaceutical Compounding*, April 2005.



Women's Health Connection

P.O. Box 6338

Madison, WI 53716-0338

Address Service Requested

PRESORTED
STANDARD
U.S. POSTAGE
PAID
MADISON, WI
PERMIT # 1

Get Connected . . .

A yearly subscription to *Connections* is available for \$12.00 (4 issues per year). For faster processing, please use our online ordering form, which is available under the *Connection Newsletters* topic at:

www.womenshealthconnection.com

If you prefer, you may use this order form. Make your check payable to:

Women's Health Connection
P.O. Box 6338
Madison, WI 53716-0338

Name _____

Address _____

City, State, Zip _____

Or call **1-800-366-6632** to charge your subscription to either Mastercard or Visa.
This subscription form may be photocopied.

Connections is a publication of Women's Health Connection, the educational division of Women's International Pharmacy. Published four times per year, *Connections* is dedicated to the education and management of PMS, menopause, infertility, post-partum depression, and other hormone-related conditions and therapies.

This publication is distributed with the understanding that it does not constitute medical advice for individual problems. Although material is intended to be accurate, proper medical advice should be sought from a competent healthcare professional.

Copyright © February 2007, Women's Health Connection
This newsletter may not be reproduced or distributed without the permission of Women's Health Connection.

Publisher: Constance Kindschi Hegerfeld, Executive VP
Women's Health Connection

Co-Editors: Michelle Davenport and Carol Petersen, RPh, CNP
Women's Health Connection

Written by: Nicole Resnick, PhD

Illustrated by: Amelia Janes

Layout by: Vicki Hudson

Printed on recycled paper

