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The Value of Compounded Bioidentical Hormone Therapy

As a man or woman entering "middle age", you may begin to notice changes in your body. Sometimes the changes are subtle, like you just don't feel as peppy or vital as you once did. A few pounds may be added, maybe you don't sleep as well, or perhaps your mood has changed. These changes are often due to declining hormone levels and may intensify as you grow older.



In the past two decades, after articles were published that discussed negative side effects from manufactured hormone therapy, the interest in options to conventional hormone therapy grew, and women, men, and their physicians sought information on compounded bioidentical hormone therapy (cBHT). For multiple reasons, including lack of response to traditional therapy, customized hormone therapy has become the choice for many.

Compounding is the preparation of a custom formulation of a medication to fit a patient's unique needs which cannot be met with commercially available products. Compounding permits the dose, dosage form, and route of administration to be customized and titrated to obtain the desired clinical effect in each individual patient while minimizing any potential side effects. This is why so many patients prefer cBHT as compared to manufactured products which are available only in limited dosage forms and strengths. Millions of women now rely on customized therapy for menopausal issues, fertility challenges, and other hormonal imbalances, and men concerned about loss of strength and vitality benefit from customized therapy as well.

OUR COMMITMENT TO QUALITY

For decades, pharmacists around the world have compounded BHT using the highest quality ingredients which are identical to those used in manufactured FDA-approved products. Pharmacists are required to compound from an existing FDA-approved drug product or use bulk drug substances known as active pharmaceutical ingredients (API) that meet US Pharmacopeia-National Formulary (USP-NF) standards in applicable monographs. USP is a non-profit organization that sets standards for the identity, strength, quality, and purity of ingredients used to make drugs.

HORMONE TESTING

Many compounding pharmacists recommend and health care providers prescribe saliva or serum testing to confirm that dosing of cBHT is appropriate to maintain therapeutic levels and reduce the risk of side effects from excessive doses. There are often misconceptions regarding the most accurate way to test for hormone levels and the variation between salivary, capillary, and serum/plasma hormone concentrations based on the route of administration of the hormones (topical, oral, or parenteral). In general, it is widely accepted that when hormones are administered topically, saliva or capillary blood from the fingertip (which is also known as dried blood spot) provides a more accurate measurement of tissue levels than a "blood test" where a sample is drawn in a lab to measure serum or plasma hormone concentrations. Another option for hormone testing is dried urine testing for comprehensive hormones.

PROTECT YOUR ACCESS TO COMPOUNDED HORMONES

The FDA commissioned a study from the National Academies of Sciences, Engineering, and Medicine (NASEM) on the safety, effectiveness and use of cBHT. The study committee included

respected healthcare professionals, but did not include a pharmacist with patient-facing experience, a compounding pharmacist, or a physician with substantive experience in BHT. The study reviewers included one former FDA employee (and current FDA contractor) who is a long-time, well-known opponent of pharmacy compounding. The NASEM recommended "that prescribers restrict the use of cBHTs to two circumstances: when a patient is allergic to an ingredient in an FDA-approved hormone product, and when a patient requires a specific dosage form not available for an FDA-approved product."

Lloyd V. Allen, Jr., PhD, RPh, Editor-in-Chief of the International Journal of Pharmaceutical Compounding, responded: "Even though there have been dozens of hormone-containing products evaluated for safety and efficacy and approved by the FDA, there is still a need for individual compounded preparations for millions of patients... One needs to consider enhancing patient compliance and outcomes using various dosage forms, patient-specific doses and dose variations, different routes of administration, [and] different product components to achieve the patients desired response, etc... It should also be noted that cBHT formulations have been successfully compounded for decades and are not difficult to compound."

We know that FDA-approved therapies do not meet the therapy goals of many patients and that limiting access to cBHT as NASEM recommends would have far-reaching consequences for many patients. Help protect your access to cBHT! The FDA is considering restrictions on cBHT and we need to show how cBHT has helped millions of people.

Join the campaign and share your testimonial about how cBHT has helped YOU at a4pc.org/cbhtandme. Medical practitioners are encouraged to complete the [prescriber survey](#).

If you have questions, ask our compounding pharmacist.

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Have you been laid-off or furloughed due to COVID-19?

If you are having trouble paying for your cash compounded prescriptions at this time, please speak to one of our professional staff members to find out how we can help you. We do not want you to discontinue or alter your medication regiment due to financial hardship. ***We can help!***

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