

COMPOUNDED BHRT

National Academies of Sciences, Engineering, and
Medicine

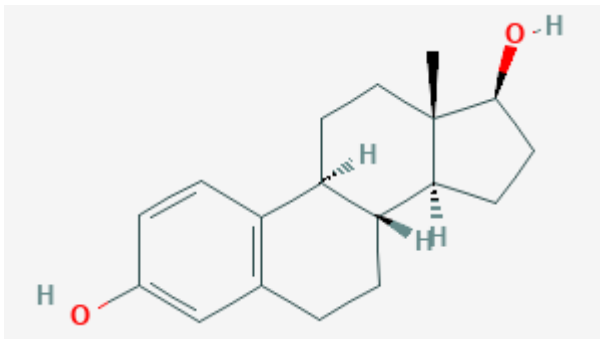
May 6, 2019

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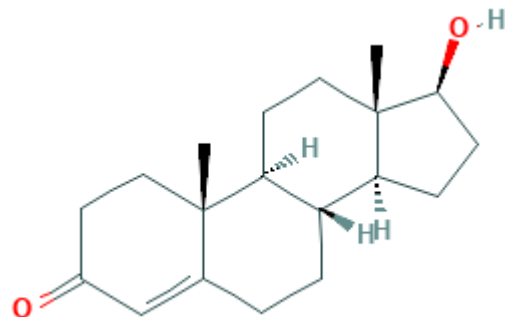
Why is there a need for compounded hormones?

- Compounded BHRT has been around for decades
- Practitioners seeking therapies that utilized hormones that are normally present within the human body
 - Structure determines function
- Many conventionally manufactured products utilize:
 - Hormone esters
 - Conjugated hormones extracted from equine urine

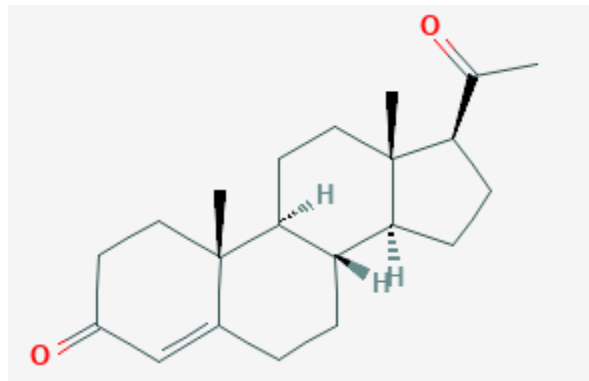
Image source: PubChem



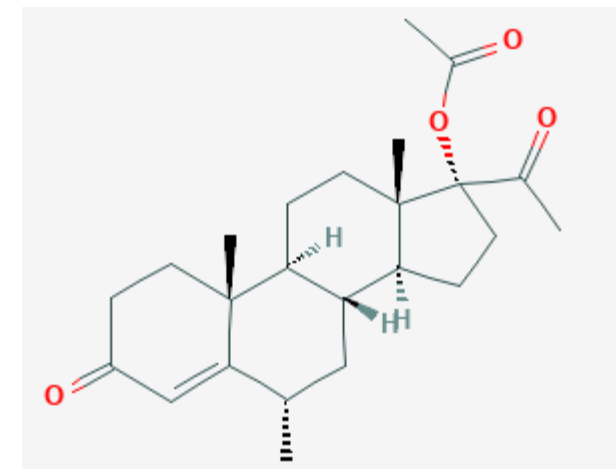
Estradiol USP



Testosterone USP



Progesterone USP



Medroxyprogesterone Acetate

FDA-approved Bioidentical Hormone Products

- Oral estradiol tablet
- Topical estradiol gel
- Topical estradiol spray
- Transdermal estradiol patch
- Vaginal estradiol cream
- Vaginal estradiol insert
- Intramuscular progesterone injection
- Oral progesterone capsule
- Vaginal progesterone cream
- Vaginal progesterone insert
- Implanted testosterone pellet
- Buccal testosterone tablet
- Nasal testosterone gel
- Topical testosterone gel
- Topical testosterone solution
- Transdermal testosterone patch
- Vaginal prasterone (DHEA) insert

Patient Populations – The Bell Curve

- FDA approved products contain most of the API that are used in compounding, and serve most of the needs of the population
- FDA approved products are available in various routes of administration – oral, topical, vaginal
- What is not addressed is the small percentage of the population that doesn't fit the mold of the mass-manufactured drugs
 - Patient compliance
 - Palatability or tactile issues
 - Dosage form acceptance
 - Convenience
 - Specialized doses
 - Adjust dosing to optimize clinical outcomes, minimize adverse reactions
 - Intolerance to excipients

Menopause from Different Standpoints

Thompson et al, 2017, Qualitative Study on Motivations for Using cBHT

Most significant appeal was not the actual cBHT itself but the clinical care associated with it.



Women want to be listened to and their symptoms validated!

Thompson et al. BMC Women's Health 2017;17:97, Fishman et al. Social Scie Med 2015;132:79-87

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Efforts to improve patient engagement & compliance

- Walgreens has partnered with Microsoft to develop software to manage patient engagement
- Alphabet (Google) has a unit called Verily Life Sciences which is developing a project to get patients to take their medications as prescribed
- CVS and Walgreens are trying to make their stores “health hubs” which will offer multiple services which are typically practitioner-provided (outside of conventional retail pharmacies)

March 5 meeting

Presentation from Dr. Timothy McPherson

- Clinical outcomes and patient satisfaction is extremely high for compounded HRT

Female BHRT Users Were Very Satisfied with Their Compounded Products

Indicate your level of satisfaction with:	Very Dissatisfied (%)	Somewhat Dissatisfied (%)	Somewhat Satisfied (%)	Very Satisfied (%)
Relief from the medical condition	0	1	19	80
Interaction with the pharmacy	0	1	14	85
Overall satisfaction	0	1	12	87
Out of pocket cost	21	31	34	14

n = 209 – 217 per item

March 5 meeting

Presentation from Dr. Timothy McPherson

- During discussion: those 14% preferred compounded HRT because they were able to get lower doses than from commercial drug products

Female BHRT Users Prefer Natural Hormones and Individualized Doses

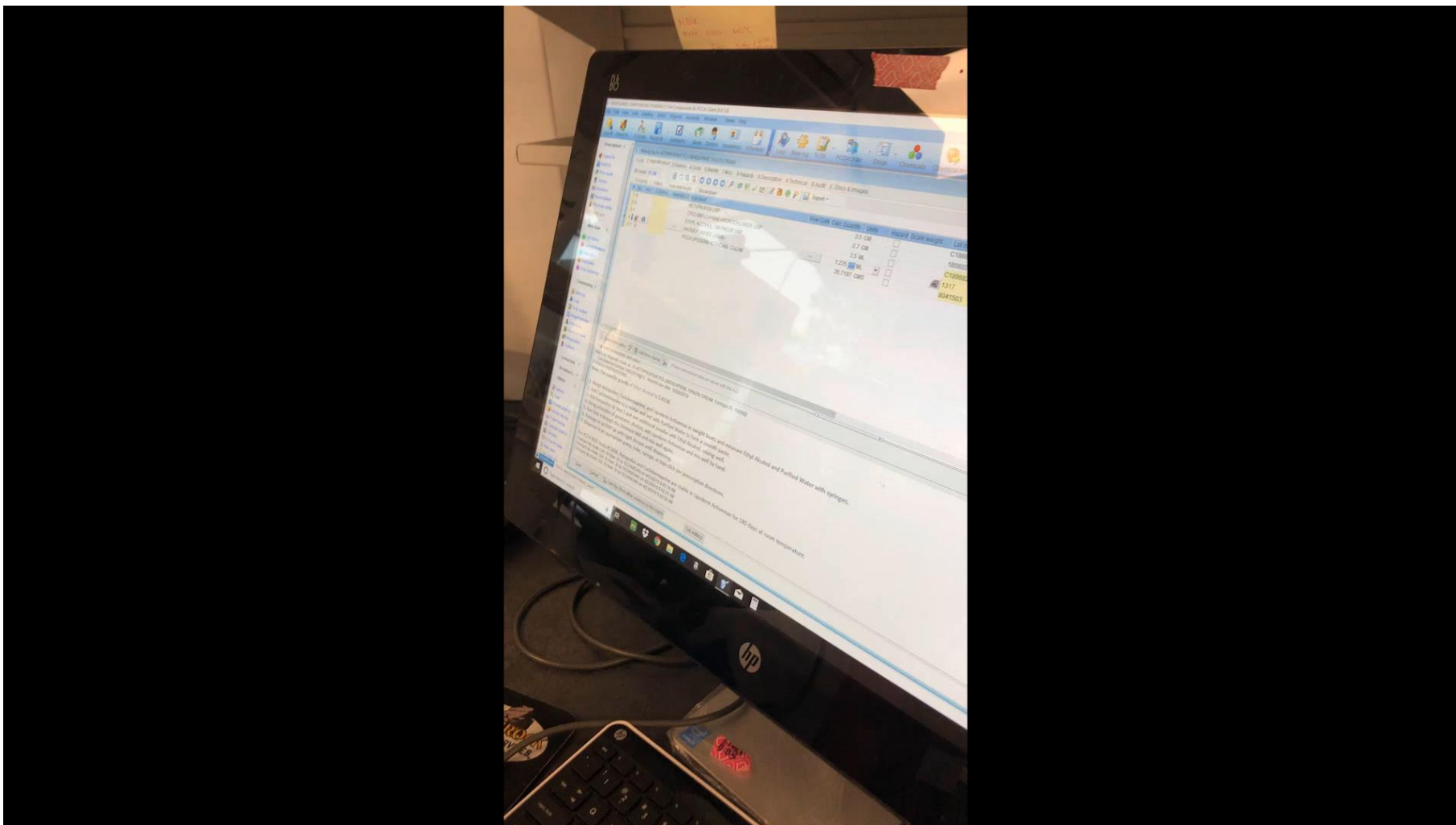
- “Why did you and your physician decide to use this compounded medication?”
 - 113 female BHRT users entered a free text response
 - 39% preferred “bioidentical” or “natural” hormones
 - “Safer,” “fewer side effects,” “healthier option”
 - Do not like “synthetic” hormones
 - Representative comments
 - “All natural/bioidentical option; I do not want synthetic”
 - “Wanted to use a more natural product + safer”
 - 14% preferred BHRT because the dose was individualized for them
 - BHRT users reported wanting to receive care from professionals who listened to them and understood, and did not dismiss, their symptoms
- Soc Sci Med 2015;132:79-87; BMC Womens Health 2017;17:97

McPherson, Fontane, Bilger –unpublished data

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*Approximately 51% of the survey participants responded to this question (113 of 222)

How Are Compounds Prepared? Video 1



How Are Compounds Prepared? Video 2



How Are Compounds Prepared? Video 3



How are compounds prepared?

- Compounding is NOT manufacturing
- USP <795> for compounded non-sterile preparations (CNSP)
- USP <797> for compounded sterile preparations (CSP)
- Pharmaceutical ingredients from FDA-registered and cGMP-inspected manufacturers
- Third-party analytical testing of compounds from FDA-registered laboratories

TSBP rules regarding written information for patients

- Texas Administrative Code §291.131 (d)(6)

(6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

WE DO HAVE CONCERNS ABOUT
SEEMINGLY UNREGULATED HORMONE
PRODUCTS SOLD WITHOUT ANY
MEDICAL TEAM OVERSIGHT



Progesterone Cream - All Natural
bioidentical P75 Maxx with
Retinol - 7.5% progesterone -
Fight Aging Naturally - 75MG...

★★★★★ 28

Progesterone Cream (Bioidential) 4oz Pump of 2000mg USP Bio-Idential Progesterone.

Paraben-Free, Soy-Free & Non-GMO. May Support PCOS,...

★★★★★ 1,785 customer reviews | 210 answered questions Amazon's Choice for "smoky mountain naturals"



About the product

- THE #1 PROGESTERONE CREAM ON AMAZON: Women deficient in Progesterone commonly use Progesto-Life with great results. Progesto-Life may provide support for women who are dealing with Menopause, PCOS, Vaginal Dryness, Insomnia, Acne, Mood, Energy, TTC.
- UNMATCHED QUALITY: Our Paraben-Free, Propylene Glycol-Free, Non-GMO, Soy-Free, Progesto-Life contains Bioidential, Micronized Progesterone USP. It is Fragrance-Free, not tested on animals, features discrete packaging, and is produced in a facility that adheres to FDA-GMP practices.
- ELITE FORMULATION: Contains 2000 mg of Micronized Progesterone (Certified USP) in a 4 ounce pump; ~21mg of Progesterone USP per serving.
- MENOPAUSE TRIO: For maximum results use Progesto-Life in conjunction with Estro-Life and our DIM. After adding Progesto-Life to your cart, simply select, "From Smoky Mountain Nutrition" on the top of this page for other products!
- 90-DAY MONEY BACK GUARANTEE: All Smoky Mountain Naturals' products are backed by our no-questions-asked, money-back guarantee.

All Natural Bio
Progesterone
Progesterone
Supply - Fight

★★★★★

\$6.66/F

more w

Get it a

pping o

y Amaz



All Natural Progesterone
Bioidential P50 Maxx -
Aging Naturally - 50MG
- 5% progesterone - Tw

★★★★★ 11

\$39⁹⁷ (\$13.32/Count)

✓prime Get it as soon as Sun, Apr 21

FREE Shipping by Amazon

About the product

- DON'T BE DECEIVED... most of the "other" progesterone creams are not All Natural. If you don't believe us take a look for yourself... check the ingredients of the progesterone cream labels from some of the top brands on Amazon. Do you see, Phenoxyethanol? Do you see acrylamide, dioxides or sulfates? BIOLabs PRO prides ourselves on having the safest & most effective All Natural Progesterone Cream on the market!
- THE BEST BIOIDENTICAL PROGESTERONE AVAILABLE- Is your current progesterone derived from nature and truly bioidential? We recommend that you find out. Don't trust ANY other Progesterone Cream that does not say, "Bioidential." This cream delivers a maximum strength 7.5% dose of Bio-identical Progesterone per pump. If it's not bio-identical progesterone it could be less effective or even harmful due to biological imbalance. Buy now and start getting results this week!
- MAXIMUM STRENGTH PROGESTERONE USP PER PUMP! 7.5% per pump! It is costly for us to create the safest and most effective product but we believe you are worth it. All Natural, made in small batches, in the USA, in an FDA approved and certified Kosher facility. If you really take your at home progesterone replacement therapy seriously, then you want the best bioidential progesterone in your body... not synthetic progestins or a cheap brand you can find at Walmart.
- BEST VALUE PROGESTERONE! This product can last up to five times longer than the cheap brands on Amazon. The easy-to-use pump delivers approximately 75 mg of USP Progesterone per pump. Other progesterone creams would require a literal handful of cream to get a comparable dosage. This is a MAXIMUM STRENGTH Progesterone cream with an industry leading 7.5% progesterone per pump, over 4500MG Per Bottle! With a 60+ day supply, this is only \$29/month, less than \$1 per day!
- SEE A HEALTHY GLOW, ALMOST INSTANTLY. Infused with the beauty product powerhouse, Retinol (Vitamin A), BIOLabs PRO P75 Progesterone cream is maximized for rejuvenation inside and out. For years, doctors have recommended retinol cream for healthy skin, and to use progesterone to fight premature aging. Now you can have both in one product! P75 is engineered for maximum bioavailability to penetrate deep into your skin and bloodstream for powerful results. Apply to inner arms or thighs.

THANK YOU
