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PRESCRIBER BRIEFING:
The Threat to Compounded Hormone Therapy

Visit compounding.com for detailed information and resources.

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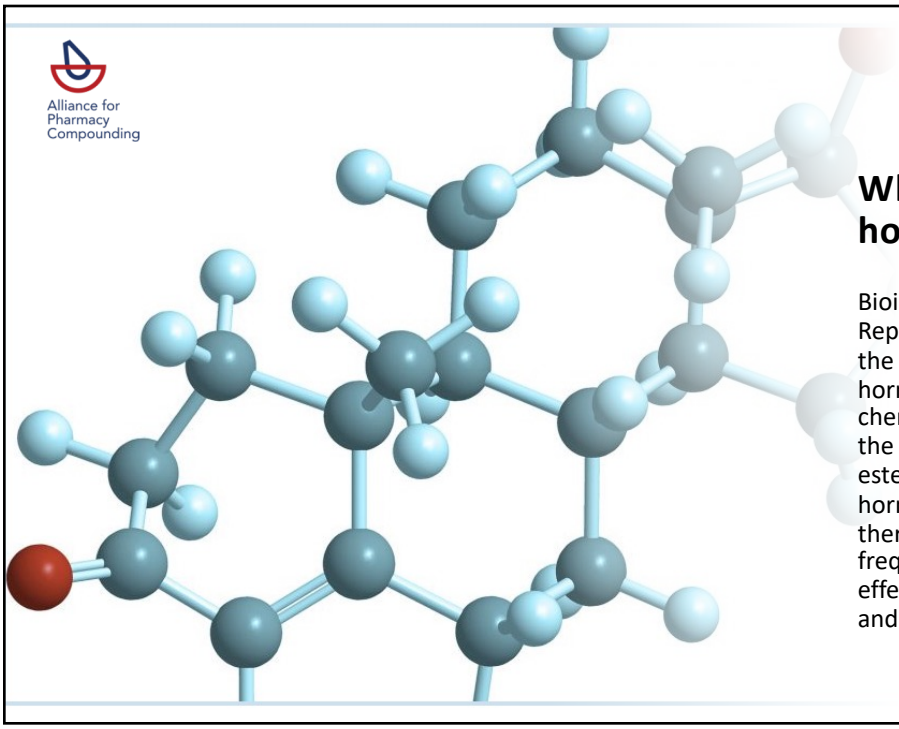

What are bioidentical hormones?

Bioidentical Hormone Replacement Therapy (BHRT) is the use of pharmaceutically pure hormones that are identical chemically to those created in the human body rather than esterified or otherwise modified hormones that are used in other therapies. BHRT is most frequently used to treat the effects of menopause and andropause.

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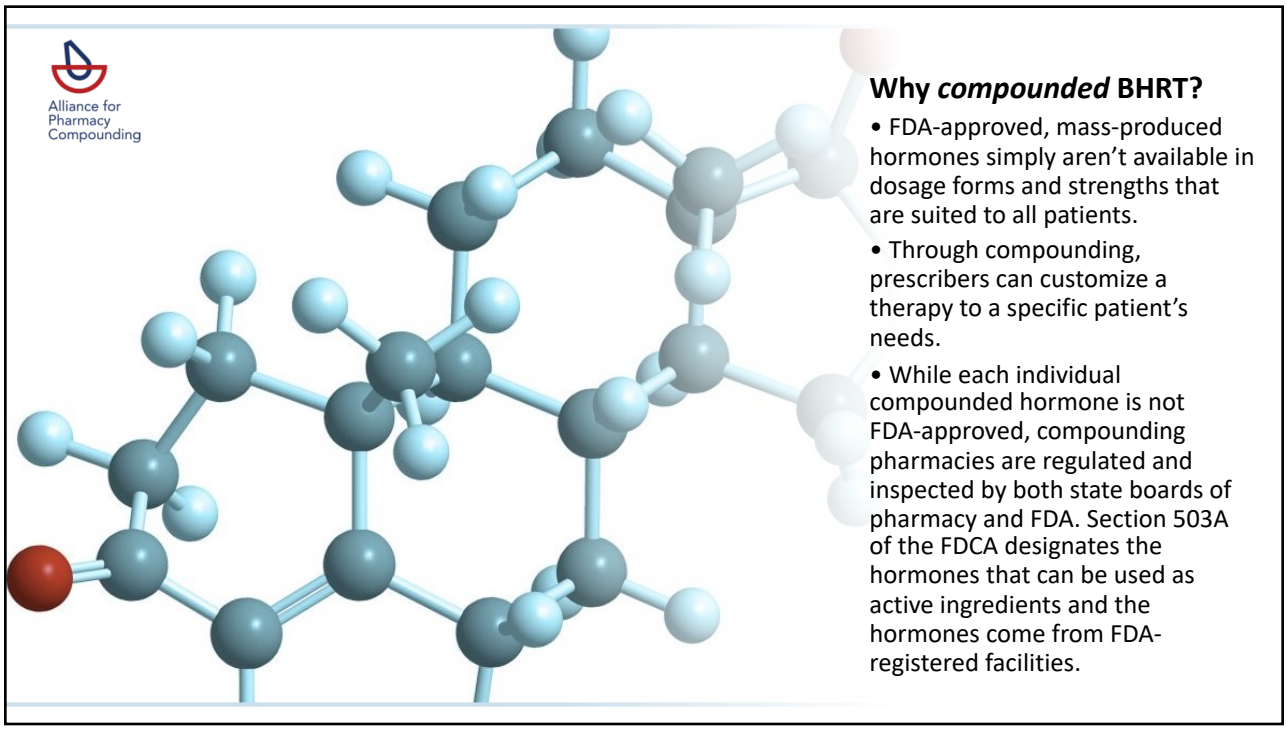
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Why *compounded* BHRT?
• FDA-approved, mass-produced hormones simply aren't available in dosage forms and strengths that are suited to all patients.
• Through compounding, prescribers can customize a therapy to a specific patient's needs.
• While each individual compounded hormone is not FDA-approved, compounding pharmacies are regulated and inspected by both state boards of pharmacy and FDA. Section 503A of the FDCA designates the hormones that can be used as active ingredients and the hormones come from FDA-registered facilities.

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Nevertheless … FDA has a longstanding bias against compounded hormones.

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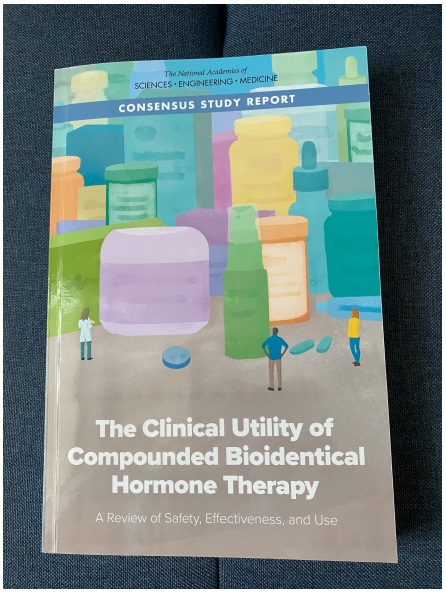
In 2020, an FDA-commissioned report recommended **across-the-board restriction of compounded hormone therapy** "unless safety and effectiveness can be proven."



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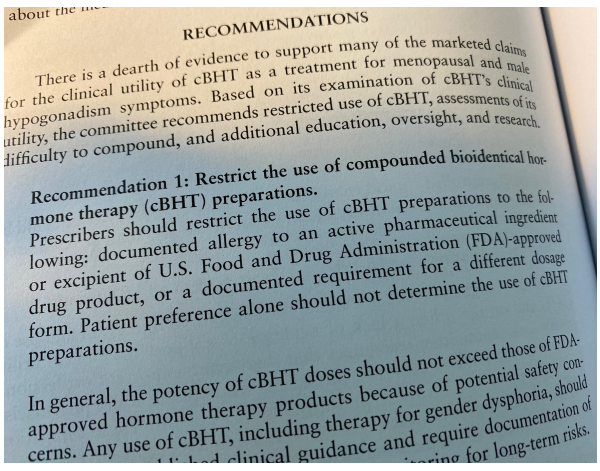
It's a stunning conclusion by an FDA-chosen panel of "experts" who had little expertise in compounding or hormone therapy. Plus, the committee only looked at <u>four</u> hormones, few of which are among the most prescribed compounded hormones.



about the

RECOMMENDATIONS

There is a dearth of evidence to support many of the marketed claims for the clinical utility of cBHT as a treatment for menopausal and male hypogonadism symptoms. Based on its examination of cBHT's clinical utility, the committee recommends restricted use of cBHT, assessments of its difficulty to compound, and additional education, oversight, and research.

Recommendation 1: Restrict the use of compounded bioidentical hormone therapy (cBHT) preparations.

Prescribers should restrict the use of cBHT preparations to the following: documented allergy to an active pharmaceutical ingredient or excipient of U.S. Food and Drug Administration (FDA)-approved drug product, or a documented requirement for a different dosage form. Patient preference alone should not determine the use of cBHT preparations.

In general, the potency of cBHT doses should not exceed those of FDA-approved hormone therapy products because of potential safety concerns. Any use of cBHT, including therapy for gender dysphoria, should [illegible] clinical guidance and require documentation of [illegible] for long-term risks.

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FDA stacked the deck.

FDA commissioned NASEM to report on cBHT, then pre-ordained the outcome, and says it will base future compounded hormone policy in large part on that manipulated report.

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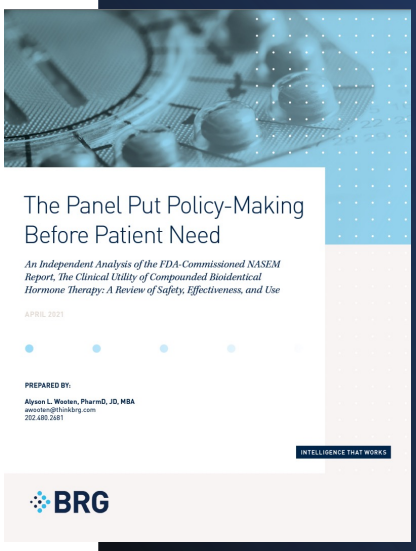
A third-party, independent analysis of the FDA-commissioned NASEM report – *based on FOIA request data* – documents egregious shortcomings of the study structure, process and recommendations, all executed by FDA staff.



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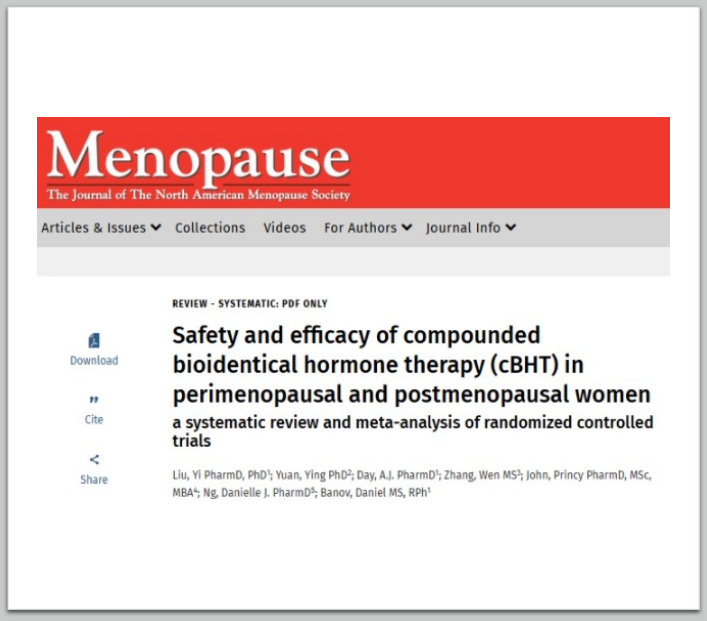
A paper, to be published this month in *Menopause*, presents the sort of thorough meta-analysis we would have expected of the NASEM committee.

- 29 RCTs / 40 articles
- While limited in scope, finds no evidence that compounded hormones pose an increased clinical risk compared to FDA-approved products.



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REVIEW - SYSTEMATIC; PDF ONLY

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Safety and efficacy of compounded bioidentical hormone therapy (cBHT) in perimenopausal and postmenopausal women

a systematic review and meta-analysis of randomized controlled trials

Liu, Yi PharmD, PhD[1]; Yuan, Ying PhD[2]; Day, A.J. PharmD[1]; Zhang, Wen MS[3]; John, Princy PharmD, MSc, MBA[4]; Ng, Danielle J. PharmD[5]; Banov, Daniel MS, RPh[1]

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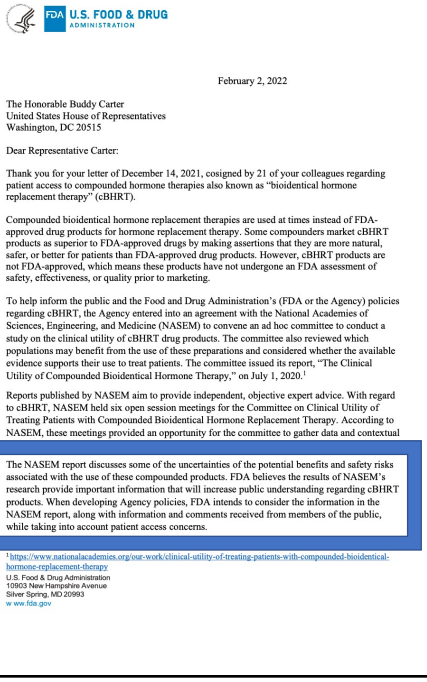
In a February letter to 22 members of Congress, FDA doubled down on its intention to rely on the NASEM report as a basis for its next steps on compounded hormones.



U.S. FOOD & DRUG ADMINISTRATION

February 2, 2022

The Honorable Buddy Carter
United States House of Representatives
Washington, DC 20515

Dear Representative Carter:

Thank you for your letter of December 14, 2021, cosigned by 21 of your colleagues regarding patient access to compounded hormone therapies also known as "bioidentical hormone replacement therapy" (cBHRT).

Compounded bioidentical hormone replacement therapies are used at times instead of FDA-approved drug products for hormone replacement therapy. Some compounders market cBHRT products as superior to FDA-approved drugs by making assertions that they are more natural, safer, or better for patients than FDA-approved drug products. However, cBHRT products are not FDA-approved, which means these products have not undergone an FDA assessment of safety, effectiveness, or quality prior to marketing.

To help inform the public and the Food and Drug Administration's (FDA or the Agency) policies regarding cBHRT, the Agency entered into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM) to convene an ad hoc committee to conduct a study on the clinical utility of cBHRT drug products. The committee also reviewed which populations may benefit from the use of these preparations and considered whether the available evidence supports their use to treat patients. The committee issued its report, "The Clinical Utility of Compounded Bioidentical Hormone Therapy," on July 1, 2020.[1]

Reports published by NASEM aim to provide independent, objective expert advice. With regard to cBHRT, NASEM held six open session meetings for the Committee on Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy. According to NASEM, these meetings provided an opportunity for the committee to gather data and contextual

The NASEM report discusses some of the uncertainties of the potential benefits and safety risks associated with the use of these compounded products. FDA believes the results of NASEM's research provide important information that will increase public understanding regarding cBHRT products. When developing Agency policies, FDA intends to consider the information in the NASEM report, along with information and comments received from members of the public, while taking into account patient access concerns.

[1] https://www.nationalacademies.org/our-work/clinical-utility-of-treating-patients-with-compounded-bioidentical-hormone-replacement-therapy

U.S. Food & Drug Administration
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Silver Spring, MD 20993
w ww.fda.gov

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Rumor mill says FDA will act soon to place compounded hormones on its "demonstrably difficult to compound*" list, effectively cutting off access to any hormone therapy that does not utilize one of the few manufactured hormone products on the market.

*Many common hormones have been compounded for a half-century or more. It's absurd to suggest they're "difficult to compound."

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If compounded hormones are restricted:

1. **Prescribers' and patients' BHRT therapy choices will be severely restricted** to the few manufactured bioidentical hormones, doses and dosage forms approved by FDA.
2. **The health of millions of Americans – women and men alike – will be affected** by a loss of therapies, dosage forms and strengths that are suited to their needs.
3. **Pharma won't fill this gap**: Generally, the economic model does not work for them.
4. **FDA will have inserted itself in the practice of medicine** and removed prescribers' ability to choose the therapy that in their judgment is best suited to their patient.

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So what are we doing about it?

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The Campaign to Save Compounded Hormones

- 2021: Raised $1.5 million to fund a digital campaign
  - Audiences: Patients, prescribers, policymakers
  - Message: FDA's threat to restrict access to compounded hormone therapies that are benefiting millions of Americans
  - Compounding.com
  - Reached 25,000,000 Americans
  - 300,000 engagements
  - 5,000+ patient & prescriber testimonials
  - 1,000+ messages to Congress

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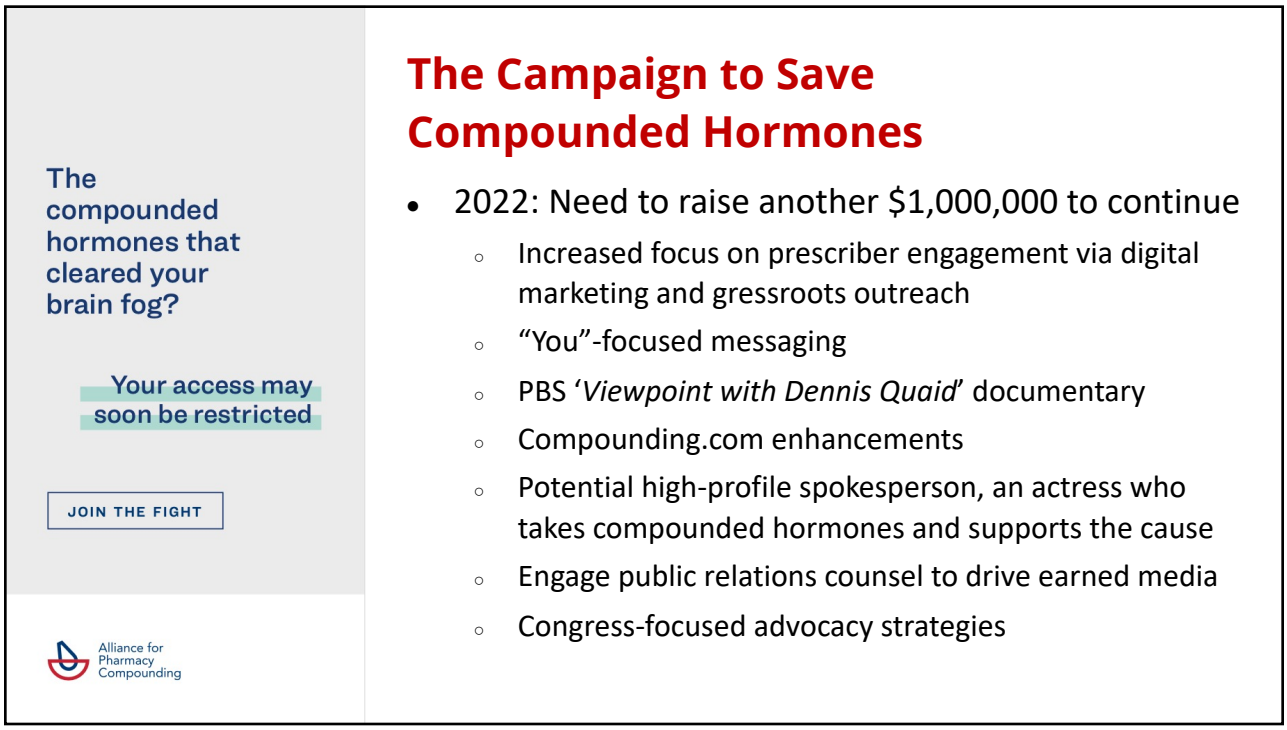

The Campaign to Save Compounded Hormones

- 2022: Need to raise another $1,000,000 to continue
  - Increased focus on prescriber engagement via digital marketing and gressroots outreach
  - "You"-focused messaging
  - PBS '*Viewpoint with Dennis Quaid*' documentary
  - Compounding.com enhancements
  - Potential high-profile spokesperson, an actress who takes compounded hormones and supports the cause
  - Engage public relations counsel to drive earned media
  - Congress-focused advocacy strategies

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1. **Utilize our campaign resources** at compounding.com
2. **Urge your patients to share their stories** at compounding.com – and send a message to their members of Congress.
3. **Reach out to Congress** yourself.
4. **Give to the campaign.** You'll see the link at compounding.com.
5. **Join APC.** Prescriber memberships are available at a4pc.org

Will you help us?

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Visit compounding.com for detailed information and resources.

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