PREScriber briefinG:
the threat to
compounded hormone therapy

Visit compounding.com for detailed information and resources.

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.
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.

Nevertheless ... FDA has a longstanding bias against compounded hormones.
In 2020, an FDA-commissioned report recommended **across-the-board restriction of compounded hormone therapy** “unless safety and effectiveness can be proven.”

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 **four hormones**, few of which are among the most prescribed compounded hormones.
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.

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.
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.

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.
Many common hormones have been compounded for a half-century or more. It’s absurd to suggest they’re “difficult to compound.”

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.
So what are we doing about it?

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
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 grassroots 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

Will you help us?

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
Visit compounding.com for detailed information and resources.