

ISSUE BRIEF:

FDA's threat to restrict compounded hormone therapy puts millions of patients at risk. Congress must confront that threat.



We continued to be deeply concerned that FDA may move to restrict access to compounded hormones – life-enhancing therapies that millions of patients have relied on for years – and that it may do so based on a deeply flawed and discredited 2020 report it commissioned from the National Academies of Sciences, Engineering, and Medicine (NASEM). FDA has stated publicly and in correspondence with Members of Congress that it intends to use the flawed NASEM study's recommendations to inform the agency's policies on compounded hormones going forward.

The report, titled *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, only considered four hormones, yet recommends across-the-board restrictions on all compounded hormones. Moreover, no one on the NASEM committee had expertise in prescribing or compounding hormones. Unfortunately, it has also been demonstrated that the report is tainted by FDA efforts to preordain the outcome in ways that render the report biased and unscientific. A third-party analysis of the NASEM study by Dr. Alyson Wooten, a director at the nonpartisan Berkeley Research Group (BRG) titled *The Panel Put Policy-Making Before Patient Need: An Independent Analysis of the FDA-Commissioned NASEM Report, "The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use"* may be found at a4pc.org/Berkeley.

The NASEM report's recommendations would interfere with the practice of medicine and prevent practitioners from treating patients with the best therapies. The report's most egregious recommendation asks FDA to consider placing hormones on the "demonstrably difficult to compound list" – despite the facts that some hormones have been compounded without difficulty for more than a half-century – which would make it unlawful to compound with those ingredients.

The NASEM report acknowledges that "[m]illions of men and women use cBHTs to alleviate symptoms associated with age-related hormone changes, such as hot flashes in menopause, or low muscle mass due to decreased testosterone." Given the enormous number of patients who are prescribed these medications, we urge that FDA to reject the NASEM recommendations and avoid disruption of treatments and the potential elimination of this important therapy option.

Though there are a limited number of FDA-approved bioidentical hormonal drug products on the market, those medications are not uniquely tailored to individual needs. Because of this, medical providers often prescribe a compounded alternative with a different dosage level, a different delivery method, or a different combination of hormones than what is available in manufactured products. Indeed, some patients may have an allergy or intolerance to a manufactured product, which necessitates a compounded medication. Access to compounded medications provides the ability for a prescribing physician to uniquely tailor and personalize medications to meet the needs of their individual patients.

THE ASK:

It's important for Members of Congress to be aware of this threat and the potential impact FDA restrictions could have on many of your constituents. Go to www.compounding.com to read and hear stories, cataloged by state, from patients whose lives have been enhanced, even saved, by compounded hormone therapy. The outcomes reported by patients are overwhelmingly positive.

House Members: Please contact the FDA to express concern about bias and lack of scientific rigor in the FDA-funded NASEM cBHT report and FDA's implicit threat to restrict compounded hormones.

Senators: Please add your name to a letter to FDA led by Senators Baldwin (WI) and Marshall (KS) urging the agency to base any action on compounded hormones on rigorous science and stakeholder input. The letter has been included in your packet. Contact Erin Dugan in Senator Baldwin's office or Charlotte Pineda in Senator Marshall's office to sign on.

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