

ISSUE BRIEF:

FDA's threat to cBHT puts millions of patients at risk. Congress must confront that threat.



When the National Academies of Science, Engineering and Medicine released its FDA-funded report on cBHT in July 2020—which included a recommendation for across-the-board restrictions on compounded hormones—FDA issued a public statement saying the agency would base its next steps on compounded hormones on the NASEM report. That statement widely was interpreted to mean FDA will act to restrict compounded hormone therapy. We're talking therapies that millions of patients rely on for their quality of life.

But a third-party analysis of the NASEM report shows it to be compromised by potential bias, conflicts of interest and bad science.

FDA touted the NASEM report, which recommended restrictions on compounded hormone therapy, as "independent" and "comprehensive," but in fact it was neither. That's one of the key findings in [the white paper](#) by Dr. Alyson Wooten, a director at the nonpartisan Berkeley Research Group (BRG). The paper is 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."* The Pharmacy Compounding Foundation commissioned Dr. Wooten to conduct the third-party, independent review of the NASEM report.

"Given the strong potential bias influencing the Committee's recommendations and the omission from the final report of key data supporting the safety and efficacy of cBHT, we recommend that FDA not rely on or consider the NASEM Report," the white paper advises.

Wooten's paper demonstrates that the agency exerted inappropriate influence and bias in almost every phase of the commissioned report, even recommending study committee appointees who had no expertise in prescribing or compounding hormones.

"The BRG paper shows how FDA inappropriately meddled in the composition of the NASEM committee, fed the committee selective research for its consideration and even advised the committee on its final recommendations for restricting compounded hormones," said Pharmacy Compounding Foundation CEO Scott Brunner, CAE. "And all so FDA could have a report that reflected its existing negative view of compounded hormone therapy. The paper reveals an FDA much more interested in documenting its own biases than in actual objective science. And it was apparently willing to spend \$1.3 million in taxpayer dollars to do it."

Dr. Wooten's review is a repudiation of an FDA staff that manipulated the process and NASEM committee members who lacked expertise in the subject matter they were engaged to study.

The white paper documents how:

- Bias may have influenced the conclusions and recommendations of the committee.
- The committee and its review team included individuals who may have been biased against compounded hormones.
- The committee did not include any prescribers or pharmacists with substantive, patient-facing experience with compounded hormones.
- Jane Axelrad, a former FDA official and outspoken critic of compounded hormones, played multiple key roles in the development of the NASEM report.
- The committee's conclusions regarding the safety and efficacy of compounded hormones are flawed.
- The definition of "clinical utility" developed and relied upon by the committee does not reflect an accurate or complete representation of the term.

- The studies relied upon by the committee do not reflect an accurate or complete representation of compounded hormones.
- The standards for evaluating the safety and efficacy of FDA-approved drugs cannot be reasonably applied to highly individualized compounded medications.
- The committee relied on the discredited 2002 Women’s Health Initiative study in developing its conclusions.
- The committee ignored the body of evidence demonstrating the safety and efficacy of compounded hormones.

“These numerous flaws render the NASEM report so thoroughly compromised as to be useless in any discussion of compounded hormone therapy,” said Brunner.

Despite those flaws, FDA continues to tout the NASEM report. In a February 2022 letter to 22 members of Congress who had written to FDA to express concern about the NASEM report, FDA doubled down on its 2020 statement, telling legislators it would base its next steps on compounded hormones in part on that NASEM report.

A report published online in February 2022 by *The Journal of the North American Menopause Society* and slated for print publication by NAMS in Spring 2022 accomplishes what was expected of – but not accomplished by – the NASEM Committee: a systematic review and meta-analysis of the existing evidence related to the safety and efficacy of commonly prescribed cBHT preparations in perimenopausal and postmenopausal women. Compared to the NASEM committee’s cherry-picking of only 13 research clinical trials covering only four hormones, that NAMS-published paper reviews a total of 29 RCTs reported in 40 articles containing 1,808 perimenopausal and postmenopausal women were included. Notably, it finds that despite variations in absorption from different types of compounded hormones, routes, and strengths, the changes of serum hormone levels were consistent with published data from FDA-approved products. While still limited in scope, this thorough meta-analysis suggests that the NASEM committee’s recommendation for restrictions due to safety concerns is at best not rooted in scientific rigor.

“Any public policy related to compounded hormones must be rooted in scientific evidence, not in FDA’s anti-compounding bias,” said Brunner. “It must also take into account abundant patient outcomes data demonstrating that these compounded therapies work well for millions of Americans.”

WHAT CAN YOU DO TO HELP?

Members of Congress need to know about this issue and the potential impact FDA restrictions may have on many, many their 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. Then join APC and provide financial support for our Campaign to Save Compounded Hormones.

CONTACT: APC’s Scott Brunner – scott@a4pc.org

March 2022