

ANALYSIS: **FDA-FUNDED REPORT ON COMPOUNDED HORMONES IS TAINTED**



A 2020 FDA-funded report published by the National Academies of Science, Engineering, and Medicine on the safety and utility of compounded hormones is compromised by potential bias, conflicts of interest and bad science – so says an independent, third-party analysis.

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, *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* was commissioned by the Pharmacy Compounding Foundation and is available at A4PC.org/BRGwhitepaper.

“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.

Background

FDA commissioned NASEM in 2019 to undertake what it said would be an objective review of the safety and effectiveness of compounded hormones. After NASEM released the final report on July 1, 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 that report.

What FDA did not say – but which the BRG paper demonstrates – was that the agency exerted inappropriate influence and bias in almost every phase of the commissioned report, even recommending appointees to the study committee who had no expertise in prescribing or compounding hormones.

“This 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. “All so FDA could have a report that reflected its existing negative view of compounded hormone therapy. The white paper reveals an FDA much more interested 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.”

“So thoroughly compromised as to be useless”

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

The white paper scrupulously 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. For example...
- Jane Axelrad, former FDA official and outspoken critic of compounded hormones, played multiple key roles in the development of the NASEM report.
- The committee did not include any prescribers or pharmacists with substantive, patient-facing experience with compounded hormones.
- 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 upon 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.

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