**ISSUE BRIEF:**

## FDA's threat to cBHT puts millions of patients at risk

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*FDA stacked the deck to get study results it can use to restrict cBHT.*
*But that "study" is little more than a selective review, and it's deeply flawed.*

The FDA, no fan of compounded hormone therapy, last year commissioned a study from the National Academies of Sciences, Engineering, and Medicine on "the safety, effectiveness, and use" of compounded bioidentical hormone therapy (cBHT).

On July 1, 2020, NASEM released its report. In what was surprising to absolutely no one, that report conveniently mirrored the FDA's concerns. Given the absence of peer-reviewed research, NASEM recommends that compounded cBHT is therefore not safe and should be restricted to FDA-approved drugs unless safety and effectiveness can be proven.

In a public statement following release of the NASEM report, FDA has indicated it may rely on that deeply flawed study to enact restrictions on cBHT, despite the fact that millions of Americans benefit from – and swear by – the therapy.

The problems with the NASEM study are numerous:

• The NASEM study committee was populated by esteemed healthcare professionals, but there was not a pharmacist with patient-facing experience, much less a pharmacy compounder, in their number. Neither was there a physician with substantive experience in bioidentical hormone therapy. Likewise, the peer reviewers for the study included few compounders -- but did include one former FDA employee (and current FDA contractor) who is a long-time, well-known opponent of pharmacy compounding.

• Although compounded drugs are exempt from the new drug approval process because they are prepared to meet individual patient needs, the foundation of NASEM's analysis seems to focus on the absence of new-drug-caliber studies of compounded meds. The report makes an illogical leap by effectively deeming cBHT unsafe unless it can mirror drug manufacturing in terms of safety and effectiveness data, labeling, AE reporting, pharmacokinetic data, and scale of clinical trials. Again, compounded medications are exempt from FDA New Drug requirements, and these formulations have been compounded for decades and are not difficult to compound.

• NASEM said it based its recommendations in large part on a review of literature, but identifies only 13 studies as having, in the judgment of the committee, suitable "rigor and relevance" – these, out of literally hundreds of studies out there, not to mention abundant patient outcomes data that could and should have been considered and weighed. In addition, of the 13 studies NASEM selected, at least four were studies of DHEA – perhaps the least frequently compounded of bio-identical hormones.

• The report calls for restricting use of cBHT to patients with allergies to FDA-approved drugs, despite the fact that many FDA-approved therapies may not meet the dosing needs of patients – a point not addressed by the report's recommendations.

• The recommendations seem to suggest that a prescriber's medical judgment and a patient's preferences should play no role in determining a proper course of treatment – a stunning assertion that is applied to no other aspect of medicine or pharmacy care. Women's needs are much more complex than the cookie-cutter approach offered by current FDA-approved drugs. The NASEM panel did not seem to recognize that

individualized therapy is the result of a balanced approach between prescriber, patient and pharmacist assessing each patient's unique needs.

• The report cites concerns over bioavailability. However, many compounders or prescribers perform saliva or serum testing to confirm cBHT is appropriate therapy. How many prescribers routinely check levels of FDA-approved products?

• The report sends mixed messages. Individualized therapy is a part of FDA's newly established goal of creating personalized therapies to target each patient. Factors such as age, weight, genetics, past medical history all contribute to appropriate treatment and dosage selection. Yet these NASEM recommendations seem to assert that FDA-approved drugs are always superior to compounded therapies.

In short, the NASEM study is yet another attempt by FDA to discredit critical compounded hormone therapies in the eyes of the public in favor of FDA-approved hormone therapies. Yet despite this effort by FDA, physician and millions of patients across the U.S. continue to see and experience the benefits of cBHRT.

**ACTION REQUESTED:** Timing is everything, and since there is not yet an FDA regulatory proposal for Members of Congress to weigh in on, we need to be educating members of Congress about cBHT and the problems with the NASEM study. Let members of Congress know that millions of Americans benefit from cBHT, and those patients will respond in anger if FDA attempts to restrict cBHT in a way that denies them access. Ask your Member of Congress to sign the bipartisan House letter to FDA on cBHT led by Reps. Pocan, Roe, Cuellar and Herrera-Beutler. A Senate letter is coming soon!

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