

QUILL LINK

Deadline: May 31, 2023 EOD

Dear Colleague:

Please join us in sending a letter urging the Food and Drug Administration (FDA) to avoid disruptions in care and preserve access to compounded hormone therapies for millions of Americans.

Healthcare providers and patients often rely on compounded hormone therapies to address individual needs that cannot be addressed through a commercially available option, such as a specific dosage level or delivery methods. These treatment options particularly impact millions of patients who rely on compound hormone therapies to address symptoms of hormone changes such as menopause or fertility challenges.

However, a National Academies of Science, Engineering, and Medicine (NASEM) report titled, "*The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use,*", included several concerning recommendations that if implemented could limit providers' ability to prescribe the most appropriate medicine for their patients. These recommendations include placing many commonly compounded hormones on the "demonstrably difficult to compound list."

The FDA has not yet moved to implement the recommendation and has promised to review NASEM's findings and "work with compounders, regulators, healthcare professionals and patients as we develop policies that ensure **continued access to compounded drugs for patients who need them**, while also protecting patients from the risks of receiving a compounded drug when an FDA-approved product is appropriate for their medical care." (emphasis added)

This bipartisan letter urges the FDA to craft patient centered policies that preserve access to current treatment options and include perspectives of all relevant stakeholders. If you would like to cosign, please use the Quill link found here. Please contact Amelia Faraco-Hadlock in Rep. Wexton's office (Amelia.Faraco-Hadlock@mail.house.gov) or Alexa Roberts in Rep. Burgess' office (Alexa.Roberts@mail.house.gov) with any questions.

Sincerely,

Jennifer Wexton
Member of Congress

Michael Burgess, M.D.
Member of Congress

LETTER TEXT

The Honorable Robert Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write to express our continued concern that millions of Americans, including many of our constituents, could lose access to compounded hormone therapies if FDA implements the recommendations contained in a July 2020 report by the National Academies of Sciences, Engineering, and Medicine (NASEM). As you know, patients and health care practitioners rely on compounded hormone therapies when commercially available options are not appropriate for individual patients, but the recommendations in the NASEM report, titled *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, could severely reduce or eliminate access to these critical medications.

Medical providers may prescribe a compounded hormone therapy for several reasons, such as when patients have an allergy or intolerance to commercially available products, requires a modified dosage level or delivery method, or needs a different combination of hormones. Unfortunately, the recommendations in the NASEM report would limit the ability of prescribers to order the most appropriate medicine for their patient.

Additionally, the recommendations in the NASEM report, if implemented, would have a disproportionate impact on patients experiencing age-related hormone changes. As the NASEM itself notes, “[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 number of patients who rely on these treatments, and that the FDA-approved bioidentical hormone drug products that are commercially available are not appropriate for all individuals, we continue to urge FDA to cautiously approach this issue and strive to avoid disruption to care.

Finally, we are concerned by reports from stakeholders that the NASEM committee that produced the report may not have included all relevant perspectives, including prescribers or compounders of hormone products. We are also aware of concerns that the report was based on a relatively limited number of studies, and that other available studies show that compounded hormone therapies provided improved patient health. We urge you to consider the perspective of all stakeholders, including prescribers, compounders, and patients, to ensure FDA policies

related to compounded hormones are patient-centered and do not limit access to care and treatment options.

Thank you for taking these considerations into account. We look forward to your response.

Sincerely,