

Cosign a Bipartisan Letter to Protect Women’s Access to Compounded Hormones

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Dear Colleague:

Please join us in sending a letter urging the Food and Drug Administration (FDA) to preserve millions of women and other patient population’s access to compounded hormone therapies.

Compounded medicines are often used by medical providers to meet a patient’s individual needs, such as a different dosage level, delivery method, or a combination of hormones than what is included in manufactured products. Research shows that up to 2.5 million women in the U.S. 40 years of age or older may rely on compounded hormones like estriol, estradiol, and progesterone.¹ These hormones are particularly important for patients going through menopause, fertility challenges, or other hormonal imbalances.

In July 2020, the National Academies of Science, Engineering, and Medicine (NASEM) released a report that contains several concerning recommendations, including considering placing many commonly compounded hormones on the “demonstrably difficult to compound list.”² If fully implemented by FDA, this recommendation would make it unlawful for medications to be compounded with ingredients on this list.

While the FDA has not yet acted upon the recommendations, the agency responded that they are “reviewing NASEM’s findings to inform our next steps regarding cBHT. We will continue to 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)

As the FDA acknowledged in its initial response to the report, patient access to compounded medications, including compounded hormones, can have a substantial impact on patient wellbeing and quality of care. NASEM’s own report acknowledges that millions of individuals currently rely upon compounded hormones for age-related³ concerns and that compounded hormones should still be available for certain patients (e.g., when the patient has an allergy to a component of a commercial drug product)⁴.

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4547729/>

² **The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use (2020).**”

³ **The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use (2020) p. 91.**

⁴ **The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use (2020), p.2** <https://www.nap.edu/resource/25791/cBHT%20Recommendations%20Insert.pdf>

We invite you to join us in co-signing this bipartisan letter which highlights the importance for women to have continued access to compounded medicines, emphasizes the need for a prescribing physician to uniquely tailor and personalize medications to meet the needs of their patients, and urges the FDA to craft patient centered policies that preserve access to current treatment options.

You can sign on to the letter [HERE](#). Please contact Amelia Faraco-Hadlock in Rep. Wexton's office (Amelia.Faraco-Hadlock@mail.house.gov) or Adrianna Lagorio in Rep. Herrera Beutler's office (Adrianna.Lagorio@mail.house.gov) with any questions.

Sincerely,

Jennifer Wexton
Member of Congress

Jaime Herrera Beutler
Member of Congress

LETTER TEXT

The Honorable Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

Millions of women and other patient populations have come to rely on compounded hormone therapies, and we are writing to urge you to preserve access to these treatment options. We have heard from constituents who are deeply concerned that they may lose access to medications they have relied on for years if FDA considers implementing the recommendations contained in a July 2020 report by the National Academies of Sciences, Engineering, and Medicine (NASEM).

If implemented, the recommendations in the report, titled *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, would limit and in some cases eliminate access to these critical compounded medications. These recommendations would interfere with the practice of medicine and prevent practitioners from treating their patients with therapies that they determine are best for their patients. The most egregious recommendation asks FDA to consider placing hormones on the “demonstrably difficult to compound list,” which would make it unlawful to compound with these ingredients.

Continued patient access is key. 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 multitude of patients, including many of our constituents, who are prescribed these medications, we urge the Agency to cautiously approach this issue in order to avoid disruption of treatments and the potential elimination of this important option.

Compounding provides personalized medicine. 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 included in manufactured products. Indeed, some patients may have an allergy or intolerance to a manufactured product, which would necessitate 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.

We ask that you please take these key considerations into account, and craft patient centered policies that preserve current treatment options. Thank you for your consideration. We look forward to your response.

Sincerely,