

Congress of the United States
Washington, DC 20515

December 14, 2021

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,



Jennifer Wexton
Member of Congress



Jaime Herrera Beutler
Member of Congress



Brian Fitzpatrick
Member of Congress



Earl L. "Buddy" Carter, R.Ph.
Member of Congress



Gregory F. Murphy, M.D.
Member of Congress



Kathy Castor
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