Congress of the United States

Washington, DC 20515

June 20, 2023

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, require a modified dosage level or delivery method, or need 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. [1,2] 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.

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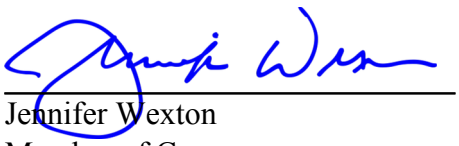
[1] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy. The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use. Jackson LM, Parker RM, Mattison DR, editors. Washington (DC): National Academies Press (US); 2020 Jul 1. PMID: 33048485. Pg. 140.

[2] Liu Y, Yuan Y, Day AJ, Zhang W, John P, Ng DJ, Banov D. Safety and efficacy of compounded bioidentical hormone therapy (cBHT) in perimenopausal and postmenopausal women: a systematic review and meta-analysis of randomized controlled trials. Menopause. 2022 Feb 14;29(4):465-482. doi: 10.1097/GME.0000000000001937. PMID: 35357369.

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

Sincerely,



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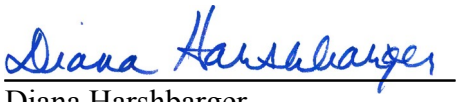

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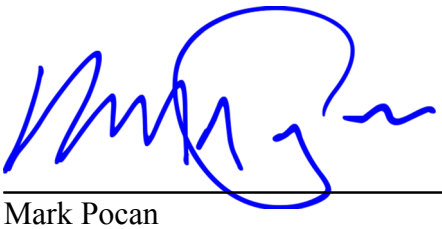

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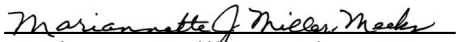

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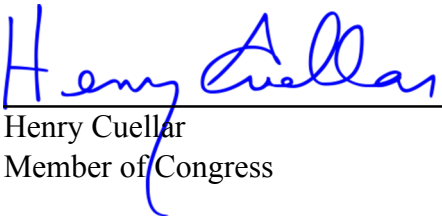

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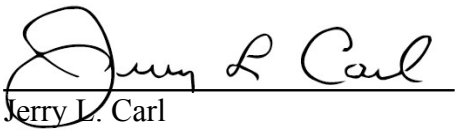

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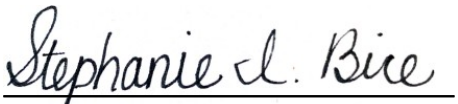

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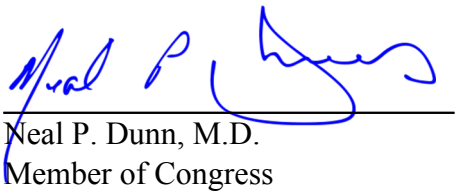

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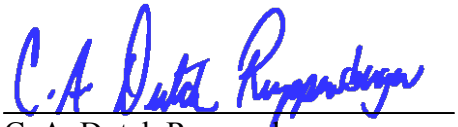

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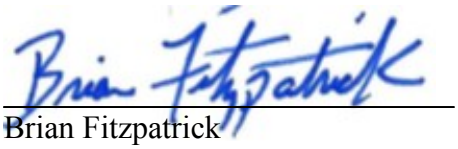

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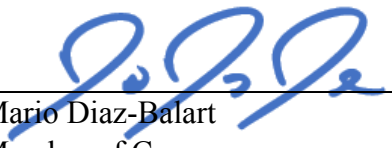

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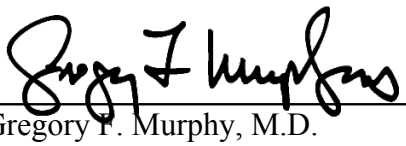

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