Congress of the United States
Washington, DC 20515

September _, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We are writing to express our concern with the July 2020 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) titled *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use.* NASEM's recommendations of compounded bioidentical hormone therapies (cBHTs) limit prescribing guidelines and severely limit the availability of cBHT. We appreciate the FDA's dedication to promoting safe dispensing of these hormones, but we ask the agency to consider the severely negative impact some of NASEM's recommendations would have on patients.

Doctors and patients should decide the best therapy. The Agency has long acknowledged that its scope does not extend to regulating the practice of medicine; however, NASEM's first recommendation would prevent doctors from prescribing cBHT preparations absent an allergy or requirement for a different dosage form. This would prevent patients from using cBHT for a variety of medically necessary reasons, such as if a diluted strength were needed. We urge the FDA to cautiously evaluate whether imposing additional restrictions, which would result in limiting what a clinician can provide as an alternative to manufactured products or prescribe for their individual patients based on their unique needs, is within the Agency's purview.

Difficult to compound recommendation. The NASEM committee also recommended that essentially all of the hormones used in cBHT be considered for the difficult-to-compound list, which would eliminate most cBHT treatment options. This recommendation could disrupt the lives of millions of men and primarily women who currently rely upon cBHT. We urge he FDA to strongly consider not accepting the NASEM recommendation that these hormones be reviewed as candidates for the difficult to compound list. Though this recommendation could be applied to numerous compounded therapies, it disproportionally limits or eliminates access for female patients.

Compounding provides personalized medicine. As detailed in the NASEM report, there are several FDA-approved hormonal drug products, but those products may not be uniquely tailored to the individual patient. cBHT options can provide either a different dosage or a different combination of hormones than what may be included in the approved products. Access to compounded medications provides the ability to uniquely tailor medications to the needs of the

individual patient, a form of personalized medicine. Many patients, especially women, have worked with their providers to find a customized hormone preparation that works for them, and their treatment options must be preserved.

Continued patient access is key. The NASEM 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." That said, the report also recommends that the use of cBHT be severely restricted or eliminated. Given the multitude of patients receiving such medications, we urge the Agency to not restrict access to these therapies. The result of such action would be the federal government inserting itself into the doctor-patient relationship. This is especially concerning given that abrupt disruption of hormonal treatments could have detrimental effects on patient health and well-being.

As the FDA continues to deliberate next steps in light of the NASEM report, and as it continues to develop its difficult-to-compound list, please take these considerations into account. We appreciate your consideration.

Sincerely,

David P. Roe, M.D. Member of Congress	Mark Pocan Member of Congress
Jaime Herrera Beutler Member of Congress	Henry Cuellar Member of Congress