

Date

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

Dear Commissioner Califf:

We are physicians who treat patients with hormonal imbalances and deficiencies or are concerned about access to those treatments. Those patients benefit greatly both from the availability of commercially available hormone products and from access to the compounded bioidentical hormone replacement therapies we prescribe for them. In many cases, commercially available hormone products simply are not suited to a patient's need. In that instance, physicians' ability to prescribe a compounded therapy customized for a specific patient is medically necessary to maintain that patient's health.

Millions of American women and other patient populations clearly benefit from and have come to rely on compounded hormone therapies. It is critical that FDA policies preserve access to these treatment options.

We are deeply concerned that FDA may consider restricting access to compounded hormones – life-enhancing therapies that patients have relied on for years – and that it may do so based on a flawed 2020 report it commissioned from the National Academies of Sciences, Engineering, and Medicine (NASEM).

The report, titled *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*, only considered 13 studies. [A recent article published in the journal *Menopause*](#) has shown that there were more studies to consider than what the NASEM report cited, and that based on that larger pool of studies, compounded hormones appear to be no less safe than commercially available hormone products. Moreover, no one on the NASEM committee had expertise in prescribing or compounding hormones. Unfortunately, it has also been demonstrated that the process that led to the NASEM recommendations may have been tainted. A third-party analysis of that NASEM study may be found at a4pc.org/Berkeley.

The NASEM report's recommendations would interfere with the practice of medicine and prevent us as practitioners from treating our patients with therapies that in our medical judgment are best for our patients. The report's most egregious recommendation asks FDA to consider placing hormones on the "demonstrably difficult to compound list" – despite the fact that some hormones have been compounded without difficulty for more than a half-century – which would make it unlawful to compound with those ingredients.

Despite the issues raised with the NASEM report, we do support expanded education on the use of bioidentical hormones for all healthcare practitioners involved in caring for these patients. In addition, we support creating a reasonable, consistent framework for adverse event reporting for compounded medications.

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 enormous number of patients who are prescribed these medications, we urge that FDA to reject the NASEM recommendations that would disrupt or eliminate these important therapy options.

Access to compounded medications provides the ability for a prescribing physician to uniquely tailor and personalize medications to meet the needs of individual patients. For example, when necessary, 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 available in manufactured products. Furthermore, some patients may have an allergy or intolerance to a manufactured product, which necessitates a compounded medication.

We urge that you please take our input into account and craft patient-centered policies that preserve our ability as health care providers to prescribe compounded hormones.

Sincerely,

[LIST NAMES HERE]

cc: Rep. Frank Pallone, Chairman, House Energy and Commerce Committee
Rep. Cathy McMorris Rodgers, Ranking Member, House Energy and Commerce Committee
Sen. Patty Murray, Chairwoman, Senate HELP Committee
Sen. Richard Burr, Ranking Member, Senate HELP Committee