September 21, 2020

Commissioner Stephen Hahn, MD
U.S. Food & Drug Administration
Address
Washington, D.C. ZIP

Via electronic mail

Dear Commissioner Hahn:

The undersigned organizations represent thousands of pharmacy compounding professionals. We write today regarding 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.

We are writing to express our serious concern with the conclusions and recommendations contained in the NASEM report on compounded bioidentical hormone therapy (cBHT). As the report correctly states, "[m]illions of men and women use cBHTs" to treat symptoms associated with hormone imbalance. This is particularly true for women who have struggled to find a hormone option that meets their needs. The reality of the recommendations of the NASEM study is that it advocates severely restricting or eliminating cBHT treatment options for these millions of patients based on a remarkably selective review of research.

First, we want to briefly comment on the make up of the NASEM committee. While all of the panel members are extremely well- qualified in their field of expertise, there were no members of the committee with current and relevant expertise in either the compounding or prescribing of cBHT despite the fact that these individuals are readily available. As such, the "expert" committee had no experts in the field of study. The lack of this perspective perhaps contributed to the issues we have identified in the final conclusions and recommendation in the report, and we believe this deficiency contributed to what we see as a report that fails to recognize or respect the choices that have been made by patients and providers seeking remedies and treatments that are very personal in nature.

We are also concerned that the NASEM committee went well beyond its charge, particularly when recommending that almost all hormones that are used in cBHT be considered for FDA's difficult to compound list. NASEM's charge was to examine the clinical utility of treatment options, and this technical recommendation could instead result in the out right prohibition of most if not all cBHT treatment. This could mean that the millions of patients referenced by the NASEM study could have the medical treatment they depend upon suddenly disappear. The committee clearly did not have expertise in the technical and nuanced

area of the difficult to compound list, and declined offers of additional information, failing to have a thorough discussion of the process and meaning of placing an item on this list. Hormones are no more difficult to compound than many other medications, and this recommendation could remove treatment options for patients, particularly women, who have personal medical issues that cBHT has successfully addressed.

Given the widespread use of cBHT by a large number of patients and prescribers, the NASEM deliberations also failed to identify a pattern or significant quantity of adverse events that warrant such aggressive and punitive recommendations. The use of cBHT simply does not seem to have been a fit for this kind of project conducted by an organization used to examining studies and clinical trials for one-size-fits-all products associated with the FDA drug approval process.

We will continue to work with FDA on this important issue, and will provide additional information to back up our concerns. However, we wanted to convey to you our serious alarm with these recommendations. They can potentially affect millions of patients nationwide by intruding upon personal medical decisions and the patient/provider relationship.

Thank you for this this opportunity to comment. Please contact the Alliance for Pharmacy Compounding's Scott Brunner at scott@a4pc.org if you need additional information.

Sincerely,

Alliance for Pharmacy Compounding
National Community Pharmacists Association
National Alliance of State Pharmacy Associations