

October 7, 2019

Donald R. Mattison, Chair
Ruth M. Parker, Vice Chair
Committee on Clinical Utility of Treating Patients with
Compounded Bioidentical Hormone Replacement Therapy
National Academies of Science, Engineering and Medicine
Keck Center, Keck 765
500 Fifth St. NW
Washington, DC 20001

Dear Chair Mattison:

As three trade associations that represent pharmacy compounding professionals, we write to express concern about aspects of NASEM's "Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy" study, commissioned by the Food and Drug Administration (FDA).

The International Academy of Compounding Pharmacists (IACP) is the voice for pharmacy compounding, representing thousands of pharmacists, technicians, students, researchers and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, IACP members play a critical, often life-or-death role in patients' lives, creating custom medications that patients simply cannot get anywhere else. They are a valued part of the health care team, providing essential medications for a range of issues, including autism, oncology, dermatology, ophthalmology, pediatrics, and women's health, among others.

The National Community Pharmacists Association (NCPA) represents America's community pharmacists, including 22,000 independent community pharmacies. According to an NCPA member survey, 88 percent of NCPA's members provide compounding services. Together, NCPA members employ 250,000 individuals, and provide pharmacy services to millions of patients every day. NCPA's members are small business owners who are among America's most accessible healthcare providers.

The American Pharmacists Association (APhA) represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, specialty pharmacies, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. APhA's Academy of Pharmacy Practice and Management (APhA-APP) Compounding Pharmacy Special Interest Group (SIG), consists of more than 5,000 members.

Our concerns, outlined below, relate to nomenclature and focus in NASEM's information-gathering thus far.

1. **Nomenclature and focus.** The FDA commissioned NASEM to study "The Clinical Utility of Compounded Bio-Identical Hormone Therapy." Primarily double-blind placebo controlled clinical trials would be accepted as proof of "clinical utility," and as with many other safe, effective therapies, few such studies of cBHRT exist. Accordingly, we urge NASEM to consider a more contemporary definition of "clinical utility" in its research. Where extensive, experiential clinical use demonstrates positive patient outcomes and a preponderance of evidence-based science is available – including observational, cohort, systematic reviews, meta-analyses, etc. – those

Committee on Clinical Utility of Treating Patients with cBHRT

October 7, 2019 • Page Two

should be used as determinants of clinical utility. Our organizations can assist the Committee with accessing the abundant body of such knowledge, both experiential and scientific, that exists to inform NASEM's conclusions about the clinical utility of cBHRT.

2. **Representation of expertise and perspectives.** NASEM has not had a public meeting to fully engage practicing physicians who prescribe or pharmacists who compound extensively cBHRT and hear their perspective and documented patient results they have achieved. From our attendance, we observed that in the information gathering sessions, a greater number of presenters opposing cBHRT were given time to present than were proponents of cBHRT. In addition, the presenters supporting cBHRT were not representative of the vast number of highly credible, mainstream physicians practicing cBHRT. Given that the NASEM committee members are not experts in cBHRT and thus would benefit from the expertise of practitioners, we urge you to schedule an additional hearing to provide a forum for physician and compounding pharmacist practitioners to testify on the importance of cBHRT to patients.

If NASEM seeks to evaluate cBHRT in a scientific fashion, our organizations urge you to work within the scope of "clinical utility" and seek input from the most credible practitioners – physicians and compounding pharmacists – to gather information on their methods and patient outcomes.

Thank you for this opportunity to share our concerns. Please contact Jennifer L. Petska at Jennifer@iacprx.org or 612-723-3832 for recommendations from our organizations on physicians and compounding pharmacists with cBHRT expertise and experience to ensure the final study reflects the modern-day practice of compounding cBHRT.

Sincerely,

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International Academy of Compounding Pharmacists

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