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## NAMS Applauds NASEM Efforts on Compounded Bioidentical Hormone Therapy July 13, 2020

The North American Menopause Society applauds the efforts of the National Academies of Sciences, Engineering, and Medicine (NASEM) and endorses their recommendations on compounded bioidentical hormone therapy (cBHT). As a society, we remain committed to improving the care of midlife women through the promotion of evidence-based research, education, and clinical care.

### **The National Academies of Sciences, Engineering, and Medicine Report on Compounded Bioidentical Hormone Therapy**

Media influences and targeted marketing approaches and claims have led many patients and certain prescribers to perceive cBHT preparations as safer and more effective alternatives to FDA-approved hormone products. In fall 2018, FDA requested NASEM to appoint an ad hoc committee to examine the clinical utility of cBHT drug preparations. This committee issued their report on July 1, 2020, which highlights multiple concerns regarding cBHT:

#### **Safety concerns**

- Despite the vast number of anecdotal claims and patient reports on the safety and effectiveness of cBHT, the committee found a substantial dearth of safety and efficacy data, including little or no high-quality pharmacokinetic data to inform evidence-based conclusions on the safety and effectiveness of cBHT preparations.
- Given the inadequate labeling of compounded preparations, there are concerns about how well vital information regarding potential risks and benefits is communicated to patients and prescribers.

#### **Conclusions and recommendations**

- Given the paucity of data on the safety and effectiveness of cBHT, the committee concludes there is insufficient evidence to support the overall clinical utility of cBHT as treatment for menopause symptoms.
- The committee recommends restriction of the use of cBHT to certain situations, including
  - Allergy to specific ingredients in an FDA-approved drug product
  - Dosage needed not currently available as an FDA-approved drug product
- Patient preference alone should not determine the use of cBHT preparations.
- The Pharmacy Compounding Advisory Committee should review select bioidentical hormone therapies and dosage forms (including all cBHT preparations in pellet dosage forms) as candidates for the FDA's Difficult to Compound List. These candidates have safety and efficacy concerns related to the lack of bioavailability data and product-to-product variability as a result of drug formulation differences, stability, and quality control.
- Education for prescribers and pharmacists who market, prescribe, compound, and dispense cBHT preparations should be improved.

- The National Association of Boards of Pharmacy and state boards of pharmacy should expand and improve their oversight and review of compounding pharmacies to ensure that adequate quality standards are maintained and documented for every cBHT preparation dispensed. All compounding pharmacies should provide a standardized package insert for dispensed cBHT preparations that includes
  - Boxed warnings for potential adverse events for compounded prescriptions that include estrogens (estradiol, estriol, estrone) and androgens (testosterone), similar to boxed warnings used in FDA-approved drug products to educate users about potential health risks.
  - A clear statement that the preparation has not been FDA approved for use and that rigorous bioavailability data, such as that available on FDA approved products, are not available.
- Information on conflicts of interest should be collected and disclosed.
  - Prescribers and compounders of cBHT may have conflicts of interest arising from financial relationships (eg, ownership or investment interests held in specific cBHT formulations or companies), and such conflicts should be transparent, publicly available, and disclosed to patients at the point of care. In addition, state licensing boards should collect and archive information on such financial relationships in a publicly accessible repository.
- The evidence base on the safety, effectiveness, and use of cBHT preparations should be strengthened and expanded.

An updated *MenoNote* on cBHT will be issued to the membership later this week. A revised *Practice Pearl* on this topic will be released later this year.