DEPARTMENT OF HEALTH AND HOSPITALS

LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS
(La. Rev. Stat. §§37:1261-92)

STATEMENT OF POSITION

BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

[April 2014]

BACKGROUND. The Louisiana State Board of Medical Examiners (the "Board") has received requests for guidance from Louisiana physicians and others respecting the appropriate use of hormone replacement therapy ("HRT"), including the use of compounded bio-identical hormone therapy ("BHRT").

In response to these requests, and its own investigation and review of the subject, the Board has considered the opinions expressed by the: American Academy of Clinical Endocrinology;[1] American College of Obstetricians and Gynecologists;[2] American Medical Association;[3] U.S. Food and Drug Administration;[4] and other professional organizations and regulatory agencies,[5] as well as endocrinologists and others well-versed in the issues. Following its consideration and discussion of the issue, the Board is concerned that the interest in compounded BHRT[6] for the treatment of various conditions, combined with misconceptions associated with its use, may leave patients susceptible to treatments that are potentially harmful and subject them to financial exploitation. Accordingly, the Board believes it appropriate for the

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[1]The American Association of Clinical Endocrinologists Reproductive Medicine Committee. *Position Statement on Bioidentical Hormones*. 2007. Available at: https://www.aace.com/files/position-statements/aacebhstatement071507.pdf.

[2]The American College of Obstetricians and Gynecologists. *Compounded Bioidentical Menopausal Hormone Therapy*. Committee Opinion No. 532. *Obstetrics and Gynecology*. 2012;120:411-415.

[3]The American Medical Association. The Council on Science and Public Health. *The Use of Hormones for 'Antiaging;' A Review of Efficacy and Safety*. 2009. Available at: http://www.ama-assn.org/resources/doc/csaph/csaph-rep5-a09-exec-summ.pdf.

[4]The U.S. Food and Drug Administration. *Bio-Identicals: Sorting Myths from Facts.* 2008. Available at: http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm049312.pdf.

[5]The Endocrine Society. Position statement: *Bioidentical Hormones*. 2006. Available at: https://www.endocrine.org/~/media/endosociety/Files/Advocacy%20and%20Outreach/Position%20Statements/All/BH_Position_Statement_final_10_25_06_w_Header.pdf; U.S. Preventative Services Task Force. *Menopausal Hormone Therapy for the Primary Prevention of Chronic Conditions*: The U.S. preventative services task force recommendation statement. Annals of Internal Medicine. 2013;158:47-54; The North American Menopause Society. *The 2012 Hormone Therapy Position Statement of The North American Menopause Society*. 2012. Available at: http://www.menopause.org/docs/default-document-library/psht12.pdf?sfvrsn=2; The Tennessee Board of Medical Examiners. *Position statement: Hormone Replacement Therapy*. 2012. Available at: https://health.state.tn.us/boards/Me/PDFs/ME_HRT_Policy.pdf; The Alabama State Board of Medical Examiners, Medical Licensure Commission. *Use of non FDA approved hormones.* (*Newsletter and Report*, Vol. 25, No. 4, (Oct-Dec. 2010)). Available at www.albme.org.

[6]Bioidentical hormones' are defined by American College of Obstetricians and Gynecologists and Endocrine Society as 'plant-derived hormones that are chemically similar or structurally identical to those produced by the body. Bioidentical hormones include commercially available products that are approved by the U.S. Food and Drug Administration (FDA) . . . as well as compounded preparations that are not regulated by the FDA.' *See:* The American College of Obstetricians and Gynecologists. *Compounded Bioidentical Menopausal Hormone Therapy*. Committee Opinion No. 532. *Obstetrics and Gynecology*, Id. The Endocrine Society. Position statement: *Bioidentical Hormones*. 2006, Id.

protection of the health, safety and welfare of the citizens of this state, and the physicians who provide their medical care, to formally express its views on the subject.

FINDINGS. Initially, the Board recognizes that HRT is an acceptable modality of treatment for women who suffer from menopausal symptoms. The Board also appreciates that in certain limited instances, compounded HRT may be indicated in the absence of an FDA approved drug to accommodate a patient's particular allergy or other medical condition. Nevertheless, in all instances, the decision to prescribe HRT should be individualized to each patient based upon the patient's clinical history and other risk factors. In addition, prior to prescribing this therapy, the patient should understand the potential risks and benefits of the treatment.

In the meantime, compounded BHRT has been marketed to physicians and patients in Louisiana and elsewhere for the treatment (or prevention) of a variety of medical conditions, as well as to rejuvenate memory and sexual function and reverse the aging process.[7] Indeed, despite the fact that *all* hormone therapy drugs — irrespective of whether they are FDA approved or compounded by a pharmacist — may increase the risk of heart disease, breast cancer and dementia in some women,[8] patients are led to believe by celebrity advertisements, anecdotal claims and other testimonials that compounded HRT are a natural, safer, risk-free alternative to FDA-approved prescription HRT. Therefore, it is no wonder that often times, in the Board's review of this practice, patients are not adequately informed of the potential risks of compounded BHRT and in some cases the diagnosis of hormone deficiency disorders is not based upon reliable laboratory evidence or an appropriate evaluation of the patient's history and physical condition.

STATEMENT OF POSITION. In announcing this Statement it is the intent of the Board to: (i) protect the public from misconceptions concerning the safety and efficacy of compounded BHRT; and (ii) provide guidance to Louisiana physicians seeking to provide quality care to their patients:

- The phrase "bio-identical hormone therapy" has been recognized as a marketing term by the FDA and not one based on scientific evidence.[9]
- The description of compounded products as "bio-identical" implies that they are natural or identical to hormones made by the body when in fact both compounded BHRT and conventional HRT are derived from either plant or animal source before extensive chemical processing and modification.
- There is no clinical evidence to support claims that compounded BHRT has no risks or fewer risks and side effects than conventional FDA approved products.
- Most compounded preparations have not undergone rigorous clinical testing for purity and potency, the manufacturing processes for compounded BHRT are not regulated, and there is a lack of pharmokenitic data for commonly prescribed compounded BHRT preparations. Therefore, these formulations can be inconsistent in dose, purity and potency and carry no assurance of efficacy or safety.
- Compounded BHRT preparations are not regulated by the FDA, have no official labeling, and do not conform to the requirements of providing warnings and information about contraindications.

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[7] Bioidentical hormone therapy: Clarifying the Misconceptions, Cleveland Clinic Journal Of Medicine, Vol. 78, No. 12, p. 835 (Dec. 2012).

[8] The U.S. Food and Drug Administration. *Bio-Identicals: Sorting Myths from Facts*. 2008, Id.

[9] As noted by the FDA: 'BHRT is a marketing term not recognized by the FDA. Sellers of compounded 'bio-identical' hormones often claim that their products are identical to hormones made by the body and that these 'all-natural' pills, creams, lotions and gels are without the risks of drugs approved by the FDA for menopausal hormone therapy (MHT). FDA-approved MHT drugs provide effective relief of the symptoms of menopause such as hot flashes and vaginal dryness. They also can prevent thinning of bones. FDA has not approved compounded 'BHRT' drugs and cannot assure their safety or effectiveness.' The U.S. Food and Drug Administration. *Bio-Identicals: Sorting Myths from Facts*. 2008, Id.

Post-market surveys of such hormone preparations by the FDA have discovered inconsistencies in dose and quantity.[10]

- Many providers and advocates of compounded BHRT recommend the use of salivary hormone level testing as a means of tailoring hormone therapy. Nevertheless, such testing has not been clinically validated and does not consistently provide a reasonable representation of endogenous circulating serum hormone levels. In short, there is no evidence that salivary hormone levels areuseful for adjusting hormone therapy dosages. [11]
- Misleading claims purport the necessity of using compounded BHRT to obtain individualized preparations when FDA-regulated hormone therapy is available in various doses and dosage forms administered by different routes, allowing for individualization for each patient's needs.[12]
- Compounded BHRT are often considered experimental. Therefore, they are often not covered by insurance or third-party payors and many patients must pay for them out-of-pocket.[13]

Guidance to Physicians. The initiation of HRT must be consistent with sound clinical judgment and the appropriate standards of care. Therefore, before commencing hormone therapy physicians should: assure that the treatment is indicated; insure that the patient is adequately informed of the potential benefits and risks of such therapy; and monitor the patient's therapeutic response to assess and manage the effectiveness of its continued use and/or modify or discontinue therapy. Under no circumstances should physicians promote treatments that are unsafe or make claims concerning the safety or efficacy of unproven treatments. Prescribing or utilizing hormone therapy (or any other therapy) in a manner that is inconsistent with the standards of care constitutes unprofessional conduct[14] and conduct in contravention of the Board's rules and the Louisiana Medical Practice Act.[15]

These opinions, it must be emphasized, are not predicated on a medical determination that *all* compounded hormone replacement therapies are improper or that *all* physicians or companies promoting their use are acting in an inappropriate manner. However, given the potential for patient harm and the possibility of patient exploitation from the use of untested, unregulated and expensive compounded BHRT products that have not been not been shown to be safe and effective, the Board believes that it essential that physicians seeking to use these products do so in compliance with the laws and rules administered by the Board.

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[10]FDA Center for Evaluation and Research Report: Limited FDA Survey of Compounded Drug Products, Jan. 2003. Available at http://www.fd.gov/cder/parmcoomp/survey.htm.

[11]The U.S. Food and Drug Administration. *Bio-Identicals: Sorting Myths from Facts*. 2008, Id.; Bioidentical hormone therapy: Clarifying the Misconceptions, Cleveland Clinic Journal of Medicine, Id.; The American College of Obstetricians and Gynecologists. *Compounded Bioidentical Menopausal Hormone Therapy*. Committee Opinion No. 532. *Obstetrics and Gynecology*. 2012, Id.

[12]Journal of the American Medical Association, Vol. 200, No. 5 (Feb. 6. 2008).

[13]Bioidentical hormone therapy: Clarifying the Misconceptions, Cleveland Clinic Journal of Medicine, Id.

[14]The Board's rules on unprofessional conduct, LAC 46:XLV.7603A provide, in pertinent part: 'A. [I]n the exercise of its duties the board has determined to define the term *unprofessional conduct*, as set forth in R.S. 37:1285(A)(13), as [C]onduct that includes but is not limited to the departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice.'

[15]Under the Louisiana Medical Practice Act (the "Act"), the Board may take action against the license of a physician as a result of: La. Rev. Stat. §37:1285(A): '(13) [U]nprofessional conduct;' '(14) [C]ontinuing or recurring medical practice which fails to satisfy the prevailing and usually accepted standards of medical practice in this state;' and '(30) [V]iolation of any rules and regulations of the board, or any provisions of this Part.'