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Endocrine Society takes strong stance against custom-compounded bioidentical hormone products

Written by Lu-Ann Murdoch on April 19, 2016 for CanadianHealthcareNetwork.ca

No rationale for routine prescribing of these unregulated, untested, potentially harmful products.

A statement released by the Endocrine Society discusses the history, clinical and legal ramifications, potential risks and harms associated with custom compounding of bioidentical hormone products.

The Endocrine Society, based in Washington, DC, is global organization representing professionals from the field of endocrinology. Some of the key points highlighted in the Society's comprehensive, 25-page statement are summarized below.

The claim that custom-compounded menopausal hormone therapy is safer, more efficacious and less likely to cause cancer than U.S. Food and Drug Administration (FDA)-approved menopausal hormone therapy is not supported by any peer-reviewed publications or appropriately designed randomized controlled trials.

The practice of assessing hormone deficiency or monitoring hormone therapy using salivary testing lacks evidence. Physicians often prescribe compounded bioidentical hormone therapy based on salivary hormone testing; however, there is no scientific evidence that a correlation exists between a patient's symptoms and salivary hormones.

In addition, salivary hormone assays are not standardized, do not have independent quality control programs, and lack an accepted reference range. Evidence-based guidelines recommend that hormone therapy be individualized on the basis of symptoms (not hormone levels) for menopausal women using hormone therapy.

Numerous FDA-approved formulations, both oral and non-oral, are recommended for menopausal hormone therapy. There is no scientific or clinical rationale for using compounded estrogen or progesterone preparations of unknown pharmacokinetics when several on-label pharmaceutical preparations are available.

In addition, there is a real risk of harm associated with inadequate progesterone dosing. Custom-compounded testosterone products for women can result in overdosing and harm.

FDA-approved menopausal hormone therapies have a large body of scientific data to support their use, risks and benefits. These products should be used for menopausal symptoms, rather than compounded bioidentical preparations.

The Endocrine Society, the American College of Obstetricians and Gynecologists, the American Society for Reproductive Medicine and the North American Menopause Society have all concluded that there is no scientific evidence to support claims of increased efficacy or safety for custom-compounded bioidentical estrogen or progesterone regimens over FDA-approved hormone therapies.

Furthermore, custom-compounded therapies are lacking in quality control, scientific efficacy and safety data. In addition, there is a significant risk of patient harm from underdosing, overdosing or contamination resulting in life-threatening illnesses, as recently observed by an epidemic of fungal meningitis linked to a single compounding pharmacy.

New FDA regulations are expected to lead to improved safety and quality control of compounded hormone products in the United States. In the meantime, the use of custom-compounded hormone therapies should be limited to individual situations in which no FDA-approved products are available.

Reference

1. Santoro N, Braunstein GD, Butts CL, et al. Compounded bioidentical hormones in endocrinology practice: an Endocrine Society scientific statement. J Clin Endocrinol Metab 2016;101:1318-43.