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News Release

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TTUHSC Professor to Give Presentation at ACOG Meeting

Kauffman's lecture examines ethical implications of bioidentical hormone replacement therapy.

More than 1 million people experience menopause every year in the United States, according to the National Institute on Aging. Menopause and the time leading up to it, known as perimenopause, can cause a variety of symptoms such as hot flashes, low libido, weight gain, sleep issues, vaginal dryness, pain with intercourse and mood swings. These symptoms, for the most part, are due to either a fluctuation or a drop in hormone levels.

Treatment of these menopausal symptoms with hormone replacement therapies (HRT) began in the 1940s; the first high-quality clinical trials on HRT and chronic postmenopausal conditions were started in the United States in the 1990s.

Robert Kauffman, M.D., a professor of obstetrics and gynecology at Texas Tech University Health Sciences Center (TTUHSC) was selected to present May 20 at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting in Baltimore. His presentation, "Non-FDA-Approved Postmenopausal HRT in Clinical Practice. Is it Safe? Is It Ethical?" examines the safety and benefits of hormone replacement therapy for symptomatic menopausal women. It also investigates the large market of non-FDA-approved formulations that have been promoted as safer or more effective than conventional products despite little or no evidence to support such claims.

"There are multiple dosages and formulations of estrogen, testosterone and progestins which have been approved by the FDA and produced by pharmaceutical companies under strict FDA oversight that cover purity, efficacy, bioavailability and safety," Kauffman said. "Nevertheless, many practitioners prefer to prescribe customized doses and formulations of hormones that are not subject to rigorous clinical trial study to prove that they are at least non-inferior to FDA approved and supervised products."

Called bioidentical hormone replacement therapy (BHRT), this emerging trend in the health care space has gained favor with people who choose to inject it in pellet form just below the skin. Customized BHRT cream, pills and pellets do not have any quality safety data according to Kauffman. The only truly natural estrogen product is Premarin. Estradiol and progesterone are synthesized from plant precursors in both FDA-approved and bio-identical

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compounded products. Plants do not make estradiol or progesterone. The FDA has also approved several synthetic forms of progesterone that have superior absorption from the GI tract compared to natural progesterone.

Kauffman, a certified menopausal practitioner by the North American Menopause Society, has followed the world literature on BHRT for more than 20 years.

“I have reviewed a number of books and publications that support bioidentical hormones and find nearly all of the research incomplete in the best case and deceptive in the worst case,” he said. “The pharmacies that make them have not done placebo-controlled trials of efficacy, safety or bioavailability that the FDA requires. Also, all hormone products require a randomized, placebo-controlled trial for 12 weeks to prove efficacy for hot flashes and a one-year trial to study safety at the endometrium. FDA approved products have this.”

“Many doctors, pharmacies and others who prescribe these bioidentical hormone products have made claims of disease prevention that have not been validated by clinical scientific studies,” Kauffman explained. “The claims of disease prevention can be found on several internet sites and in publications by people with no medical training.”

Kauffman said more than 40 medical organizations, including the American Medical Association (AMA), ACOG, North American Menopause Society, the International Menopause Society and the Endocrine Society, strongly recommend against the use of compounded bioidentical hormone products except in two very narrow cases: when an allergy exists or when a specific dose is not available in FDA-approved products. He said both of those cases are rare.

“Serum and salivary hormone levels cannot be used to determine the dosage of hormones to be given, yet such claims are made by promoters of bioidentical hormone therapy so they can provide customized dosages.” Kauffman said. “This is nonsense. There is zero evidence that BHRT is safer or more effective than FDA-approved products.”

Kauffman expressed concern about health care providers who promote BHRT to patients.

“Even signs in the office promoting BHRT or hormone pellets may be seen by patients as coercion and erode patient trust in the medical establishment,” he said. “Doctors have a moral obligation to protect patients from medical harms and the financial burdens of prescribing non-FDA-approved hormone therapies. According to the AMA Principles of Medical Ethics, physicians have an obligation to offer only products that the claim of benefit is based upon peer-reviewed literature that are unbiased, sound, systematic and reliable. Hormone pellets, for instance, greatly increase the cost of medicine, and there is no evidence in the scientific literature that pellets are safe or better than lower cost alternatives. In fact, emerging literature suggests hormone pellets increase patient harm in several domains.”