



Bryan K. Perkins, M.D. Jonathan B. Lupton M.D. James R. Dunlop, M.D.
Michael L. Boothe, M.D. Rajalakshmi Venkatesh, M. D. Jessica L. Bell, D.O.

8051 S. Emerson Ave. Suite 400 - Indianapolis, IN. 46237 - Phone (317) 865-3600 - Fax (317) 885-3850

ACOG Reiterates Stance on So-Called “Bioidentical” Hormones

Washington, DC—In response to recent media attention being given to so-called bioidentical hormones, the American College of Obstetricians and Gynecologists (ACOG) reiterates its position that there is no scientific evidence supporting the safety of compounded bioidentical hormones.

In November 2005, ACOG issued a committee opinion regarding “Compounded Bioidentical Hormones” that stated its concerns about bioidenticals. More recently, the US Food and Drug Administration (FDA) issue warning letters in 2008 to several pharmacies in the US that make compounded bioidentical hormones. Some of these pharmacies claimed the compounded hormones were superior to FDA-approved hormone therapies and that they also prevented or treated serious diseases, such as Alzheimer’s disease, stroke, and various cancers. The FDA stated that the pharmacies’ claims of safety and effectiveness were false, misleading, and a article “Bioidenticals: Sorting Myths from Facts” at www.fda.gov/consumer/update/bioidenticals040808.html.

Despite celebrity testimonials touting scientifically unfounded benefits of compounded bioidentical hormones, the bottom line is that most have not undergone rigorous clinical testing for safety or efficacy, nor are they approved by the FDA. ACOG also stresses that salivary testing of a woman’s hormone levels is not useful because they vary within each woman depending on her diet, time of day, the specific hormone being tested, and other variables. Although monitoring salivary hormone levels is promoted by some as means of ‘tailoring’ a hormone treatment to an individual, hormone therapy does not require customized dosing.

The decision of whether or not to take hormone therapy for menopausal symptoms is highly individualized, based on a woman’s health, risk factors, and personal wishes. There are a number of FDA-approved hormone therapy products available in a variety of formulations. ACOG advises women to talk with their doctor about both the benefits and risks of HT.

The American College of Obstetricians and Gynecologists is the national medical organization representing over 52,000 members who provide health care for women.

Patient Signature

Date

Witness

Date