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New Data Shows Synthetic Hormone Replacement Yields No Muscle Mass Advantage Dr. Randolph Suggest Bioidentical Testosterone Replacement as a Viable Clinical Alternative

JACKSONVILLE BEACH, Fla. (August 26, 2010) – Published in the August 3rd issue of *Menopause: The Journal of The North American Menopause Society*, new findings from a six year analysis of the Women's Health Initiative (WHI) study, a large U.S. clinical trial exploring the effects of synthetic combination estrogen-progestin hormone replacement therapy (HRT), indicate that HRT has no long-term muscle mass advantage. Although the WHI study was not designed to address the short-term risks and benefits of hormones for the treatment of menopausal symptoms, earlier analysis (3 yr) suggested a short-term preservation of lean body mass. "The results are not necessarily surprising given the side effects and sometimes lethal health risks associated with the synthetic hormones used in the study - Premarin®, a synthetic estrogen, and Prempro®, the combination of Premarin and Provera®, a synthetic progesterone often called progestin," comments C.W. Randolph, Jr., M.D., R.Ph., an expert in the field of bioidentical hormone replacement therapies.

The WHI study was abruptly halted in July 2002, three years earlier than intended, because findings irrefutably showed synthetic estrogen replacement to be dangerously linked to an increased risk of breast cancer, heart attack, stroke and Alzheimer's disease. "Prempro was supposed to enhance health, not endanger it, but five years into the eight-year study, they put a stop to it, and announced that the side effects weren't worth the risk," said Randolph. Although the trial has ended, researchers are still analyzing the WHI data.

Randolph finds many faults with the WHI study; the first being the use of Premarin, a synthetic estrogen made from the urine of pregnant mares. "In 1975, clinical studies reported a link between the synthetic horse estrogen in Premarin and uterine cancer. Based on my clinical experience and the output of multiple research studies, the FDA should have immediately pulled the dangerous drug off the market." Non-bioidentical hormones can be natural - to a horse - but are not bio-chemically identical to a woman's hormones. Premarin is an example of this. Many women experience side effects because the chemical structure does not match the molecular structure of hormones produced by a woman's ovaries.

"The study also uses progestin," citing the second fault in the study. "Unfortunately, bioidentical progesterone is often confused with progestin, the synthetic version of human progesterone used in the WHI study." Unlike bioidentical hormones, synthetic hormones are not derived from a natural substance and are not biochemically identical. Synthetic hormones were created by pharmaceutical companies in an attempt to mimic the effects of female natural hormones. The difference between synthetic progestins and progesterone is very significant: progestins are given to women to prevent pregnancy, whereas progesterone is used to assist fertility. "In regards to the WHI study, progestin is a potent vasoconstrictor, decreasing blood flow to the heart and brain, therefore constructing blood flow to the skeletal muscle. Of course the recent analysis found no long-term muscle mass advantage," states Randolph. "A decrease in blood flow decreases oxygenation, which biologically contributes to an overall decrease in muscle development."

Studies have also shown that testosterone therapy has important effects on many parts of our bodies. It builds muscle and bone, assists brain function and is associated with a sense of well-being. It also has a protective effect against cardiovascular disease in both men and women. "If testosterone replacement therapy was used among the control groups in the study, results would have shown an increase in the amount of muscle in the body," claims Randolph. "Unfortunately, it is not typical for traditional gynecologists and primary care physicians to recommend the testing of testosterone levels for women."

"Multiple clinical studies have linked long-term use of synthetic hormones to an increased risk of heart disease, cancer, and other health problems. In contrast, multiple studies have linked bioidentical hormones to health benefits such as a reduced risk for breast cancer, cardiovascular disease, Alzheimer's disease, diabetes,

osteoporosis, as well as improved brain and nervous system function and quality of life. In addition, bioidentical hormone replacement therapy has been used for decades both in Europe and here in the U.S. with virtually no documented side effects,” says Randolph. “Multiple clinical studies have confirmed that BHRT is safe and effective. Many of my medical colleagues and I feel it’s time the National Institutes of Health or the American Medical Association commissioned a head-to-head clinical study comparing the safety and effectiveness of synthetic hormone replacement versus bioidentical hormone therapy.”

Resources

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5. Shufelt CL, Braunstein GD. Safety of testosterone use in women. *Maturitas* 2009 May 20;63(1):63-6.

About Randolph Medical Enterprises

Randolph Medical Enterprises is a healthcare company defined by both an unrelenting attention to clinical excellence in the field of gynecology medicine and unparalleled passion and commitment to inform and empower not only our patients, but also women, men and medical professionals across America – about the safety and medically proven health benefits of bioidentical hormone replacement therapies (BHRT), vitamins and other nutritional supplements. Their mission is fulfilled through the company’s four business entities; Dr. Randolph’s Ageless and Wellness Medical Center, in-house compounding dispensary, Natural Medicine Store and Natural Hormone Institute.

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