



One of the Nation's Leading Bio-Identical Hormone Doctors and the Natural Hormone Institute Co-Founder Speak Out on FDA's Attempts to Crack Down on Natural Hormones

The health, well being, and freedom of hundreds of thousands of pre-menopause and menopause women is at stake.

Jacksonville, Florida ([PRWEB](#)) January 16, 2008 -- "The Food and Drug Administration's (FDA) new policy about bio-identical hormones could potentially deny hundreds of thousands of women access to bio-identical hormone therapy," urges C.W. Randolph, Jr., M.D., R.Ph, one of the nation's leading bio-identical hormone physicians, and Genie James, M.M.Sc., his co-founder of The Natural Hormone Institute of America. "We want people to know that this is an egregious example of a multi-billion dollar pharmaceutical giant (Wyeth) wielding financial and political power in an effort to regain an eroding market share and female healthcare consumer trust."

Last week, the FDA announced that there's no evidence that "bio-identical" hormones therapies (BHRT) mixed by individual pharmacists are any safer than prescription hormones made by drug companies such as Wyeth. They warned seven pharmacy operations about misleading safety and effectiveness claims of BHRT products. The FDA stopped short of taking immediate action to stop the practice of mixing hormones or compounding them by individual pharmacists as Wyeth has sought since it filed a petition with them in 2005.

Dr. Randolph, who is the best selling author of "From Hormone Hell to Hormone Well" and "From Belly Fat to Belly Flat," originally practiced as a compounding pharmacist before returning to medical school. He established his OB/GYN practice in Jacksonville, Florida in 1986 and - like most physicians at that time - prescribed synthetic hormone therapies such as Premarin, Provera and later Prempro. Dr. Randolph stopped prescribing these pharmaceutically manufactured synthetic hormones because of the side effects experienced by his patients.

"Long before the output of the Women's Health Initiative (WHI) validated the health risks associated with synthetic hormone replacement [such as an increased risk of breast and uterine cancers, heart attack, stroke and increased risk of dementia I was concerned," says Dr. Randolph. "I drew on my background as a compounding pharmacist to research safe and effective alternatives. For more than a decade, I have prescribed bio-identical hormone therapies (BHRT) for literally tens of thousands of patients. Not only do my patients report that they 'feel like themselves again', they also remain side effect free. My clinical experience validates the medical research substantiating the safety and efficacy of BHRT."

Why is the FDA attacking BHRT? "Money, politics and power," Ms. James, the co-author of Dr. Randolph's books, responds. "There are currently close to 38 million women in the U.S. entering pre-menopause or menopause. This is a huge market. When the results of the WHI study were first released in 2002, the sales of synthetic hormone therapies dropped almost 50% immediately. It is worth noting that synthetic hormone formulations are patentable. Bio-identical formulations can not be patented because their molecular structure originates in nature, e.g. the human body."

"The issue here is not the safety of women who are choosing BHRT as their treatment of choice for menopausal and pre-menopausal symptoms, it is dollars. Wyeth's financial reports, which are available online at www.wyeth.com, suggest an ongoing and significant decline in the sales of the Premarin synthetic hormone family of products; e.g. from over \$2 billion in 2002 to \$880 million in 2004; a 68% decline in sales."



"Many women who stopped taking synthetic hormones therapies began to do their homework and research alternatives," continues Ms. James. "The result is that in the last five years there has been a significant upsurge of women choosing (and physicians prescribing) BHRT as an effective alternative that is formulated to match the structure found in the human body, a common practice in other medical treatment areas such as in the treatment of the thyroid.. No wonder Wyeth is worried. And, for anyone doubting the influence that a multi-billion pharmaceutical company might have on a government regulated agency such as the FDA, I would suggest that they read the book by Marcia Angel, M.D. (former editor in chief of The New England Journal of Medicine) The Truth About Drug Companies: How They Deceive Us and What To Do About It."

Last week, when the FDA issued the warning to compounding pharmacies across the nation, they stated that they should halt the compounding of medications containing estriol. "The FDA is way out of bounds here," says Dr. Randolph. "Like many commonly prescribed drugs (e.g, Phenobarbital, quinine, tinidazole), estriol has a monograph from the U.S. Pharmacopeia (USP), but is not currently a component of an FDA-approved drug. When it passed the FDA Modernization Act in 1997, Congress clearly indicated that drugs with a USP monograph could be compounded. In addition, the practice of medicine and pharmacy is legislated at the state level. The FDA officially does not have jurisdiction in this area."

"As Ms. James stated, the fundamental issue at stake is much more critical," says Randolph. "The larger issue is the health and well being of millions of American women who, with their physicians, want safe and effective hormone replacement therapy. The big pharmaceutical muscles are working to do away with BHRT, despite medical studies and clinical evidence validating it as a safe and effective solution for women suffering from symptoms of hormone imbalance."

"There is now real data linking a decreased incidence in U.S. breast cancers with a decrease in the number of prescriptions written for synthetic hormone therapies. Now think about this: during these same years, we have seen lock-step increases in the number of prescriptions written for BHRT. Why isn't the government funding a study examining the inverse relationship between the rise in the popularity and use of BHRT and the decline in the incidence of breast cancer?" asks Ms. James.

For more information on bio-identical hormones, go to www.hormonewell.com. For media inquiries, contact Nanette Noffsinger at nanette @ burkehollowmedia.com or 615-776-4230.

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