

FDA'S CURRENT POSITION ON BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

In April 2008, the FDA published a brochure that noted that: "A [patient] should be able to get a compounded hormone therapy drug when [the] physician decides that it will best serve the [patient's] specific medical needs."

The same brochure (found at www.fda.gov/consumer/updates/biidenticals040808.pdf) is also included as part of the literature you are given as a new patient) also states that the "FDA is not aware of any credible scientific evidence to support claims made regarding the safety and effectiveness of compounded BHRT [Bio-Identical Hormone Replacement Therapy] drugs."

I suspect that the FDA is being unduly influenced by Drug companies and their Lobbyists, many of which manufacture drugs that compete with bio-identical hormones. For example, in Oct. 2005, Wyeth Pharmaceuticals asked the FDA to take action against pharmacies that were compounding bio-identical hormones. Wyeth manufactures the widely used and commonly prescribed Premarin® and Prempro®, which are conjugated equine estrogens (hormones) manufactured from horse urine, that are not bio-identical to human hormones. Bio-identical hormones are created to match the exact biological structure of the hormones that human bodies manufacture.

You may have heard of the "Women's Health Initiative ("WHI")." Two arms of the WHI consisted of clinical studies of over 27,000 women and the effects of "Prempro®," and "Prempro®, which, again, are manufactured by Wyeth Pharmaceuticals. The study was cut short years ahead of the planned completion date because interim monitoring suggested that these widely prescribed horse urine hormones were responsible for a 26% increase in invasive breast cancer, a 29% increase the risk of heart disease, and other ill effects. The study suggested some benefits but they did not outweigh the serious risks the interim monitoring revealed. Additional analysis of the data suggested further detrimental results. A synopsis of the study can be found in Wright, MD, and Lenard PhD, Stay Young & Sexy, Smart Publications 2010 at pp. 40-48. Wright and Lenard noted that "The FDA's primary response [to the WHI] was to alter the official Premarin® and Prempro® labels - on **all estrogen replacement products**, not just the [conjugated equine estrogens] proven by the WHI to cause problems. " *id.* at p. 43, meaning that bio-identical hormones, which are not created out of horse urine, have been saddled by the FDA with the same warnings that the FDA applies to Premarin® and Prempro®.

As a medical professional, I disagree with the FDA's position. I have familiarized myself with the research on BHRT, and I believe there are many credible studies that support the use of BHRT drugs. I can provide portions of that research to you upon request. I have reached the conclusion that using bio-identical hormones is in the best interests of my patients who have documented hormonal deficiencies.