

STAY HEALTHY!

By J. Manuel Cordova, M. D.t

Medicines, Compounds--Laws and the Truth Part II.



In my previous article, (December 2010) I tried to give an overview of “counter drugs” and nutritional supplements. Some experimental and preliminary reports require a follow- up of testing protocols before final marketing approval. Today, medicine claims are based on proven results.

It is important to mention here the battle involving Wyeth Pharmaceuticals and the compounding industry, and the prescriptions prepared by local pharmacies. For those interested in catching up on the shenanigans between Wyeth Pharmaceuticals and the FDA over the past few years, I recommend reading Joe Pizzorno’s “Integrative Medicine” in *A Clinician’s Journal*.

1. Bioidentical hormones are purported to have the exact molecular structure as endogenous hormones made in the human body, and in theory produce the same physiological responses. Upwards of two million women in the US use such hormones on a daily basis for relief of symptoms associated with menopause and premenopause.

Companies involved in the manufacture and sale of compounded hormones claim such compounds are safer and more efficacious than synthetic prescription hormones sold by drug companies. Synthetic hormones do not have the same chemical structure as endogenous hormones, and may elicit different responses in the human body.

Such potential variation has been indicated, though without definitive proof, in the increased incidence of diseases reported in the 2002 Women's Health Initiative (WHI), which linked the synthetic hormones Premarin® and Prempro® to elevated risk of stroke, breast cancer, heart attacks and circulatory disease.

The growing industrial and legislative battle over synthetic vs compounded hormones culminated in an October 2005 citizen's petition to the Food and Drug Administration (FDA) filed by Madison, NJ-based Wyeth Pharmaceuticals, one of the world's largest pharmaceutical and health-care products companies. Wyeth requested the FDA to designate compounded bioidentical hormones as a "new drug" subject to all FDA restrictions and requirements regarding the manufacture and sale of new drugs.

A public, political, and medical maelstrom soon followed.

To be continued

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