Raging Hormones: Wyeth Hopes FDA Will Stop Compounding Pharmacies from Selling Bioidentical Hormones

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The latest results from the Women’s Health Initiative (WHI) have generally exonerated estrogen alone as a culprit in increasing the risk of breast cancer when used as hormone replacement therapy (HRT) without the addition of a progestin (e.g., Prempro). This news ups the ante on a “Citizen Petition” by Wyeth Pharmaceuticals to the Food and Drug Administration (FDA).

In late 2005, Wyeth requested that the FDA clamp down on compounding pharmacies that sell “bioidentical” hormone replacement therapy (BHRT), which became more popular after the initial WHI results in 2002. Those results, now partially discredited, linked synthetic estrogen, such as Wyeth’s product, to breast cancer. This news sent women in search of plant-based estrogen replacements.

Wyeth’s sales of Premarin (a combination of synthetic hormones derived from pregnant mare’s urine) were hurt by the 2002 results. The most recent findings, published in JAMA (April 12, 2006), could bring women back to Premarin, to breast cancer. News sent women in search of plant-based estrogen replacements.

Wyeth believes that compounding pharmacies are essentially manufacturing large batches of product, a practice that takes these pharmacies out of the realm of compounding. In effect, this eliminates the protections that the FDA affords compounding pharmacies, such as performing clinical trials to prove a medication’s safety and effectiveness. Wyeth argues that the pharmacies are selling hormones without informing patients of the risks of HRT.

That has apparently made no difference to the many thousands of women who, in the wake of the 2002 WHI findings, transferred their allegiance from Premarin to plant-based medications. These products are said to be uniquely developed according to a woman’s personal hormone profile; this is the promise that compounding pharmacies make.

The FDA has received more than 2,000 negative comments about the Wyeth petition from women who have been very satisfied with the BHRT they have obtained from pharmacies. They are aghast that the FDA might side with Wyeth.

Compounded therapies contain estrogen as well as other ingredients, such as estriol (a weak estrogen) and pregnenolone (a precursor to dehydroepiandrosterone and progesterone), which are not commercially available in any current products.

The inclusion of estriol in the compounded products has caused considerable unease in the medical community. Robert W. Rebar, MD, executive director of the American Society for Reproductive Medicine (ASRM), says, “This estrogen does not appear in any FDA-approved drug and thus may carry unknown health risks.”

He cites other concerns. The ASRM is troubled that some compounding pharmacies are determining the appropriate hormone dose based on a saliva test. Salivary testing may not provide an accurate measurement of a woman’s hormone levels; only a blood sample is considered to be an accurate measurement. The ASRM also contends that BHRT does not belong to a class of drugs with an indication for individualized dosing.

Wyeth is also uneasy about the advertising being promoted by compounding pharmacies. The company isn’t alone in this regard either. Debra Ness, president of the National Partnership for Women and Families, explains:

Much of the BHRT promotional materials that the National Partnership has reviewed are completely devoid of scientific substantiations. Unsupported comparative claims of superiority are, unfortunately, convincing many women that BHRT products are interchangeable with FDA-approved hormone therapies, despite the fact that these products have not undergone the rigorous safety and effective testing normally required for approval of new drugs.

Compounding pharmacies have a different take, of course. They say that customers come to them with a physician’s prescription in hand; moreover, they claim that some groups supporting Wyeth’s petition are doing so because of the financial support they receive from Wyeth. The IACP says that Wyeth gave the ASRM $75,000 toward its 2005 annual meeting.

Compounding pharmacies have a lot of women on their side, so it will be difficult for the FDA to totally agree with Wyeth. More likely, the FDA will advise these pharmacies that they should start including package inserts with every prescription they fill. Apparently, the pharmacies are doing this only sporadically; even when they do so, the information does not conform with that specified by the FDA’s “Menopause and Hormones Information Campaign.”

As a result of the failure of these pharmacies to provide full prescribing information, the National Consumer League has agreed with Wyeth about BHRT. Ironically, these are normally estranged bedfellows. The fact that they concur on the need for compounding pharmacies to divulge all of the risks of BHRT almost guarantees that the FDA will require additional, if not full, disclosure.