



Family Pharmacy Compounding Specialists

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I am very disappointed that Wyeth Laboratories has filed a complaint (docket number 2005P-0411) with the U.S. Food and Drug Administration (FDA) regarding bio-identical hormone replacement therapy (BHRT). I am a pharmacist who provides compounded (BHRT) to both women and men. Women have always been in search of a more physiological means of replacing hormones. However, since the results of the Women's Health Initiative study were released several years ago, more and more women are looking for a safe alternative to treat their menopausal symptoms. The use of BHRT has provided this option for women.

As a compounding pharmacist, each preparation that is made is for a specific patient based on a prescription from a physician. This triad (patient, physician, pharmacist) allows for individualization of hormone replacement therapy. Every woman has different needs when it comes to hormone replacement therapy and compounding BHRT allows us to meet that need. Another take home point is that compounding BHRT should not be looked at as manufacturing since each preparation is individualized.

My patients who are on BHRT have seen a big improvement in their quality of life. Here is an example of one of my patients who came into the pharmacy to review her hormone test results. One of her complaints (among two dozen symptoms listed) was that she has not been able to sleep through the night for the last 20 years. She had tried many different medications in the past, including commercially available medications such as those manufactured by Wyeth. I spent time with her and her physician to decide what the best BHRT regimen would be for her. After a few weeks she returned to the pharmacy with tears in her eyes, gave me a big hug and told me she was sleeping through the night for the first time in 20 years and she felt wonderful. Her life had changed with BHRT. We cannot take this option away from her and all the other women who have benefited from BHRT.

Please reject Wyeth's petition (docket number 2005P-0411). Wyeth does not have the patient's best interest at heart in this matter. They are the company that funded the Women's Health Initiative trials that revealed using their product(s) causes more harm than benefit in women. This petition is only in their financial interest.

Sincerely,

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