

Menopausal women find advocate in Phoenix

Philanthropist leading charge to keep specialized therapy

By Kristin Park
SPECIAL FOR THE REPUBLIC

Phoenix resident Michelle Robson is leading a nationwide charge against Wyeth Pharmaceuticals, a global pharmaceutical giant.

Two years ago, she could barely get out of bed. After having a complete hysterectomy at 44, Robson's experienced severe joint pain, fatigue, insomnia, mental foginess and gastrointestinal issues. Robson

suffered through a year of doctor appointments and nine prescribed medications before getting relief through bio-identical hormone-replacement therapy, or BHRT.

Now, Robson fears that ac-



Michelle Robson

cess to these customized medications that restored her ability to function may soon be taken away. Wyeth Pharmaceuticals filed a Citizens Petition in October with the United States Food and Drug Administration, asking the agency to regulate the compounding and dispensing of BHRT medications.

"This petition has really stayed under the radar

About Premarin and Prempro

Premarin and Prempro are hormone-replacement therapies produced by Wyeth Pharmaceuticals.

Premarin, as its name is derived, comes from the urine of pregnant mares. Prempro is a combination of Premarin and a synthetic progestin.

According to Wyeth's Web site, Premarin became the most-prescribed drug in the

United States in 1992 and five years later was Wyeth's first product to reach \$1 billion in sales. Production suddenly dropped after the 2002 Women's Health Initiative national study of Prempro was cut short after showing a high incidence of blood clots, heart attacks, strokes and breast cancer for women taking the drug.

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screen," Robson said. "I want people to know what's going on. We need to start acting."

About two weeks ago, Robson, a philanthropist who lives in the Biltmore Estates, formed the Robson Foundation for Healthy Women, Healthy Choices, a grass-roots women's health organization spurred by Wyeth's petition.

"Our most important job as women is to stay informed on what's out there and the choices we have," Robson said.

Wyeth, which produces synthetic hormones Premarin and Prempro, asserts that the petition was made in the interest of women's health. Ginger Constantine, Wyeth's vice president of women's health and bone repair, said the pharmaceutical company is concerned that there is a current mass marketing of compounded drugs for menopausal women.

"The compounded products are not being studied sufficiently," Constantine said. "Are women being adequately warned? We just want to inform women. It's just about transparency."

Currently, state boards regulate pharmacy practices. Constantine said she is worried that consumers of compounded medications assume that they have been tested by the government and are safe. They often are marketed as being safer or more effective alternatives to FDA-evaluated and approved medications.

"We're for healthy choices," Constantine said. "We're not against compounding. What we're against is unlawful compounding."

BHRT medications are comprised of plant-based hormones that are compounded, or custom-mixed, by a pharmacist. They are considered by many to be a more natural al-

About Michelle Robson

Michelle Robson is a philanthropist and community volunteer whose work on various women's and children's causes, as well as the arts, has earned her numerous civic awards and citations. She is currently chairman of the Arizona Character Education Blue Ribbon Task Force.

She also is active with the Arizona Foundation for Women and Childhelp USA. Robson lives in the Biltmore Estates with her husband, Ed. Between them, they have 6 children and 14 grandchildren.

Her foundation's e-mail address is hwhc@robson.com.

ternative to commercially manufactured hormones. The compounding of bio-identical hormones offers women the ability to take the smallest possible amount of hormones according to their menopausal symptoms.

For Robson, who uses a testosterone cream that is not FDA-approved, the result of the petition might take away her choice. Since bio-identical hormones represent growing market competition for Wyeth's hormone medications, Robson believes that the petition is a way for the pharmaceutical company to remain competitive.

This sentiment is shared by other individuals who are joining Robson in the fight against the petition.

Elizabeth Vliet, a women's health specialist in Tucson, said that existing state regulations regarding compounding medication are adequate. She said that Wyeth's petition to the

FDA would bring an end to all compounding, not just that of BHRT medications.

"As the petition is written, yes, it would end compounding," Vliet said. "If approved, it will be devastating to millions. It will not only affect menopausal women, but others who depend on compounded medications, such as kids with autism who need dye-free medications, and cancer patients in hospice who need specialized pain medications."

The FDA has declined to comment regarding the petition and its possible ramifications toward general compounding.

Since Wyeth's petition was

filed, the FDA has received over 43,000 e-mails and letters in opposition, representing one of the largest petition responses in the history of the agency. Many are posted on the FDA's Web site and come from husbands and relatives of women who depend on customized BHRT medications to function. The FDA will not give a time frame on its decision regarding the petition.

In the meantime, Robson is busy spreading word of the petition and encouraging people to e-mail the FDA.

"I really believe that I was meant to go through all that I did so I can help others," Robson said.



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