

Use of "bioidentical" female hormones questioned

LOS ANGELES - There is no evidence that so-called "bioidentical hormones" are safer than synthetic hormones for menopausal women and there is a risk that they may not meet quality standards, a medical group warned on Monday.

"There are a growing number of women who are seeking therapy with bioidentical hormones, but there is a lot of misinformation about the assertion that these are plant-derived and therefore more closely mimic the estrogen that is in a woman's body," said Dr. Michele Curtis, associate professor of obstetrics and gynecology at Houston's University of Texas Medical School.

Sales of female hormone replacement drugs, such as Wyeth's Premarin, have plummeted in the wake of a U.S.-financed study that uncovered health risks associated with their long-term use.

Compounded "bioidentical hormones" are plant-derived hormones that are prepared and packaged as a drug by a pharmacist.

The formulations present the same risk as commercial drugs, but because they are unregulated, patients may not be informed of the risk, the American College of Obstetricians and Gynecologists said.

The U.S. Food and Drug Administration requires drugmakers of FDA-approved products that contain estrogen and progesterone to include a warning about increased risk of heart disease.

Compounded products are not approved by the FDA and pharmacies offering these products are exempt from including the warnings.

"These are hormones. They act just like estrogens that are commercially produced," Curtis said.

QUESTIONS ABOUT QUALITY

The ACOG also said most compounded products, including bioidentical hormones, have not undergone rigorous clinical testing and there are concerns regarding their quality.

In 2001, the FDA analyzed a variety of 29 product samples from 12 compounding pharmacies and found that 34 percent of them failed one or more standard quality tests, the group said.

"When a pharmacist compounds a drug, there is no way to know the concentration or to be sure that a patient is getting the same product every time," said Stephen Simes, chief executive of BioSante Pharmaceuticals, which expects to file this year for FDA approval of a patch that delivers bioidentical hormones through the skin.

He said bioidentical hormones might be safer than commercial hormone replacement therapy, but so far there have been no long-term studies to find out.