

New York Times Article - Published: March 30, 2004

Possible Peril Found in Menopause Cream

By ANAHAD O'CONNOR

A popular cream that eases the symptoms of menopause exposes women to higher levels of the hormone progesterone than has been commonly thought, researchers have found. Pro-Gest, one of more than two dozen creams containing natural progesterone, is a widely used alternative to synthetic hormone therapies that have been linked to a higher risk of breast cancer and heart disease. Millions of tubes of progesterone cream are sold annually.

Because they can be purchased over the counter, the creams are generally considered less potent, and therefore less harmful, than federally regulated progesterone pills.

But research reported Thursday has raised questions about the creams' safety. A group of women that used Pro-Gest to relieve hot flashes and night sweats and a group that took the hormone pill Prometrium later had the same levels of progesterone in their bloodstreams, said Dr. Anne Hermann, who conducted the study at Bassett Healthcare in Cooperstown, N.Y.

Dr. Hermann presented the results at a conference of the American Society for Clinical Pharmacology and Therapeutics in Florida. "Millions of women are using these creams, thinking that because they're natural and sold over the counter they are safe," she said. "The reality is that they are putting themselves at risk."

However, Dr. Deborah Moskowitz, director of research and development education for Emerita, the division of Transitions for Health Inc. that makes Pro-Gest, said there was no solid evidence that natural progesterone carried health risks. "The fact is that progestin and progesterone are different," Dr. Moskowitz said.

The findings come at a time when hormone use is sharply declining. In 2002, the Women's Health Initiative study found a heightened risk of breast cancer and heart disease among women who used a common hormone therapy. That study looked at synthetic progesterone, or progestin, taken in combination with estrogen to relieve hot flashes

and other symptoms of menopause.

Natural progesterone is considered to carry some of the same health risks as its synthetic version, "until research shows otherwise," said Susan Cruzan, a spokeswoman for the Food and Drug Administration.

"We're asking manufacturers to do further studies," Ms. Cruzan said. "Until we have that information, women who use any of these products should work with their doctors to use the lowest effective dose for the shortest duration of time."

Dr. Moskowitz said that the Women's Health Initiative "did not look at natural progesterone, and it didn't even look at progestin by itself."

She also said there were flaws in Dr. Hermann's research. The study looked at women who applied 40 milligrams of Pro-Gest twice a day, she said, a higher dose than recommended. On its Web site, the company recommends a dose of 20 milligrams twice a day, but says that women can use as much as 40 milligrams twice a day. The researchers said the dosage used by their subjects was consistent with the directions on the cream's label.

Dr. Hermann, however, said that the dosage issue was moot because many women use the creams like body lotion, slathering them on without regard to dosage.