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Study confusion leads women's health doc to launch 'Truth About Hormones Campaign'

TUCSON, Ariz. (April 6, 2007) – One of the nation's pioneering women's health physicians today announced a nationwide "Truth About Hormones Campaign," pledging to undo misinformation about hormone therapy that has plagued American women for decades.

Noting that a recent French study and a newly updated U.S. government study confirm what she has been saying publicly for many years, Elizabeth Lee Vliet M.D. said she would begin a series of informational appearances in cities across America to educate women about overall hormone health. Times and locations will be announced later.

"Even the recent hormone headlines don't get it straight, and it's time that the women in America have access to information just as European women have had for more than 30 years," said Vliet, winner of the Arizona Foundation for Women's Voice of Women award for 2007 and founder of HER Place (www.herplace.com), a medical practice in Dallas and Tucson devoted to women's health. "We're in the most progressive country in the world, yet American women are stuck in the 1960s when it comes to information about hormones. I intend to change that."

Vliet made the comments in response to an April 3 announcement from the National Institutes of Health that it was reversing some of the more alarming findings in its 2002 Women's Health Initiative (WHI) study. Vliet has contended all along that the WHI study was seriously flawed.

Vliet also pointed to a recent study known as ESTHER (short for Estrogen and Thromboembolism Risk), which was funded primarily by French government health agencies. Among other findings, the study found that gels and patches are safer than pills for women undergoing hormone therapy. Method of delivery is just one of several hormone issues on which Americans have been misinformed, said Vliet, who also espouses the use of FDA-approved bioidentical hormones over more commonly used, horse-derived estrogens that were used in WHI.

"In the United States, the ESTHER study comes as a surprise to women and most doctors," said Vliet, who prescribes gels, patches and other transdermal hormones for most of her patients suffering from the symptoms of menopause.

"But these differences shouldn't really be a surprise," Vliet continued. "European women and their doctors have known about the differences in hormones for over 30 years, and I've been writing about them since the early 1990s. It is past time for American women to

catch up to their European sisters and to demand that health-care providers give them the safest, most up-to-date therapies available.”

ESTHER showed that women taking oral estrogens were four times more likely to have a blood clot – such as a potentially deadly deep-vein thrombosis, or DVT – than women using estrogen in a transdermal gel or patch delivery. In fact, women using estradiol gel or patches had no more blood clots than women using no hormones at all (placebo).

Vliet said the latest WHI and ESTHER developments come at an especially opportune time:

- While recent news coverage has illustrated how women were misinformed about risks by the initial WHI study, women still aren't getting the full story. For example, the risks that remain are not the same for all types of hormones or all hormone delivery methods.
- According to the Coalition to Prevent Deep-Vein Thrombosis, a recent survey found that 60 percent of Americans have not heard about DVTs, despite the fact that, according to the coalition, they kill “more people in the United States than AIDS and breast cancer combined.”
- The North American Menopause Society issued a March position statement on hormone use, saying “there is some evidence that transdermal 17-beta estradiol may be associated with lower risk of deep venous thrombosis than oral estrogen.”

Another group, the International Menopause Society, has long recognized the lower risk of transdermal delivery in its position statements.

Vliet has been a forceful speaker on the lecture circuit for years and has authored numerous books about hormones and women's health, beginning with *Screaming to Be Heard: Hormone Connections Women Suspect And Doctors Ignore* in 1995 (revised in 2001). Her newest book is *The Savvy Woman's Guide to Hormone Headlines: What America Got Wrong About Estrogen*.

Throughout her career Vliet has encouraged women to pay more attention to hormones, be more selective about their hormone therapies and seek out physicians who are knowledgeable about hormones' effects. She said up to 80 percent of the patients for whom she prescribes hormones take them transdermally, or through the skin.

“I wrote about lower risk of blood clots with non-oral estrogen in the first edition of *Screaming to Be Heard*,” Vliet said. “Studies since the 1970s have shown this important difference between oral and transdermal estrogen. More recent data have indicated even more strongly that the way hormones are delivered plays a major role in safety versus complications.”

An estimated 4 million menopausal women use hormones to relieve hot flashes, mood swings, diminished sex drive, depression, osteoporosis and other symptoms. Of American women taking prescription hormones over the past 50 years, 80 to 85 percent have taken pills – usually Premarin (a mixture of horse estrogens) or Prempro (horse estrogens plus a potent synthetic progestin). “These products contain hormones that are unlike the ones that women produce naturally,” Vliet said.

European women, on the other hand, have traditionally used products that contain bioidentical estradiol and progesterone, hormones that are molecular copies of what the human body makes.

Another critical factor, Vliet said, is the difference in the way the hormones are delivered. Seventy percent of women in France and Italy use transdermal forms of estradiol such as gels, lotions or patches that have been approved by their regulatory bodies (similar to the Food & Drug Administration in this country). Meanwhile, only 3 percent of American women use transdermal estradiol. "This despite the fact British researchers first published studies in the 1970s showing reduced risk of blood clots with non-oral estrogen," Vliet said.

The U.S. market has been dominated by the horse-derived estrogen pills, Premarin, or its companion Prempro, which also contains a more potent synthetic progestin.

EstroGel, Estrasorb, Climara and Vivelle DOT are among the transdermal options approved by the FDA in the United States. EstroGel, for example, was approved in France in 1974 and has been the most widely used form of estradiol in all of Europe for three decades. When did American women have access to this? Not until 30 years later, when the FDA approved it in February 2004. "So it seems the French have handled women's hormone therapy a lot better than the Americans for a long, long time," Vliet said.

The primary difference between oral and transdermal delivery is that oral estrogens must first be metabolized, or changed, in the liver, Vliet said. This "first pass" through the liver stimulates production some clotting factors and proteins that lead to both negative effects (including possible blood clots) and positive effects (such as an increase in HDL, or "good" cholesterol).

The bottom line, Vliet said, is that women should talk to their doctors. "If you are using, or considering using, estrogen to relieve menopausal symptoms, ask your doctor if you can try EstroGel or one of the patch brands that are FDA-approved bioidentical options for estradiol."

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