

July 15, 2002

Dear Patients of Northeast OB/GYN Associates:

By now you have probably become aware of a recent study of hormone replacement therapy (HRT), which yielded some negative results. We know that you are probably very confused, and are unsure whether to continue your medication. Please allow us to quickly summarize what was known about HRT prior to this study, and what was found in this study.

HRT was initially marketed to treat hot flashes and other estrogen deficiency symptoms of menopause. Most studies have shown HRT to be beneficial in preventing heart disease and osteoporosis. There has also been evidence to suggest less risk of colon cancer and Alzheimer's dementia. Some studies have shown no increase in the risk of breast cancer, while others have shown a slight increase in breast cancer risks. We have known that it may increase the risk of blood clots in the legs or lungs in some women. We have also known that it may increase the risk of endometrial (uterine) cancer unless progesterone is given with the estrogen. In women without a uterus, estrogen can be given alone.

The previously mentioned study was published in the *Journal of the American Medical Association (JAMA)* on July 9, 2002. The Women's Health Initiative followed a large, diverse group of healthy menopausal women over an average of 5.2 years. One group had previously had a hysterectomy, and received estrogen (Premarin 0.625 mg) or a placebo. Over 16,000 women still had a uterus, and received estrogen plus progesterone (Prempro 2.5 mg) or a placebo. The study was stopped early in the women on Prempro because several negative trends were noted. The study is still going on for the women on Premarin only, because the negative trends were not observed in that group.

The study discovered that for every 10,000 women per year of therapy receiving Prempro:

- 7 more than expected had heart attacks or other coronary events (37 vs 30)
 - 8 more than expected had strokes (29 vs 21)
 - 8 more than expected had blood clots in the lungs
 - 8 more than expected were diagnosed with breast cancer (38 vs 30)
- (The increase in breast cancer risk was not seen until after 4 years of use)

On the positive side:

- 6 less than expected were diagnosed with colon cancer
- 5 less than expected had hip fractures

Some of these results were very surprising (particularly the increase in the risk of heart attacks), and like you, we are trying to determine where to go from here. Please do not panic, the overall risks are still very low. Breast cancer occurred in less than 1/10 of one percent per year of use. We would like to help you make the individual decision that is right for you, taking into account your risks for specific conditions that may be harmed or benefited by HRT use. Unfortunately, we have been overwhelmed with calls, and it may be difficult for you to get an appointment as quickly as you would like. Continued HRT use for the time it takes to be seen should not be detrimental. However, if you are uncomfortable with using the medication until you have talked to us, you may discontinue it. There is no problem with doing this, though you may experience a few hot flashes. Keep in mind that the increase in breast cancer risk was not seen until after 4 years. Also, recall that these risks were not seen in the women on Premarin alone, and this part of the study is continuing. If you desire to continue on HRT, there are several options available. It may be safer to switch to a different estrogen and progesterone, or a lower dose, or a transdermal delivery system. Evista is a medication that has many of the benefits of HRT, but is not associated with an increase in breast cancer (and may, in fact, be protective). There are also non-hormonal medications that may be used to treat specific symptoms or risk factors.

We want to emphasize that we are concerned about you and your health, and we regret that we have been unable to personally answer all your calls this week. We look forward to meeting with you as soon as possible to discuss your individual concerns. Please contact us if we can provide any further assistance.

Sincerely,

The Physicians of Northeast OB/GYN Associates