

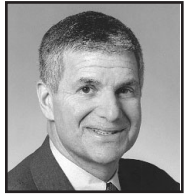
Health Horizons

A FOCUS ON WOMEN'S HEALTH ISSUES



FROM THE OFFICE OF DR. STEVEN R. GOLDSTEIN

JUNE 2004



A Word From The Doctor

In July 2002, the Women's Health Initiative dropped a bombshell on the American public. Many patients felt confused and bitter at a medical establishment that had seemingly misled them. "How could they get it so wrong?" As many of you aware Dr. Goldstein had been tapering and discontinuing hormone therapy after 4 years in women well before the WHI released its results. The WHI was not new news but was the **culmination** in a series of previous studies that pointed in that direction.

However experiences like the WHI simply underscore more than ever the importance of patient education and physicians who take the time to explain information to their patients. Much of what was thought about HRT came from observational studies which we now realize to be flawed. Double blind randomized placebo controlled trials the gold standard of clinical research is all that we should accept in the future. There is so much information available to patients especially now in this internet age it is difficult for someone to know what is accurate and whom they can trust. I began this newsletter and continue to publish it to try to address topics that I see of being important to my patients – questions that constantly come up in day to day practice. I have attempted to explain things in plain language. So much of what I concentrate on is promoting wellness and if something does happen then early detection is our main weapon. With most traditional medical approaches a doctor is dealing with advanced disease process and then tries to put out "forest fires". In this office I want to blow out matches or at worst extinguish small brush fires before problems accelerate. Don't put it off - if you or your family are due call us and come and see me. If you have been a patient of mine and insurance problems have forced you to switch doctors, but like so many others you are just not pleased with the change in care "PLEASE" call our office, most of the time we can work out some arrangement.

Dr. Goldstein is a Professor of Obstetrics and Gynecology at New York University Medical Center. He has written 5 medical textbooks, numerous chapters, research articles, and hundreds of National and International Presentations to other doctors.

This newsletter published periodically underscores his conviction that education of the patient is just as important in this day in age as it is a physician. His first book "Could it be perimenopause" describes a unique phase up to a decade before your first hot flash on fluctuating levels of unopposed estrogen (not the absence of estrogen seen in menopause) can cause some subtle and not so subtle bleeding abnormalities and subtle and not so subtle sociopsychosomatic symptoms (sleep disturbances, mood swings, free floating anxiety, inability to concentrate, memory lapses). His other book the estrogen alternative what every woman needs to know about hormone replacement therapy and SERMs the new estrogen substitutes was a manifestation of his unique position as perhaps the worlds foremost authority on what this category of drugs (SERMs) do to the reproductive system.

BIRTH CONTROL PILLS: Still so much misinformation!

So many patients, intelligent educated patients, are still wary of hormonal cycle control (that is birth control pills). Whether for contraception or control of the perimenopause (or both!) so much is not explained PROPERLY. I still encounter so many patients who need correct information. We do know that estrogen is a **promotor** of breast cancer (see below); not an inducer but a promoter. Postmenopausal women who take estrogen have a 10-20% increase in their risk of breast cancer – that is 1.1 – 1.2 times the background or baseline rate. When something is **causal** you expect increases of 3 – 4times the background rate. With cigarette smoking, and lung cancer there is a 12 times increase or 1200%, not 10 or 20%! Unfortunately women inappropriately extrapolate this fact onto the use of birth control pills in premenopausal women. There is no parallel. I understand however how most women look at the pill, then realize it contains estrogen and progesterone and then they look at their breasts, look at the pill, look back at their breasts and probably think they are crazy to put this into their body. What isn't explained clearly enough is that these pills work by **suppressing** your own ovarian function – in other words, these hormones are **instead** of your own estrogen not on top of your own. If hormones were that bad we would remove ovaries after women completed their childbearing. There is good scientific

evidence that birth control pill use lowers ovarian cancer, lowers uterine cancer and in the previous studies did not increase breast cancer ... and the pills in those studies were up to 2 - 4 times as much hormone as some of today's low dose pills! Furthermore some women claim that pills aren't "natural". Realize what "nature" expected... most women would have 8 children, nurse them all for 12 – 15 months (there are no bottles or formula in nature) and have 2 -3 miscarriages along the way. Instead of the roughly 500 menstrual cycles that modern women are having nature never planned for more than 300! Suppression of ovulation and the menstrual cycle is closer to what "nature" had in mind. I am not advising patients to have 8 children and nurse them all for more than a year – just realize that our modern society is anything but "natural". Birth control pills can be tremendously beneficial especially to women who are experiencing perimenopausal symptoms of erratic levels of unopposed estrogen – exacerbation of mood swings, sleep disturbances, memory changes, free floating anxiety as well as any bleeding irregularities. If you are a non smoker and have normal blood pressure low dose birth control pills are safe right up until menopause. If you need more information or still have questions call us or come in for a consultation.

HRT: Now that the dust has settled.

First in July of 2002, the WHI, and then in May 2003, the WHI Memory Study (WHIMS) showed us that estrogen + progesterone does not reduce heart disease and Alzheimer's – in fact it results in a small but statistically significant increase in heart attacks, strokes, dementia (in those women over 65), breast cancer and blood clot, as well as less hip fracture and less colon cancer. The consensus is that the only real indication for hormone therapy is relief of disruptive menopausal symptoms (hot flashes, night sweats) with the lowest effective dose for the shortest period of time possible. In July 2002, 6 million women were on hormone therapy. By May 2003 it was 2.7 million. But a recent study showed 25% of women who stopped hormone therapy had to go back on because of the severity of their symptoms. In the past women took hormone therapy so as not to be inconvenienced; now I believe patients need to be a bit more than simply inconvenienced (although each case is unique) to justify going on or continuing with therapy.

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HRT: Now that the dust has settled.

The evidence, however, points clearly to the fact that estrogen + progesterone has 3-10 times more risk of breast cancer than estrogen alone. In the past only women with a hysterectomy were allowed to take unopposed estrogen because of the risk of pre-cancer and cancer of the uterus. However only 7% of women who take estrogen alone will even develop the first level of hyperplasia (simple) and this is reversible with a course of progesterone. What I have advocated (and many physicians are now following) is using transvaginal ultrasound to allow some women to reduce their progesterone to as little as 2 times per year instead of the traditional **daily** or even 10-14 days per month. If the endometrial echo is easily visualized (as it will be in most women without fibroids) transvaginal ultrasound can be used to dramatically reduce the amount of progesterone needed for endometrial protection. If you are on hormone therapy, or know someone who is, see if you are a candidate for this "less than monthly" progesterone.

Ovarian Cysts: So misunderstood.

Tell a patient she has a "cyst" on her ovary and it instantly strikes fear in her. Yet all a "cyst" is, is a fluid filled structure. In fact a normal healthy premenopausal ovary forms "cysts" each month, the largest of which, the dominant follicle bursts at the time of ovulation. If it doesn't burst and continues growing it can cause a "follicular cyst", or if there is some small amount of bleeding into ovulation you can get a "hemorrhagic cyst". These are all normal variants and often called functional (or in some cases dysfunctional) cysts. These virtually always go away on their own (in medical language – self limited) and sometimes physicians use hormonal cycle control (birth control pills) to prevent them. The problem is virtually all ovarian tumors – benign or malignant – will usually have some cystic portion. Thus it is essential to be able to use judgment and experience to distinguish functional cystic change on ultrasound from tumors and

understand what benign looks like and what the more suspicious for malignant ones look like as well. Transvaginal ultrasound has become increasingly sophisticated and rarely is exploratory surgery even by the laparoscopic route necessary. One last very important point: unlike cervix, breast, uterus where there are well defined precancer stages that we aggressively trying to find "before they cross the line"... with ovarian tumors they are malignant or benign from the start. That's why obviously benign cystic structures do not need to be removed unless they cause pain or change over time.

SERMS (Selective Estrogen Receptor modulators): Evista (Raloxifene)

SERMs are emerging as a category of drugs that may well deliver the promises left unfulfilled by estrogen for improving overall long term women's health. In years gone by, it was believed that estrogen reduced heart disease, preserved bone health, and made a woman look and feel better. Today we know that the only real indication for hormone therapy (estrogen and progesterone replacement) is relief of disruptive transitional menopausal symptoms (hot flashes, sleep disturbances, dry vagina).

Apparently, the SERMs (Evista was introduced in 1997, others are in final development) offer great promise. They bind to the estrogen receptor so that in some tissues, they function like estrogen while in other tissues they are estrogen blockers. The gold standard of clinical testing is the double blind randomized placebo-controlled studies. Remember how medical science got into trouble because observational studies showed that hormone replacement therapy prevented heart attack, so much so, that the FDA almost changed the labeling for estrogen. However, when appropriate (randomized double blind placebo controlled trials) were done (WHI) not only does the HRT not reduce heart attack but there is actually a small increase in the incidence.

All the studies done so far with Evista have been of the randomized placebo controlled double blind type. In those studies, Evista has consistently been showed to 1) build and preserve bone mineral density in postmenopausal women at risk for osteoporosis, 2) reduce osteoporotic fractures in women with osteoporosis, 3) reduce breast cancer (72% compared to women taking no med-

ication) in osteoporotic women studied up to 4 years, 4) reduce heart attacks 30% in a subset of osteoporotic women who were deemed to be at high risk for heart disease who were studied through 4 years as well. There are ongoing trials looking at heart disease primarily (RUTH study) and breast cancer primarily (RUTH study and STAR trial). These studies involve women at high risk for heart disease as well as women at high risk for breast cancer and are not simply osteoporotic women undergoing therapy. However, if these studies corroborate what we have seen initially, it will come as no surprise in light of the foreshadowing that the completed studies have already indicated.

You might ask why isn't everyone on Evista? It sounds almost too good to be true. First, unlike estrogen, Evista does not treat hot flashes or vaginal dryness. Thus, only women who are distantly menopausal (usually more than 3-4 years) and beyond the worst symptom phase are candidates, since using Evista in earlier menopausal women can sometimes actually increase their hot flashes. In addition, although it does not worsen vaginal dryness, it does not help the natural atrophy that menopause brings. Thus, if women are sexually active, they also need local intravaginal estrogen. Fortunately, this can be given such that it stays in the vagina with little or no absorption into the rest of the body. Finally, Evista is an estrogen in the venous system. This means that a women's risk of blood clot in the legs or lungs is from about 1/1,000 on no medication to 3/1000 on Evista (which is the same as estrogen). Thus women with a past history of blood clots, during or after pregnancy, or while on birth control pills, should probably avoid Evista. It is however, an easy drug to take - empty or full stomach, morning or evening, upright or lying down.

Dr. Goldstein helped design the studies that proved Evista was a safe compound (especially in the uterus). He has also helped Wyeth, NovoNordisk and now Pfizer with their SERMs that are in development. He recently was asked to author The American College of Obstetrician and Gynecologist's (ACOG) practice guidelines bulletin on SERMs which is distributed to all 40,000 Ob/Gyn's nationwide. Feel free to ask him or the staff about further information.

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If you would like to see a specific health issue addressed, please contact us at:

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