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# Subcutaneous Hormone Pellet Therapy- Not Alternative Medicine, but an Alternative to Bad Medicine

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For eight decades subcutaneous hormone pellet therapy has been utilized in patients. Currently they are used to treat peri-menopause, menopause, and andropause patients in five continents. The safety and efficacy of both estrogen and testosterone pellet therapy has been documented throughout the world's peer reviewed journals. In 2002, the initial data from the Women's Health Initiative revealed an increased risk of breast cancer, venous thrombosis (VTE), heart attack and stroke from the use of PremPro, a synthetic estrogen and progestin. Although the flaws from this study have been published many times it continues to be held as the "gold standard" for hormone replacement therapy. It seems as the investigators from this study continue to want to scare the patients and their physicians into using hormone replacement sparingly and only for short durations. All the W.H.I. study has done is reduce the quality of life for millions of women.

The American College of Obstetrics and Gynecology in its Committee Opinion 352 from December 2006, and reaffirmed in

2012, stated that medicine cannot advance without innovation.

"Innovation in Obstetrics and Gynecology has always been one of the ways we as physicians advance healthcare for our patients."

Examples include robotic surgery, chorionic villous sampling, vaginal birth after cesarean section, and continuous birth control pills to treat endometriosis. The American College of Obstetrics and Gynecology went on to say a clinician should share their results with colleagues and teach these techniques to other physicians. A.C.O.G. believes innovation should move to clinical trials. After Dr. Greenblatt introduced subcutaneous hormone pellet therapy in 1939 there have been many numerous clinical trials to support the efficacy and safety worldwide. The fact subcutaneous hormone pellet across the United States and in five continents by Board Certified Ob-Gyn's, Family Physicians, and Urologists attest to its standard of care.

The American College of Obstetrics and Gynecology Committee Opinion 532, dated August 12, 2012, calls into question just how the committee could overlook the large number of studies performed worldwide on bio-identical hormone replacement therapy and conclude that hormone replacement therapy is no longer indicated for long term health improvement. They state there is a lack of evidence to support superiority claims of bio-identical hormones over conventional menopausal hormone therapy. In the background section of the Committee Opinion it says, the belief that replacing hormones lost by waning ovarian function was dispelled by the W.H.I. This is complete nonsense and is not subscribed to by the majority of Board Certified Ob-Gyn's. As we all know Committee Opinions are just opinions and not guidelines for Standard of Care. The W.H.I. looked at only two drugs: PremPro and Premarin. They are both synthetic hormones (with the estrogen component being equine estrone) and both are oral preparations. The risk of blood clots and breast cancer were known prior to the study by numerous other clinical trials. Medroxyprogesterone acetate, the synthetic progestin, also increases risk of breast cancer; in fact we knew that is caused breast tumors in beagle dogs in the 1950's. Most gynecologists had moved on to safer preparations including transdermal, oral bio-identical and subcutaneous hormone therapy prior to 2002. The ESTHER Study from France published in

Circulation in 2007, showed oral, not transdermal estrogen, was associated with VTE. None of the studies utilizing subcutaneous hormone pellet therapy have shown an increase risk of VTE, heart attack, stroke, or breast cancer. In addition, W.H.I. did not utilize any of these preparations and therefore conclusions about these cannot be made based on W.H.I. data. Ronald Young M.D., a prominent Houston Ob-Gyn, and an investigator in the H.E.R.S. Study and the W.H.I. in a recent interview agreed the W.H.I. was flawed. He stated you just don't give estrogen in those doses to women at that age (average age of women in W.H.I. was 64) very often. His comments were prompted by the recent randomized controlled trial in the BMJ 2012; 10:1136 showing cardiac protection in long term use of hormone replacement therapy.

Most importantly, the Committee Opinion does say that compounding is used to provide treatment for patients when the exact product needs are not commercially available or different routes of administration are required. In order to appropriately balance hormones, individual dosing is necessary and requires multiple pellet doses for estradiol and testosterone. In addition, only subcutaneous hormone pellets achieve constant blood levels. This is exactly what the Committee was addressing. They go on to say other potential advantages include greater dosing flexibility and lower dose preparations. I totally agree with A.C.O.G. on this point. Furthermore, subcutaneous hormone pellets contain F.D.A. approved compounds without fillers. They can be and should be tested by an independent lab for purity and potency, allaying one of A.C.O.G.'s concerns, and meeting the litmus test for proper dosing.

The real issue here is that the opinion in this report deals with estrogen and progesterone and does not deal with the treatment of hypo-testosteronism in females or males. Safety and efficacy has been established by multiple clinical studies for 80 years. There is no study to support the Committee Opinion that F.D.A. approved hormones are more efficacious than individualized compounded hormones. In fact, the F.D.A. still allows the sale of PremPro knowing the serious side effects from this synthetic preparation. Safety of statins and bisphosphonates has all been called into question during

the last year. Worldwide safety and subcutaneous hormone pellet therapy has an eight decade safety net that has never been called into question. On the Committee's list of F.D.A.'s approved products, testosterone is missing yet Testopel is an F.D.A. approved hormone.

The Committee opinion, again, is just an opinion about hormone replacement therapy and it is certainly not speaking to the benefits of subcutaneous hormone pellet therapy which does benefit long term health by conferring benefits to the brain, heart, lipids and bones. Newer research seems to be showing long term benefits to the breast as well.

It seems to me that the American College of Obstetrics and Gynecology had it right back in 2006. Innovative Medicine is a dream that becomes reality when backed up by clinical studies. At a time in our history when aging healthier and living happier is of paramount importance to most men and women, we must as clinicians do everything possible to facilitate this. Not balancing hormones, scaring patients, and disseminating myths from the W.H.I. is bad medicine. Balancing hormones and using the safest most physiologic delivery method to achieve this is not alternative medicine but an alternative to bad medicine.

Sincerely,

Gary S. Donovitz MD, FACOG

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