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**Hormone Replacement
Therapy: A Women's
Health Care Crisis**

Hormone Replacement Therapy: A Women's Health Care Crisis

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Over the past two decades, US health care has been challenged with many issues. As we approached the new millennium, the challenges became monumental. This has necessitated a paradigm shift in disease management in various fields of health care, including women's health.

This article addresses numerous health care challenges facing women of all ages today, especially in the areas of **premenstrual syndrome (PMS)** and menopause management. The American Wellness Alliance (AWA) has created a paradigm shift in women's health care by providing safer, cost-effective, innovative, viable options for women challenged with these frustrating issues.

Traditionally, **hormone replacement therapy (HRT)**

has been used in menopausal women for treatment of various menopausal symptoms that include hot flashes, mood swings and vaginal dryness.

HRT was also embraced as a part of a preventive health care concept for protection against cardiovascular disease, dementia and osteoporosis.

These perceived benefits were weighed against potential risks associated with HRT, such as high risk of breast cancer and deep vein thrombophlebitis. These discussions were made part of patient counseling by physicians regarding HRT.

In the fall of 1997, a Women's Health Initiative (WHI) study was initiated by the National Institutes of Health (NIH). The study was designed to evaluate use of HRT by healthy women

Dr. Kumar and patient Becky Washburn





PHOTO BY DAVID EVERETTE, A BETTER IMAGE

Dr. Kumar in her countryside home

for disease prevention.

The WHI study included 16,000 healthy, postmenopausal American women with a uterus between ages 50-79. The scheduled end date of the study was 2005; however, the estrogen and progesterone arm of the study was discontinued in 2002. The estrogen-only arm was discontinued in 2004 because of risks greater than benefits. Risks included increased risk of heart attacks, strokes, breast cancer and blood clots. **Following the suspension of the WHI study, the Federal Drug Administration (FDA) implemented a “black box warning label” for HRT, which is a class-warning label indicative of the WHI results.**

Recently, the 2007 American College of Obstetricians and Gynecologists Compendium described the risks associated with compounded bio-identical HRT, which are even greater than with conventional HRT. FDA reported greater than 34% compounding errors with compounded bio-identical HRT. Other disadvantages with compounded bio-identical hormones include cost and inconsistent absorption, to name a couple.

GUIDELINES FOR HRT TREATMENT

HRT is not recommended for prevention of menopausal symptoms. HRT should be used for the shortest duration of

time and in the smallest dose required for relief of menopausal symptoms.

The results of the WHI study created a lot of anxiety and frustration for physicians treating women and their patients. Women who were seeking other options tried **selective serotonin reuptake inhibitors (SSRIs)** with some degree of success. Many of these were associated with troublesome sexual side effects and in rare instances there were suicidal tendencies. Therefore, SSRIs were not considered a viable option for menopause management long term.

These results created the need to evaluate other alternative estrogens and progesterone. DEVI Fembiotics XR are agents that relate to women’s life and are a type of cellularbiotic. Hormonal balance is an important aspect of women’s life. Hormonal imbalance leads to menopausal symptoms, PMS, menstrual cramping and abnormal bleeding. Fembiotics naturally maintain hormonal balance in women.

Women in pursuit of alternative therapies have embraced **over-the-counter (OTC)** botanical alternatives. However, a majority were generally dissatisfied with the incomplete responses that they were able to achieve. The reason for the partial responses is explained by the fact that these OTC products generally use **single system/symptom modulators (SSMs)**

containing only one major ingredient or botanical alternative. The danger, risk and troublesome side effects associated with synthetic progesterone are not the same as those associated with natural progesterone due to the difference in chemical structure.

PHYTOESTROGENS (DIETARY PLANT ESTROGENS)

Plants do not make estrogen; plants make sterol molecules, which exert weak estrogenic activity. Phytoestrogens have structural similarities to human estrogens. Types of phytoestrogens include isoflavones, lignans and coumestans.

1. Isoflavones: genistein and daidzein are plant sterol molecules found in soy and garbanzo beans.
2. Lignans: constituent of cell wall of plants that become bioavailable as a result of the effect of intestinal bacteria on grains, e.g., flaxseed.
3. Coumestans: not a significant source of phytoestrogens, e.g., red clover, sunflower, bean sprouts.

American diets increase plasma levels of sex hormones and decrease sex hormone binding globulin (SHBG), which increases the exposure of peripheral tissues to the effects of circulating estrogens. Isoflavones decrease luteinizing hormone (LH), which secondarily depresses estrogen production.

Lignan and isoflavonoid glycosides become hormone-like compounds through the action of intestinal flora. They exert:

- Weak estrogenic and antioxidant activity
- Act on intracellular enzymes
- Protein synthesis
- Growth factors
- Cell proliferation, differentiation
- Angiogenesis
- Decrease incidence of cancer and atherosclerotic disease (with intake of bioflavonoid)
- Diphenolic isoflavonoids and lignans are cancer protective compounds.

Diphenols (in bean products)

- Decrease cancer risk by modifying hormone metabolism and production
- Decrease cancer cell growth
- Provide a large amount of fiber

Fiber

- Modifies level of sex hormones by increased gastrointestinal motility
- Alters bile acid metabolism
- Partially interrupts enterohepatic circulation
- Increases estrogen excretion by decreasing the rate of estrogen reuptake in the enterohepatic system

Patient Testimonial

I began having horrible stabbing pains in my right cheekbone in the fall of 2002. At first the pain came once or twice a month, always when I was splashing water on my face to wash it. The pain made my knees buckle and was gone as fast as it came. By spring of 2003, the pain, when it came, was more excruciating and was of a longer duration each time. Then, on August 3, 2003, I had the worst and longest lasting pain episode so far. I had bitten down on a piece of celery. It felt like I had bitten down on a sharp butcher knife that was electrified. This horrible pain went on and on. When it finally stopped, I was shaking so hard that I couldn't dial the phone to call for help. I thought that I was having the world's most severe tooth pain, which had ended with no trace of a toothache. I called my dentist and he was able to see me the next day.

I wish I could say that he knew just what was wrong with me and was able to help. Unfortunately, he drilled a tooth and insisted that I was just overreacting to a tiny cavity. By the time the novocaine wore off, I was in terrible pain again. I called the dentist and he assured me that I could not possibly be in pain. The pain stopped again and I was starting to think that maybe it was my tooth. I did not connect the pain in my cheek to the pain in my tooth and jaw until much later. Two days after the visit to the dentist, I had the worst pain of my life. This time it was triggered by answering my cell phone. I was in a ball on the floor when the pain finally stopped. My husband thought I was having a stroke. I remember him frantically asking me what was wrong. When I tried to tell him that I was having that terrible pain, speaking set it off all over again. Every time the pain stopped, it would start up as soon as I tried to tell my husband what was wrong. Finally I had to write, "Take me to the emergency room" on a Post-It note, and off we went.

In the emergency room it was determined that I probably had trigeminal neuralgia. I was given seizure medicine and a referral to a neurologist. I was not given pain medication because there is no pain pill for nerve pain. While on increasing doses of seizure medication, my pain episodes increased in frequency and duration.

I was not responding well to medication. It just wasn't working to

control my pain.

I underwent a Gamma Knife procedure in September of 2005 and was hoping to be free of pain, but there I was again, experiencing lightning bolts of pain in my right jaw and also in my eye. I experienced over 100 episodes of pain on Easter Sunday 2006 while trying to enjoy the day with my children and grandchildren. My fear at the return of my pain was mighty. This was the end of my second short remission. My first remission was for about a year. I had a glycerol rhizotomy in September 2003 to damage the trigeminal nerve where it branches under the cheekbone.

I was again taking up to 800 milligrams of Tegretol daily, which doped me up while being only minimally effective at reducing my symptoms and making it unsafe to drive a car. I felt that my life was over. I started taking TNStat XR in April of 2005, after years of extreme pain. Although I was skeptical, I was willing to try this new protocol. My trust in Dr. Kumar and Jullian Grante carried me through many dark days.

I clearly remember Jullian's voice saying, "I promise you, it will work." I heard those words every time I looked down at the capsules in my hand just before I put them into my mouth, three times a day, day after day.

About three weeks had passed when I started to detect a change in the intensity of my pain. (I would never have kept taking the capsules for this long with no change in my pain, but I didn't feel that Jullian would promise me if he didn't believe with all of his heart that it would work.)

As the weeks went by, my pain decreased in intensity and frequency. Today I have no pain, and I take no seizure medication.

It makes me cry to think how my life was before and how my life would be without the help of Dr. Kalyani Kumar and Jullian Irving Grante of the American Wellness Alliance. I have what I never had before, control of my pain and control of my life. The work of Dr. Kumar, Jullian and the AWA through the Alliance's Scientific Research and Technology Division, is impacting the lives of children, adults and families across Virginia, America and around the world.

— Rebecca M. Washburn

Soy

- Contains biologically active isoflavones (aglyconic isoflavones), binds to estrogen receptors, not safe for women with estrogen dependent breast cancer
- Studies show 45% decrease in vasomotor symptoms with soy

Wild yam

- Contains plant sterol dioscorea, which converts to progesterone in the body, which reduces estrogen dominance, therefore it is effective in PMS, menopause, dysmenorrhea and abnormal uterine bleeding
- Plant sterols used as precursors in the biosynthesis of progesterone (no inherent biological activity)

Mexican yam

- Contains diosgenin (an estrogen-like substance) effective for uterine cramps

Black cohosh

- Reduces LH
- Has positive effects on sleep disorders, mood disturbances and hot flashes
- Weak estrogenic effect
- Binds to estrogen receptors and mimics estrogen effects
- Black cohosh effective for hot flashes, sleep disorders, anxiety, mood swings, depression, dysmenorrhea and PMS

Estrosym XR, which is a part of the **DEVI Fembiotics XR Healthcare Management System for Women**, is a unique blend of dietary plant estrogens and progesterone that naturally regulates and maintains hormonal balance in women. **Estrosym XR** contains a proprietary blend of nova soy, wild yam and black cohosh.

Indications for **Estrosym XR**:

- Menopausal symptoms, hormonal imbalance
- PMS
- Abnormal uterine bleeding
- Dysmenorrhea
- Antioxidant
- Improve lipid profile
- Heart health
- Bone health
- Cancer protective

Contraindications of **Estrosym XR**:

- Contemplating pregnancy in the near future
- Pregnancy, lactation
- Breast cancer



Prescription medicine versus natural hormones

The **DEVI Fembiotics XR Healthcare Management System for Women** offers a safe and effective alternative for HRT and PMS in most situations. Botanical alternatives, such as those in the DEVI Fembiotics XR Healthcare Management System for Women, should be considered as a primary modality option prior to prescription HRT treatment whenever feasible. **WHI study results necessitate this paradigm shift from HRT to Fembiotics XR in women's health care whenever feasible.**

Women are encouraged to continue their annual check ups with their obstetrician and gynecologists while they are using products in the DEVI Fembiotics XR Healthcare Management System for Women. In addition to the DEVI Fembiotics XR Healthcare Management System for Women, the American Wellness Alliance Immune Health Management Group has developed the following Cellular Biotic LifeKare Systems for disease management, in partnership with the Alliance's Scientific Research and Technology Division:

- **StealthAID XR "Cellular Management of HIV/AIDS"**
- **HepKARE XR "Cellular Management of Hepatitis A, B & C"**
- **DB STAT XR "Cellular Management of Diabetes"**
- **TN STAT XR "Cellular Management of TN (Trigeminal Neuralgia)"**
- **MS STAT XR "Cellular Management of Multiple Sclerosis"**
- **ALZI STAT XR "Cellular Management of Alzheimer's Disease"**
- **ONC KARE XR "Cellular Management of Cancer"**
- **MRSA STAT XR "Cellular Management of Methicillin Resistant Staph. Aureus." ■**

Dr. Kumar has had a distinguished career as a physician, educator and innovative pioneer in medicine. As a result of her work and comprehensive research in the areas of technology to improve the quality of health care delivery services and disease prevention strategies, Dr. Kumar has earned numerous awards, recognition and acknowledgments from community-based organizations, the White House, Health/Human Services, Centers for Disease Control, National Institutes of Health, senatorial and congressional representatives.

The Congressional Leadership Council named Dr. Kumar "Physician of the Year" in the years 2002-2005. The National Republican Congressional Committee's Physician's Advisory Board honored Dr. Kumar with the "Pioneer of Healthcare Reform" in 2004. In both 2005 and 2006, the Consumer Research Council of America named Dr. Kumar "One of America's Top Obstetrician and Gynecologists."

Dr. Kumar began her medical career in 1981 and received her medical degree from Osmania University, Hyderabad, India, and completed her residency training in OB/GYN at St. Vincent's Hospital, Staten Island, NY. Dr. Kumar has held positions as Director of Gynecologic Surgery at Virginia Institute for Laparoscopic and Laser Surgery at Columbia Henrico Hospital and served as Director of the Mid-Atlantic Microendoscopy Columbia Hanover Outpatient Center in Richmond, VA. Dr. Kumar's exceptional surgical skills and techniques have over the years earned not only the respect and admiration of her peers and patients, but also from physicians and administrators representing such renowned hospital systems as St. Mary's, which is part of the Bon Secours National Healthcare System.

Dr. Kumar has served as faculty for various gynecologic endoscopy courses to include laparoscopic hysterectomy, office hysteroscopy, microlaparoscopy and other operative laparoscopic techniques both nationally and internationally, including Kuwait, Bahrain, United Arab Emirates, the United Kingdom, Singapore, France, Dubai, Italy, Israel, Canada and India.

Dr. Kumar is the author of numerous articles in medical journals and publications. As an internationally recognized authority in the science of "Cellular Biotics and Immune Health Management," Dr. Kumar lectures and teaches classes on immune health management for hospital systems, physicians, health care professionals, local, state and federal governmental agencies, and corporate businesses.

Dr. Kumar is the author and coauthor of books, such as *Creating the Paradigm Shift: In American Healthcare*, 2006; *Achieving Optimal Health through Intercellular and Molecular Medicine*, (ICMM), 2005; *The Immunologic Management of HIV/AIDS*, 2004; and the *Immunologic Management of the Common Cold and Influenza*, 2003.

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In June of 2004, Dr. Kumar was invited to Washington, DC, to make a presentation to senior officials as part of her national health care model at the Department of Health and Human Services, in the office of Disease Prevention and Health Promotion, "Achieving Optimal Health through ICMM." During this historical briefing, Dr. Kumar also introduced the Alliance's "Healthcare Performance Zones" concept (wellness-optimal health, prevention-predisease state and treatment-disease state), which promotes helping individuals to maintain "optimal health," which ultimately reduces the national burden of health care cost.

Dr. Kumar is the inventor of "Cellular Biotic LifeKare System for Disease Management." This patented process of "DNA recognition and cellular repair" has led to the development of various "strategic health care alliances" with major medical institutions in the United States and around the world. Such alliances will greatly impact the development of "global health care strategies" to assist in the management of disease. Dr. Kumar has worked with adults and families impacted with the HIV/AIDS virus and hepatitis in her native India since 2003. Returning twice a year to work with Alliance physicians and health care partners at hospital facilities across the region, Dr. Kumar believes that the human spirit is empowered when one serves another without regard to one's social or economic status.

As a result of her never-ending quest for knowledge, comprehensive cellular research and vision for the creation and implementation of health care concepts, Dr. Kumar has successfully introduced numerous Cellular Biotic LifeKare Systems. These "life changing" Cellular Wellness and Immune Health Management Protocols were developed and patented to address such diseases as HIV/AIDS, hepatitis, Alzheimer's, diabetes, stroke, Parkinson's, arthritis, multiple sclerosis, trigeminal neuralgia, lupus, chronic fatigue syndrome, women's health issues and various forms of cancer.

Dr. Kumar's work and clinical experience has made significant contributions in improving national and international health care policy. Since retiring from her full-time medical practice in September of 2006, she has aggressively pursued her personal and professional goals to promote Cellular Wellness solutions as essential to helping millions of children, adults and families across America and around the world to achieve optimal health.

On October 1, 2006, Dr. Kumar transitioned from a 25-year career in public service as a physician and surgeon to assume the full-time responsibilities of President and Chief Medical Officer of the American Wellness Alliance.

During this period, Dr. Kumar received one of the highest personal and professional honors she could have ever imagined when her senatorial and congressional representatives recommended her to serve as America's next US Surgeon General.

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