

**Testimony on Biologically Identical Hormone Therapy  
House Subcommittee on Human Rights and Wellness  
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The U.S. Congress must take action to protect and improve the health of women in America. Congress must stop the FDA from illegitimately attempting to restrict compounding pharmacies from providing women in America with the benefits of natural, biologically identical hormone therapy. Congress should also consider underwriting a study of biologically identical hormones like the one that it funded in the Women's Health Initiative study which clearly demonstrated the adverse effects of drug company counterfeit (non bio-identical) hormones.

**The Health Problems of Women in Midlife**

Women in midlife experience a host of health problems related to an imbalance and decline of their sex hormone levels. These problems may include one, some or all of the following symptoms: premenstrual breast tenderness, mood swings, fluid retention, weight gain, and headaches, including migraines. They may also experience irregular menstrual cycles, heavy periods, breakthrough bleeding, fibroid tumors, fibrocystic breast disease, osteoporosis, fatigue, weight gain, hair loss, cold extremities, decreased mental sharpness, depressed and irritable moods, joint and muscle aches and pains, insomnia and loss of libido. At menopause, the symptoms of hot flashes, night sweats and vaginal dryness may also occur. These problems have been addressed by conventional medicine using synthetic, counterfeit (non bio-identical) hormones produced by drug companies for hormone replacement therapy (HRT). Additionally, other types of drugs have been prescribed to ameliorate these symptoms, such as, anti-depressants, anti-anxiety and anti-inflammatory drugs, sleep preparations,

diuretics, anti-migraine and headache medications, etc. Often times the menstrual irregularities that women experience lead the physician to recommend a hysterectomy. This surgery of course eliminates the problem of dysfunctional menstrual bleeding but does not address the underlying cause of the menstrual abnormality, that being hormonal imbalance.

Both the **Women's Health Initiative (WHI)** published in the **Journal of the American Medical Society (JAMA)** in July, 2002 and the recent **United Kingdom study on Breast Cancer and Hormone Therapy**, published in the **Lancet**, a premier British medical journal, on August 9, 2003, underscore the harmful effects of conventional, counterfeit (non bio-identical) hormone replacement therapy. In the British study, the treatment using the non bio-identical equine (horse) estrogens (e.g., Premarin, Cenestin and Ogen) with progestin agents proved to be the most dangerous combination. The progestins studied were medroxyprogesterone (Provera), norethisterone, norgestrel and levonorgestrel, all non bio-identicals of human progesterone. The non bio-identical hormone combination that is most commonly used in America is Prempro, which was the primary medication that was studied in the WHI. These drugs caused a significant increase in the incidence of breast cancer, stroke, pulmonary embolism (blood clots to the lungs) and cardiovascular disease.

**Biologically identical human estrogens and progesterone were not used in either study.**

There have been at least five medical studies, published in major medical journals, since 1989 that had reported the same findings that were found in the WHI and in the United Kingdom study on Breast Cancer and Hormone Therapy.

It was not until the results of the WHI were published on the front pages of the newspapers and magazines across the country that mainstream medicine realized that there was a problem. The pharmaceutical industry and conventional medicine have been promoting these counterfeit (non bio-identical) hormones for decades as essential ingredients to good health for women in midlife and menopause. But all one had to do was to listen to the complaints of the women taking these counterfeit (non bio-identical) hormones to know that these drugs were unhealthy for them.

Women taking these counterfeit (non bio-identical) hormones commonly complain of low energy, weight gain, depressed moods, an inability to think clearly, joint and muscle pain, poor sleep and loss of libido, just to list a few of the symptoms. Doctors have been prescribing drugs, most commonly antidepressants, to mask these symptoms which are caused by conventional HRT.

Due to the widespread dissemination of this information, and often misinformation, on HRT in the press and because of their concern about medical liability, many physicians have begun to recommend that women discontinue HRT or have begun to warn women of the potential risks that their use may cause. This has left a void in the treatment of the numerous health problems that women experience due to the hormonal imbalances and declines that occur in mid life.

What is the drug industry's answer to these studies? Wyeth is now promoting a new low dose Prempro. The drug companies are attempting to fill this void by advertising the use of drugs as an alternative to HRT. Is it really surprising that millions of women have lost faith in mainstream medicine with its multi-drug solution to their problems?

### **The Prevention of Breast Cancer**

The Johns Hopkins University School of Public Health published an article in the 1981 American Journal of Epidemiology demonstrating a 5 fold increase in breast cancer and a 10 fold increase in death from all other types of cancers in women with progesterone deficiency.

What is the unifying principle? Women with low levels of progesterone have a significant increase in breast cancer. Women who take non bio-identical progestins, which turns off the ovaries' production of naturally occurring progesterone, also have a significant increase in breast cancer. The unifying principle is that low levels of human progesterone increase the risk of breast cancer.

It has been clearly demonstrated that the incidence of breast cancer dramatically increases when woman have low levels of progesterone or when they take non bio-identical hormones. It has also been scientifically demonstrated that hypothyroidism, a low thyroid condition, is also

associated with a significant increase in all types of cancer. This is due to the state of low oxidative metabolism, an environment in which cancer thrives, which is caused by hypothyroidism. Counterfeit (non bio-identical) hormone replacement therapy leads to hypothyroidism.

There has been a tremendous push for the "Cure for Breast Cancer" and cancer in general. This slogan accepts the premise that the occurrence of cancer is a foregone conclusion. No woman wants to develop breast cancer, hoping for a cure. Women want and deserve safe, effective measures for the prevention of breast cancer and the other maladies that occur during mid life.

There is a huge, multi-billion dollar cancer industry in America. There is also a multi-billion dollar pharmaceutical and insurance industry in America, as well as a multi-billion dollar medical industry in America. None of these is promoting the prevention of cancer to any significant degree. Exercise, healthy eating and elimination of smoking are encouraged, but there is no money to be made by these industries in the prevention of disease. Healthy people do not need drugs for the relief of symptoms in midlife or for the treatment of cancer. Healthy individuals have minimal requirements for medical services.

The primary goal of medicine should be to prevent disease by enabling people to obtain and maintain health and wellness rather than the treatment of disease. The old adage remains true, "An ounce of prevention is worth a pound of cure." The lion's share of our efforts should be directed toward the prevention of cancer. American women have an extraordinarily high incidence of breast cancer when compared with women in other areas of the world. This is due in large part to the hormonal imbalances and declines that occur in mid life, as well as to the widespread use of the counterfeit (non bio-identical) hormone agents that have been promoted over the past 40 years. They cause progesterone deficiency in women. Birth control pills contain many of the same progestins, non bio-identical progesterone, which were found to be dangerous to women's health in the WHI. It is the progesterone deficiency caused by non bio-identical hormone agents that has increased the risk factor for breast cancer and other cancers among American women.

Faced with significant health problems in midlife and with an increased risk of breast cancer and cancers of all kind women feel hopeless and helpless. Women are looking for a solution that is safe, effective and natural.

## The Solution

The solution is **Biologically Identical Hormone Therapy (BIHT)**. First, the use of any counterfeit (non bio-identical) estrogens and counterfeit (non bio-identical) progestins should be immediately discontinued. Secondly, biologically identical progesterone as well as biologically identical estrogens should be given to women when indicated. These biologically identical hormones are indicated when the symptoms of hormonal decline first occur, most commonly around 35 years of age. Premenstrual symptoms such as breast tenderness, headaches, mood swings and depression, fluid retention, weight gain, as well as irregular and heavy periods, are common signs of progesterone deficiency. These should be treated with biologically identical progesterone premenstrually. A significant amount of data already exists in current medical literature, as well as the clinical experience of the physicians at the Hotze Health & Wellness Center in treating thousands of women, to promote further study of the use of **Biologically Identical Hormone Therapy (BIHT)** for treating women's health problems in mid life.

Biologically identical hormones are hormones that have the same molecular structure as the hormones produced by the human body. They are derived from plant sources and are chemically formulated in the lab to be identical in structure to the hormones that humans produce. Drug companies make chemical changes to these biologically identical hormones in order to create a hormone like drug that is patentable. Natural occurring substances, such as human hormones, cannot be patented. This is the reason that the pharmaceutical companies have no interest in investing in the research and development necessary to make these biologically identical hormones commercially available.

Biologically identical hormones are only available through compounding pharmacies which purchase these hormones in bulk from FDA approved pharmaceutical companies. The compounding pharmacies then fill prescriptions, tailored for the individual patient, based upon a physician's prescription.

The review of the literature on human progesterone, published by Bruno de Lignieres, M.D., in **Clinical Therapeutics** in 1999, indicated that biologically identical (human) progesterone has a host of benefits without any significant side effects. The Postmenopausal Estrogen/Progestin Interventions (PEPI) Study, in 1995, recommended biologically identical

progesterone, over the non bio-identical progestins, as the first line of therapy when treating menopausal women with intact uteruses. Of course this recommendation was not followed because the pharmaceutical companies could not patent biologically identical progesterone. Without the ability to patent progesterone and develop a proprietary label, the pharmaceutical companies could not profit from its production. Only by changing the molecular structure of progesterone, in order to create non bio-identical progestins, could the drug companies obtain a patent.

### **The FDA's Illegitimate Actions**

The FDA has recently decided to declare all compounding as manufacturing in order to justify their illegitimate claim of jurisdiction over compounding pharmacy. This action flies in the face of the fact that when pharmacies were exempted from FDA jurisdiction in the 1938 Food, Drug, and Cosmetic Act essentially all pharmacies practiced compounding. Since 1938, the FDA has left regulation of drug compounding to the States. Now the FDA is attempting to intimidate pharmacies and state boards of pharmacy by issuing compliance policy guidelines on compounding which have no force of law. This is a clear case of federal usurpation of states' rights as relates to pharmacy.

The means of distribution of the medications is the point that differentiates compounded pharmacies from drug manufactures. Neither the volume of medications produced nor the type of equipment used is a basis for differentiation between compounding pharmacies and pharmaceutical manufacturers.

### **Compounded Pharmacy Distribution**

Compounded medications are prepared in the pharmacy from bulk active ingredients and distributed based upon an individualized prescription for a patient written by a physician or veterinarian or for the discretionary use by these practitioners in a medical facility. This is known as the pharmacist – physician -patient triad and is what differentiates compounding pharmacy from pharmaceutical manufacturing. The dosage or route of administration of the medication usually varies from that of commercially available products. Compounded preparations may require the customized combining

of different medications as determined by the physician or veterinarian, working directly with a pharmacist.

Pharmacies are governed and licensed by their respective State Boards of Pharmacy and were exempted from the jurisdiction of the Food and Drug Administration (FDA) by the 1938 Food, Drug and Cosmetic Act.

### **Pharmaceutical Company Distribution**

Drugs manufactured by pharmaceutical companies are mass produced and distributed to wholesale distributors for resale. These drugs have limited dosage strengths and means of administration. They are not individualized for a specific patient. There is no direct personal interaction between the pharmaceutical manufacturer and the practitioner, pharmacist or patient.

Pharmaceutical manufacturers are governed and licensed by the FDA.

Pharmaceutical manufacturers are required to pay drug user fees for all new drugs approved by the FDA. This amounts to approximately 15% of the FDA's annual budget. In 2005, drug user fees from pharmaceutical companies are projected to be approximately \$ 270,000,000. The pharmaceutical companies are known to have filed complaints with FDA against compounding pharmacies.

There is a legitimate concern that the FDA is being used by pharmaceutical companies to deter the growth of compounding pharmacy.

In November of 2003, the U.S. Congress refused to approve the establishment of an FDA commission that would have investigated and proposed regulations for the practice of compounding pharmacy. Working through its agents in the US Congress, the FDA supported a Senate amendment, Section 626, to the 2003 Medicare Prescription Act. This amendment would have set up a commission, under the auspices of the FDA, to investigate and propose regulations for compounding pharmacies. This amendment was not included in the House version of this bill. In the Joint Conference Committee, which met to reconcile the 2003 Medicare Prescription Act, the House members of that committee refused to allow Section 626 to become part of the act.

## **Actions**

1. Congress must stop the FDA from illegitimately attempting to restrict compounding pharmacies from providing women in America with the benefits of natural, biologically identical hormone therapy.
2. It is imperative that a study be conducted to determine the safety and efficacy of Biologically Identical Hormone Therapy (BIHT). The Federal Government should underwrite this study. The results could spawn a Wellness Revolution in America that would free millions of women from the health problems that develop in mid life, as well as decrease women's risk for the development of breast cancer. In turn this could save billions of dollars in health care expenses.