



Women's Hormone Center of Northern Virginia, PC.

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Comments on “BIOIDENTICAL HORMONES” - March, 2009

Below is an article that was published in the Wall Street Journal on Mar 16th, 2009. Two of my patients have been kind enough to give me a copy of the article, to warn me of what's out there. My comments are dispersed throughout the article. This type of article is exactly why there is so much “confusion, ignorance and misinformation” about hormone replacement. Please judge for yourself who the “special interests” and “opportunists” are.

. The authors of this article are “Drs. Schwartz, Holtorf and Brownstein, founding members of the Bioidentical Hormone Initiative, a nonprofit group of physicians dedicated to patient and physician education (www.bioidenticalhormoneinitiative.org.)”

“Mainstream medicine has been given a wake-up call on a matter critical to the health of 65 million women in the U.S. At issue are the options for treatment of menopause symptoms that cause significant health problems for women in mid-life as their bodies produce fewer hormones. It doesn't seem like a complicated problem, given advances in medical science. Yet hormone-replacement therapy has become a textbook example of how special interests, a confused medical establishment, and opportunists can combine to complicate the issue and deny patients access to safe and effective treatments.

Until seven years ago, women going to conventional doctors were prescribed the FDA-approved synthetic hormone Premarin, (SINCE WHEN IS SOMETHING THAT IS EXTRACTED OUT OF THE URINE OF HORSES *SYNTHETIC*? I BELIEVE THAT THE TERM *SYNTHETIC* SUGGESTS THAT THE PRODUCT IN QUESTION IS “MAN-MADE”. CLEARLY HORSE URINE IS NOT MAN-MADE,) derived from the urine of pregnant horses; Provera, a synthetic progestin; or Prempro, a combination of the two. ACTUALLY AS OF 2002, THERE WERE DOZENS OF ESTROGEN AND PROGESTIN PRODUCTS AVAILABLE ON THE MARKET, PREMARIN HAD A LARGE MARKET SHARE, BUT CERTAINLY WAS NOT THE ONLY PRODUCT AVAILABLE. Premarin was the best selling drug in the U.S. in 2001, generating \$2 billion a year for Wyeth. ACTUALLY ACCORDING TO BLUE CROSS STATISTICS FOR THE US (BLUECROSSMN.COM) AND ALSO WORLD SALES STATISTICS ACCORDING TO IMSHEALTH.COM, LIPITOR WAS THE LEADER IN SALES IN 2001. IN FACT PREMARIN WAS NOT EVEN IN THE TOP 10 DRUGS SOLD IN THE US.

In 1994 a study led by the National Institutes of Health called the Women's Health Initiative (WHI) was started with the hope of establishing that Premarin and Provera would, beyond relieving menopause symptoms, protect aging women from heart attacks, strokes, osteoporosis and cancer. IDEALLY ANY STUDY IS DONE WITH THE PURPOSE TO FIND THE TRUTH, NOT TO ESTABLISH THAT A DRUG IS A WONDER DRUG, BUT TO FIND OUT IF IT IS. CLEARLY, BASED ON THE WAY THE WHI WAS DESIGNED, (GIVING THE DRUG AT THE WRONG TIME TO THE WRONG POPULATION, THEN REPORTING THE RESULTS IN A DISTORTED MANNER), THE WHI HAD ABSOLUTELY NO INTENTION OF SHOWING ANYTHING POSITIVE ABOUT PREMPRO OR PREMARIN. FURTHER, NOONE IN HIS RIGHT MIND WOULD EVER PROPOSE THAT ANY ESTROGEN PRODUCT COULD REDUCE STROKES. WE'VE KNOW THAT ESTROGEN IF ANYTHING HAS A SMALL ADVERSE EFFECT ON STROKE, CERTAINLY WOULD NOT PREVENT STROKES.

On July 9, 2002, however, the WHI came to an abrupt halt. The study proved unequivocally that the drugs were *unsafe* and significant factors in increasing the risk of heart attacks, strokes, and breast cancer in the more than 16,000 women studied. IN THE WORDS OF THE DECEASED DR. TRUDY BUSH, A WORLD RENOWNED HORMONE EPIDEMIOLOGIST, “NO ONE STUDY HAS A MONOPOLY ON THE TRUTH.” INDEED, THE WHOLE IDEA THAT ONE STUDY COULD *UNEQUIVOCALLY* PROVE ANYTHING IS NAIVE AT BEST AND ABSURD AT WORST. IN FACT, IF ONE ACTUALLY WERE TO *READ* THE ARTICLE FIRST PUBLISHED IN 2002 BY THE WHI, YOU WOULD

FIND THAT THE PREMPRO GROUP HAD A SLIGHTLY LOWER DEATH RATE THAN THE PLACEBO GROUP. HOW IS THAT CONSISTENT WITH THE CLAIM OF “UNEQUIVOCAL HARM”? IN FACT, A 2006 ARTICLE FROM THE WHI (JOANN MANSON ET AL) REPORTED THAT ON FURTHER ANALYSIS OF THEIR DATA THEY FOUND *SIGNIFICANT REDUCTION* IN HEART DISEASE AMONG THE WOMEN WHO WERE UNDER THE AGE OF 60 WHEN THE STUDY WAS STARTED. ANOTHER LATER WHI PUBLICATION (2006) ALSO SHOWED A STATISTICALLY SIGNIFICANT REDUCTION IN BREAST CANCER IN THE GROUP TAKING PREMARIN. SO CLEARLY THIS IS NOT “UNEQUIVOCABLE” HARM.

It's time for a fresh look at bioidenticals.

This led doctors to take millions of women off Premarin, Prempro and Provera overnight. Predictably, these women started to feel horrible in the aftermath of the drugs' sudden withdrawal, and their physicians told them there were no alternatives. Instead they prescribed antidepressants or birth control pills with shoddy results. I BELIEVE IT WAS TIME MAGAZINE THAT BACK IN 2002 INSTRUCTED WOMEN THAT THEY SHOULD TAKE A COMBINATION OF PROZAC, AMBIEN AND LIPITOR IN PLACE OF THEIR EVIL HORMONES. SO YES, INDEED, MANY WOMEN DID JUST THAT, SADLY. AS FOR SUBSTITUTING BIRTH CONTROL PILLS FOR HRT, THAT'S KIND OF RIDICULOUS, SINCE THE DOSE OF HORMONES IN AN AVERAGE BIRTH CONTROL PILL IS ABOUT 6 TIMES WHAT YOU GET IN PREMPRO. I CERTAINLY WOULD NOT DO THAT, AND I SERIOUSLY DOUBT THAT THIS WAS A WIDESPREAD PRACTICE. I WOULD LOVE TO SEE THE WRITERS' SOURCE OF DATA ON THIS CLAIM.

One year after this disaster, the American College of Obstetrics and Gynecology developed new guidelines that encouraged physicians to prescribe the same drugs in lower doses for shorter periods of time. Yet, and this is key, the safety of this “low dose option” was *never* proven scientifically. THIS IS THE WHOLE PROBLEM WITH THE BIOIDENTICAL CAMP. COMPOUNDED ESTRADIOL-BASED PRODUCTS ARE FINE, I HAVE A NUMBER OF PATIENTS WHO USE THEM, BUT THE BIGGEST PROBLEM WITH THEM IS THAT, BECAUSE EACH BATCH IS DIFFERENT AND EACH COMPOUNDER MIXES THINGS UP DIFFERENTLY, THERE IS NO DATA ON LONGTERM EFFICACY OR EVEN SAFETY ON COMPOUNDED PRODUCTS. SO THE POT SHOULD NOT CALL THE KETTLE BLACK. THEY CLEARLY HAVE ABSOLUTELY NO DATA TO PROVE SUPERIORITY EITHER, DESPITE THEIR PASSIONATE CLAIMS FOR SUCH BASED ONLY ON THEORY. FURTHER, TO SET THE RECORD STRAIGHT, IN CONTRAST TO THE ABOVE CLAIM, THERE ACTUALLY IS EFFICACY AND SAFETY DATA ON LOW DOSES OF PREMPRO. THE “HOPE STUDY” WAS DONE FOR THAT PURPOSE. NO DRUG IS EVER APPROVED BY THE FDA WITHOUT SUCH DATA.

Meanwhile, many conventional physicians have ignored the effectiveness of “bioidentical” or natural progesterone, which is formulated to be identical to the progesterone molecule that is produced by the human body. THE LANDMARK PEPI TRIAL PUBLISHED IN 1997 COMPARED PROMETRIUM TO PROVERA. “MAINSTREAM” DOCTORS HAVE BEEN USING PROMETRIUM FOR MANY YEARS; WE CERTAINLY HAVE NOT IGNORED IT. BEFORE PROMETRIUM WAS ON THE MARKET, MANY “MAINSTREAM” DOCTORS DID HAVE PROGESTERONE COMPOUNDED. I REMEMBER DOING SUCH BACK IN THE LATE 80'S. THE PROBLEM WITH NATURAL PROGESTERONE IS THAT IF IT IS USED ORALLY ONCE A DAY, YOU NEED TO USE A HUGE DOSE TO ACHIEVE ENDOMETRIAL PROTECTION. PROGESTERONE WORKS A LOT BETTER AS A CONTINUOUS 24-HOUR A DAY INFUSION, AS THE PRE-MENOPAUSAL OVARY PROVIDES, BUT THAT WOULD BE VERY IMPRACTICAL FOR HRT PURPOSES.

There are 25 years of scientific research with hundreds of studies in the U.S. and Europe that have demonstrated that bioidentical hormones, estradiol and micronized progesterone, are equally or more effective than synthetics---and safer. ACTUALLY, IF YOU READ THE PEPI TRIAL, MICRONIZED PROGESTERONE DID NOT PROTECT THE ENDOMETRIUM QUITE AS WELL AS PROVERA DID, THOUGH THEY WERE CALLED “EQUIVALENT” IN THE STUDY. I WILL CERTAINLY ADMIT THAT NATURAL PROGESTERONE DOES YEILD A MORE FAVORABLE CHOLESTEROL PROFILE THAN DO THE MAN-MADE PROGESTINS, BUT THE MAN MADE PROGESTINS WORK BETTER IF A SINGLE ORAL DAILY DOSE IS USED FOR THE PURPOSE OF PROTECTING THE ENDOMETRIUM. SIMILARLY, ESTRADIOL WILL YEILD THE SAME BENEFITS AS PREMARIN WILL, BUT IF USED ORALLY, TWICE A DAY DOSING IS PREFERABLE (IE, LESS CONVENIENT.) THEY ALL HAVE THEIR VALUE IN DIFFERENT SITUATIONS. THUS IT'S NICE TO HAVE A VARIETY OF PRODUCTS TO USE FOR DIFFERENT

PATIENTS. Yet mainstream medicine has buried its head in the sand and refused to take these studies seriously. AU CONTRAIRE, PROMETRIUM IS WIDELY USED. ALSO, ALL OF OUR ESTROGEN PATCH PRODUCTS, SEVERAL ORAL PRODUCTS, AND THE VAGINAL RING AND TABLET PRODUCTS ALL CONTAIN ESTRADIOL. I CAN'T UNDERSTAND WHY THE WRITERS WOULD MAKE SUCH A CLAIM.

While Europeans have long used bioidenticals, no commercially available bioidentical hormones existed in the U.S. until 1998, when a few pharmaceutical companies obtained FDA approval for an array of bioidentical estrogen preparations and one progesterone preparation. IN TRUTH, ESTRACE, AN ORAL ESTRADIOL PRODUCT, RECEIVED ITS APPROVAL FROM THE FDA ON JULY 28, 1975. THE FIRST ESTRADIOL PATCH WAS INTRODUCED ABOUT 10 YEARS LATER. Unfortunately, due to drug companies running the medical profession by controlling what goes into medical education, most doctors never get educated about bioidentical hormones or the way in which different hormones work. APPARENTLY THE WRITERS HAVE NEVER ATTENDED A MEETING OF THE NORTH AMERICAN MENOPAUSE SOCIETY OR READ ITS JOURNAL, MENOPAUSE. With Premarin, and Provera dominating the market, drug companies had no incentive to spread the word.

Today the distinction between bioidentical/natural progesterone and the synthetic progestin Provera remains widely misunderstood. (MAINLY DUE TO THE MISINFORMATION THAT ONE GETS FROM ARTICLES LIKE THIS ONE!) Progesterone is used by fertility specialists to protect pregnancy, while medroxyprogesterone (Provera) is used in the morning after pill and in birth control pills to prevent pregnancy. PROVERA HAS NEVER BEEN A COMPONENT OF EITHER THE MORNING AFTER PILL NOR OF ANY BIRTH CONTROL PILL. ALL ONE HAS TO DO TO FIND THIS OUT IS TO READ THE LABELS, OR THE PDR. Their actions are totally different and antithetical. THE DIFFERENT EFFECTS IN THESE CASES ARE DUE TO DIFFERENT DOSES, NOT DUE TO INHERENT DIFFERENCES BETWEEN THE PRODUCTS.

Sadly, seven years after the WHI study finding Premarin/Provera unsafe, the hormone-replacement debate can be summed up in three words: confusion, ignorance, misinformation. Meanwhile, millions of women have embraced bioidenticals, leaving their conventional physicians looking stubborn and foolish. I WOULD ARGUE THAT THOSE WHO MAKE FALSE STATEMENTS IN THE WALL STREET JOURNAL ARE THE FOOLISH ONES.

The medical establishment must stop kowtowing to drug companies and start serving women's best interests—and that involves widely prescribing bioidentical hormones. This will lead to healthier, happier women and, in the long run, help reduce America's skyrocketing healthcare costs." WOULD THE AUTHORS PLEASE OFFER SOME SOLID CLINICAL EVIDENCE TO SUPPORT THESE TWO FINAL CLAIMS? CERTAINLY THE WIDE PRESCRIPTION OF COMPOUNDED BIOIDENTICALS WILL LEAD TO HEALTHIER AND HAPPIER OWNERS OF COMPOUNDING PHARMACIES AND THEIR INVESTORS, BUT I DON'T KNOW OF ANY DATA SHOWING THAT IS ALSO TRUE OF WOMEN IN GENERAL. WE DO OF COURSE HAVE LONGTERM DATA SHOWING THAT PREPRO IMPROVES HEALTH AND WELLBING OF WOMEN. PERHAPS THE WRITERS SHOULD READ SOME OF IT.

PLEASE REALIZE THAT THE TERM "BIOIDENTICAL" IS NOT ACTUALLY A MEDICAL TERM, BUT IS ADJECTIVE THAT HAS BEEN USED BY VARIOUS INDIVIDUALS AND GROUPS TO REFER BOTH TO HORMONES THAT ARE ACTUALLY SYNTHESIZED IN A PHARMACEUTICAL PLANT TO EXACTLY MATCH THE CHEMICAL STRUCTURE OF THE HORMONES THAT ARE FOUND IN THE BLOOD OF PRE-MENOPAUSAL WOMEN (PRIMARILY ESTRADIOL AND PROGESTERONE); AND THE TERM IS ALSO USED TO SPECIFY THAT THESE HORMONES ARE TO BE HAND-MIXED BY A COMPOUNDING PHARMACIST TO A SPECIFIC RECIPE THAT IS ALLEGEDLY DIFFERENT FOR EACH INDIVIDUAL. IN FACT, IF ONE WERE TO SPEAK WITH THESE COMPOUNDING PHARMACISTS, YOU WILL FIND THAT THEY OFTEN USE FAIRLY STANDARD RECIPES FOR MANY DIFFERENT PEOPLE, MAKING THE ENTIRE "CUSTOM-MADE-FOR MY-PERSONAL-NEEDS" ASPECT SOMEWHAT SUSPECT. FURTHER, THE POWDERS THAT ARE USED TO COMPOUND THESE PRODUCTS ARE INDEED SYNTHESIZED IN PHARMACEUTICAL PLANTS, THE VERY PROPERTY THAT REMAIN (WHICH IS HARVESTED, NOT SYNTHESIZED) IS FALSELY ACCUSED OF HAVING. I PERSONALLY DON'T CARE WHETHER A PRODUCT IS SYNTHESIZED OR NOT, BUT I DO CARE THAT WE USE OUR WORDS CORRECTLY AND THAT A PRODUCT WORKS AND HAS A GOOD TRACK RECORD. ALL THESE HORMONES WORK IN CORRECT DOSES, BUT NONE IS BEST FOR ALL CASES.

AS FOR SALIVA TESTS TO "DETERMINE WHAT YOU NEED", I WOULD ASK THE PEOPLE WHO ORDER THESE TESTS IF THEY ALSO DETERMINE HOW MUCH WATER IT TAKES TO FILL UP THEIR BACK YARD SWIMMING POOL BY CAREFULLY MEASURING THE PUDDLE OF WATER THAT IS LYING ON THE BOTTOM OF THE POOL?

THAT IS WHAT THESE SALIVA TESTS ARE DOING, AND THAT JUST MAKES NO SENSE TO ME. I PREFER TO ASSESS ADEQUACY OF DOSE BY CLINICAL ASSESSMENT OF THE EFFECT OF A GIVEN DOSE; IE, "ARE THE HOT FLASHES GONE, IS SLEEP GOOD, IS SEX FUNCTION RESTORED?" ("IS THE POOL FULL")? MEASURING THE ESTROGEN IN THE SPIT OF A MENOPAUSAL WOMAN TELLS YOU NOTHING ABOUT WHAT DOSE WILL MAKE HER WELL. UNFORTUNATELY, I BELIEVE THESE TESTS ARE ALSO DESIGNED PRIMARILY TO GENERATE INCOME. PLEASE DON'T WASTE YOUR MONEY ON THESE TESTS. I HAVE YET TO FIND A PATIENT WHO COULD NOT TELL ME IF HER DOSE WAS ADEQUATE BY JUST ASKING HER HOW SHE'S DOING. WHY DO WE NEED TO MAKE THE PROCESS COMPLICATED AND EXPENSIVE? I DON'T GET IT.

HOPE THIS HAS BEEN HELPFUL TO CLEAR UP WHAT HAS BECOME A VERY COMPLICATED MATTER.
THANKS FOR YOUR TIME AND INTEREST. DONNA HURLOCK, MD MARCH 29, 2009