

Hormone Replacement Therapy and Bio-Identical Hormones

By Diane Petersen, M.D.

Hormone replacement therapy is a controversial and much-talked-about topic today in the field of gynecology. There is much confusion regarding the safety of various hormone preparations as well as debate over the effectiveness of hormone therapy to prevent serious diseases associated with aging. A generation ago the menopausal woman didn't get much attention from pharmaceutical companies and the popular press. Wow, what a difference the baby boom generation has had on this area of medicine.

Before delving into the controversies of Premarin/Provera, bio-identical or synthetic, etc., I would like to address some of what the popular press, pharmaceutical companies, and entrepreneurial pharmacies and physicians don't want to talk about. They don't want to reveal that half of the population will eventually become potential customers and they all want a piece of that pie. Think of it, if women can be convinced that life will be better with some sort of hormone therapy, the profit would be huge. I don't mean to be cynical, but it is important to realize that in large part the controversy stems from greed. The pharmaceutical companies are obviously in it for profit (or else their stockholders wouldn't be very happy). Then there are the compounding pharmacies that can place hormones into creams, ointments, lozenges and market them to you as "bio-identical" hormones. The hormones are manufactured from plants and the process for producing these hormones is not patent-protected, meaning these "generically" produced hormones can be purchased by the compounding pharmacies for use in their products. These smaller operations rely on building your trust and a personal relationship, a nice touch, but there aren't many controls in place to guarantee that you are getting exactly what you have paid for and your insurance company will likely not cover the cost of these products. The pharmaceutical companies are often using the same "bio-identical" hormones, but they have patented the delivery system (patches, gels, creams, vaginal inserts). It is important for the patient to realize that there isn't any difference in the safety profile of compounding pharmacy products and pharmaceutical company products if they are using the same hormones (most commonly estradiol). There are some hormones that may be beneficial to a patient that are not available from pharmaceutical companies; therefore the compounding pharmacies have filled the void with their products.

Another aspect to the "free market" mentality to hormone replacement therapy is the use of various laboratory evaluations to determine what replacement is perfect for the patient. There are saliva, urine and blood tests available and labs that will do some or all of these for a price. You can always find someone to facilitate having these tests performed if you are willing to pay the price. Physicians that have their own laboratories running these tests or send them to laboratories that give the physician part of the profit are in a precarious position. Some would consider this a conflict of interest. Laboratory results are only as accurate as the quality of the laboratory. Laboratory results are only useful when we have controlled studies that guide our interpretation of the results and we apply the results to the individual patient's set of symptoms and signs of menopause. Tests that are performed in my medical practice are sent to a standard laboratory. We bill a fee for

drawing and handling the blood only. The laboratory bills the insurance company or the patient.

The term “bio-identical” seems to be all over the news lately. To many of my colleagues, this is a dirty word. It implies quackery to many gynecologists because it has been used by those who would capitalize on the present controversy surrounding hormone replacement therapy. I have welcomed the use of this phrase because it emphasizes the need to strive for hormone replacement therapy that replicates the human ovarian function as closely as possible. I would compare this goal to the replacement of insulin and thyroid hormone in the body.

When I went through my residency training, there were standard levels of estrogen hormone that were given. Those doses were based primarily upon the minimum dose required to maintain optimal bone density. The most widely prescribed was Premarin, the first available estrogen hormone and produced from pregnant mares’ urine. Estrogen therapy by itself without progesterone therapy was found to cause endometrial cancer (the ovary makes estrogens, progesterone, and testosterone). In the early days of hormone replacement therapy natural progesterone initially couldn’t be formulated in a way that we could get into our bodies, therefore medroxyprogesterone “Provera” was the main progestin (synthetic progesterone). Premarin and Provera cornered the market for decades. Gradually scientific advances in the pharmaceutical industry brought us estrogens that were exactly like the ones that the ovary makes and micronized progesterone that could be absorbed into the body. Patients gradually began to demand that hormone replacement therapy be individualized to their needs, not based on what might be best “on average” or to necessarily avoid one long-term consequence of menopause. The explosion of different products all touting their advantages over their competition fueled on by these demands of the baby boom generation has made hormone replacement therapy big industry. Let the turf battle begin!

The sheer number of products and services available to navigate menopause is staggering. The news and quasi-news media has taken notice. Just recently I was linked to “Bio-identical Hormones” by way of a news dimension report that linked to a compounding pharmacy’s site that listed me as an “expert” in bio-identical hormones (without my permission, might I add). The flood of phone calls has been amazing and prompted me to write this brief explanation on this topic. I cannot possibly see all the patients that want to come in and talk about hormones. Also, I am no more of an expert than any of my partners at Women’s Health Consultants. I believe that I achieved this “distinction” because I am willing to work with a patient and if they decide to use a compounding pharmacy I will then work with the pharmacy to give that patient the best care that is possible.

Much of the controversy in HRT arises from the medical industries honest effort to find the truth. Medical research is an essential and quite difficult part of our industry. It is not like having a diagnostic study on your car, the human body has many mysteries that we have yet to solve. Studies come out month after month with new and often conflicting conclusions about the safety or risks of these various products. Reports on Premarin and

Provera, synthetic products, should not be extrapolated to describe the risks of products that contain estradiol and micronized natural progesterone. But when will the report come out that looks at exactly how and when you as an individual are taking hormone therapy? Unfortunately, that will probably be a long time from now. Large randomized, well-designed studies are very expensive and difficult to conduct. In the mean time, how do you decide if hormone replacement therapy is right for you? Finding an expert to help you with this decision might be a good idea. Realistically, some physicians do not want the potential liability of advising patients regarding hormone therapy because of the safety controversy particularly after the Women's Health Initiative (WHI) study. Other physicians may simply have decided that they do not want to keep up with the ever-growing amount of information in this field of medicine. Many patients are capable and motivated to do some of their own research. I would recommend using the National Library of Medicine at www.nlm.nih.gov if you are interested in doing your own research into the literature. There are many books that have been written for the public on this subject. While I have read many of them, I simply cannot keep up with them all. In this forum I will not endorse any specific book(s) because I have not found one that I can recommend to all patients.

I hope that you have found this to be a useful introduction to hormone replacement therapy. If you were directed to this page because you called our office to make an appointment as a new patient, please consider discussing your needs with your primary physician again. If you can start the discussion with more than "Bio-identical hormones" as the introduction, you may be pleasantly surprised how very well informed and helpful your physician can be on this subject. Good luck.