

Testimony by Carol Petersen

Thank you for the opportunity to address you on the subject of bio-identical hormones. I am the Managing Pharmacist for Women’s International Pharmacy in Madison, Wisconsin. Women’s International Pharmacy is a practice that is devoted to compounding with bio-identical or natural hormones. Compounding involves weighing hormone powders and incorporating them into creams, gels, lozenges or capsules. A new chemical substance is not created. We dispense our compounded products and those manufactured products that qualify as bio-identical. This business was started in 1985. Our business has grown in response to the success in using bio-identical hormone therapies.

I would like to speak from my viewpoint as a pharmacist. I have been working as a pharmacist since 1972. I have been personally involved with compounded bio-identical hormones since 1993. This work has been the most rewarding of my career.

Bio-identical or biologically-identical or natural hormones refer to the fact that these hormones are exact duplicates of the hormones produced in the body. They have not been altered to something similar but not identical and patent protection is not available on bio-identical compounds.

These hormones are produced synthetically or semi-synthetically. In the case of sex hormones or adrenal hormones, a compound from plants similar to cholesterol in the human body is used as a starting material. Alteration of this starting material can yield hormones that are identical to human or those that are foreign to the human body such as those in birth control pills.

Because our health care system rewards manufacturers for producing non-hormone hormones much of the data available via medical journals are from studies done using altered hormones and has nothing to do with the normal functioning of the human body. A lot of money, time and energy are spent in this country trying to establish that altered hormone-like substances can function as well as the actual hormone does in the body. It would make a lot more sense to develop the means to restore the actual hormones and, indeed, some manufacturers have done this. The estrogen patch is an example. Estradiol, a hormone natural to the human body, is delivered by a patch that retards the absorption. The patch technology is patented.

Early in my career, I started graduate school in pharmacy with an intent to study pharmaceuticals. This involves studying how a drug distributes itself in the human body. Later, I had an epiphany of sorts, when buying an updated book on the subject. Even though, you can make predictions about where a drug is in the body, it has absolutely no meaning in the context of the normal functioning of a human body.

We gain an understanding of the function of hormones from the vast work in the fields of physiology, biochemistry, endocrinology and even medicine. The amount of information generated has risen exponentially in the last two decades. Having gained that knowledge, it is only a small step to consider clinical application.

It doesn't take much medical background to understand that, if you replenish the human body with a hormone that is identical to what the body can produce itself, you can expect that the activity of the hormone can be predicted to behave exactly in the human body as if it were produced there. That is exactly what does happen.

Some have argued that there is not enough scientific study done on the clinical use of bio-identical hormones. The use of bio-identical hormones is THE most scientific therapy, you can contemplate. It is possible to identify hormone depletion by clinical symptoms and by laboratory testing in blood, saliva and urine. It is also possible to replenish a particular hormone and find that the symptoms disappear and the laboratory readings return to normal.

Years ago, a researcher at the University of Washington published some papers on the validity of N-1 studies. This means that the number of people being studied each time is only one. He maintained that the current "gold standard" of double blind cross-over studies is flawed. Trying to gather data on groups of people, who are all bio-chemically different, and extrapolating that data to predict the success or failure of a certain treatment will not necessarily apply to the individual. In reality, N-1 studies are what actually happen in clinical practice. The medical practitioner develops a treatment plan for his or her patient. If the plan does not yield the hoped for results, a different plan will be developed and started.

The process of compounding is ideally suited for the N-1 study paradigm. It is simple to address replenishing the body with hormones that have become deficient. The kind of hormones, the amount of hormone, the best way to deliver the hormones, can all be tailored to the individual.

I would like to give you a specific scenario. It is no secret that hysterectomy surgeries are one of the most performed surgeries in this country. Women submit to these surgeries in an effort to find relief from such things as pain from fibroids, endometriosis or from excessive uterine bleeding. Unless, the surgery is for cancer, all of these are unnecessary. All of these involve aberrations in the normal levels of hormones. These medical problems have solutions with identifying the metabolic problems and treating with the appropriate hormones and other support substances.

According to the HERS Foundation, about 76% of these women also have their ovaries removed. This means that the organ that has normally produced estrogens, progesterone, testosterone, some DHEA is now gone. Current medical dogma insists that these women only "need" estrogen.

The number of medical problems that ensue are limitless. Because the estrogen is not "balanced" with progesterone. These women experience anxiety, sleep disorders and weight gain. Because of this imbalance, high blood pressure develops. The thyroid gland activity is compromised leading to fatigue and pain. Blood sugar disorders lead to diabetes. Diminished testosterone leads to lack of interest in sex and a diminished zest for life as well. The function of proteins in our body is the function of life itself. Testosterone directs the synthesis of all the protein in our bodies.

In our so called "traditional" medical treatment, this woman has now become a customer for 5 to 10 drugs in an effort to treat her symptoms and the side-effects. Her quality of life is terrible. Her family and friends are alienated.

It is enormously satisfying and a thrill to help these women restore their lost hormones. When a client calls to say “You have given me back my life” or “You have given me back my mind” or the client’s husband calls to say “Thank you for giving me my wife back”, because the information and the help you directed to her has been effective. When your work is as rewarding as that, there is no question that you will do the best you can to make sure that this option is available.

In recent years, we have experienced a threat from a government agency – the FDA. The FDA would compromise the ability of pharmacists to try to meet the challenges of the needs of the individual. Pharmacists have always done this work, long before the FDA was even conceived. We maintain that the Food and Drug Act was never meant to interfere with pharmacists and physicians providing this service.

It is important to note again that compounding does not involve a chemical process that produces a new substance. There is no change to the integrity of the substance that is used. These processes include mixing, blending, heating, dissolving, measuring, weighing and encapsulating. This does not produce new chemicals. The FDA has issued several CPG’s on the issue of compounding. They are anxious to define compounding by the number of products compounded or by the sophistication of the equipment used. They speak of some mysterious line that is crossed when suddenly compounding hormones becomes manufacturing. It is confusing to the pharmacy industry and to regulators since no one knows when this “number” has become too large. I would submit that the distinction between compounding and manufacturing is easy and clear. The FDA has a clear responsibility for ensuring that man-made new chemicals that are introduced into medical practice should be thoroughly screened for potential human damage. Remember compounding produces no new chemicals. Additionally, when a practitioner seeks a compounded product for his or her patient that is specific to that patient and writes a prescription order this is a practice that no manufacturer can or is willing to do.

Finally, there are words that we use in the pharmacy industry such as “risk benefit ratios” and “drug misadventures” to address the failure of drug therapies. Using compounded bio-identical hormones makes the portrayal of these concepts unneeded.