Pellets
Hormone Implants

1. Hello, I'm Dr. Rebecca Glaser. This presentation on 'Pellets' will discuss a 'method of delivery' of hormones that is not well known, or rather, not well 'remembered' in the United States. Hopefully, by the end of the presentation you will realize that hormone replacement with pellets is the "Ultimate Hormone Therapy".

2. Hormone pellets are the best, most natural way to deliver hormones in both men and women. Implants, placed under the skin, consistently release small, physiologic doses of bio-identical hormones providing optimal therapy.

3. What are Pellets? Pellets are made up of either estradiol or testosterone. The hormones, estradiol or testosterone, are pressed or fused into very small solid cylinders. These pellets are larger than a grain of rice and smaller than a 'Tic Tac'. In the United States, pellets are made by a compounding pharmacist and delivered in sterile glass vials.

4. Why pellets? Pellets deliver consistent, healthy levels of hormones for 4-6 months. They avoid the fluctuations, or ups and downs, of hormone levels seen with every other method of delivery. It is the **fluctuation** in hormones that causes many of the unwanted side effects and symptoms a patient experiences. Estrogen delivered by subcutaneous pellets, maintains the normal ratio of estradiol to estrone. This is important for optimal health and disease prevention. Pellets do not increase the risk of blood clots like conventional or synthetic hormone replacement therapy.

5. In studies, when compared to conventional hormone replacement therapy, pellets have been shown to be superior for relief of menopausal symptoms, maintenance of bone density, restoration of sleep patterns, improvement in sex drive, libido, sexual response and performance. Even patients who have failed other types of hormone therapy have a very high success rate with pellets. In addition, there is no other method of hormone delivery that is as convenient for the patient as pellets.

6. Pellets have been used in both men and women since the late 1930's. In fact, there is more data to support the use of pellets than any other method of delivery of hormones.

7. How and where do you insert pellets? The insertion of pellets is a simple, relatively painless procedure done under local anesthesia. The pellets are usually inserted in the lower abdominal wall or hip through a small incision which is taped closed. Experience of the health care professional counts, not only in placing the pellets, but in determining the correct dosage of hormones to be used.

8. Complications from the insertion of pellets include minor bleeding, bruising, discoloration of the skin, infection, and possible extrusion of the pellet. Other than slight bruising, or discoloration of the skin these complications are very rare. Vigorous physical activity is avoided for 48 hours in women and up to 5 to 7 days in men. Antibiotics may be given if a patient is diabetic or has had a joint replaced.

9. You may wonder why you haven't heard of pellets. Pellets are not patented and not marketed in the United States. They *are* frequently used in Europe and Australia where pharmaceutical companies produce pellets. Most of the research on pellets is out of England and Australia with some from Germany and the Netherlands. Pellets were frequently used in the United States from about 1940 through the late 70's, early 80's when patented estrogens were marketed to the public. In fact, some of the most exciting data on hormone implants in breast cancer patients is out of the United States. Even in United Stated there are clinics that specialize in the use of pellets for hormone therapy.

10. If your health care practitioner says that there is no data to support the use of pellets, he or she is wrong. There is a big difference between 'no data' and not having read the data.

11. Likewise, many patients have been told by their physicians, that there is 'no data to support bio-identical hormone therapy'. It is much easier for busy practitioners to say this and dismiss the patient, than it is to question their beliefs and do the research.

12. Remember, it's your body, it's your choice. It is about how you want to feel.

13. After pellets are inserted, patients may notice that they have more energy, sleep better and feel happier. Muscle mass and bone density will increase while fatty tissue decreases. Patients may notice increased strength, co-ordination and physical performance. They may see an improvement in skin tone and hair texture. Concentration and memory may improve as will overall physical and sexual health.

14. Pellets do not have the same risk of breast cancer as high doses of oral estrogens, like Premarin, that do not maintain the correct estrogen ratio or hormone metabolites. Nor, do they increase the risk of breast cancer like the synthetic, chemical progestins used in the Women's Health Initiative Trial. In fact, data supports that balanced hormones are breast protective.

15. When a patient first starts hormone therapy there may be mild, temporary breast tenderness which gets better on its own. Hormone receptors may be very sensitive and take time to adjust. There may be a temporary water weight gain which will also resolve on its own. The body will tone up, as bone density and muscle mass increase and fatty tissue decreases.

16. Some patients begin to 'feel better' within 24-48 hours while others may take a week or two to notice a difference.

17. The pellets usually last between 4 and 5 months in women and 5-6 months in men.

18. The pellets do not need to be removed. They completely dissolve on their own.

19. Pellets are an excellent way to deliver testosterone in men, providing consistent levels of testosterone while maintaining normal estrogen levels.

20. Any time estradiol is prescribed, progesterone is also prescribed. There are progesterone (not progestin) receptors in the bone, brain, heart, breast and uterus. Progesterone can be used as a topical cream, a vaginal cream, oral capsule, or sublingual drops or capsules. If a patient is pre-menopausal she uses the progesterone the last two weeks of the menstrual cycle.

21. Hormone therapy with pellets is not just used for menopause. Women at any age may experience hormone imbalance. Levels decline or fluctuate contributing to debilitating symptoms. Pellets are useful in severe PMS, post partum depression, menstrual or migraine headaches, and sleeping disorders. Pellets may also be used to treat hormone deficiencies caused by the birth control pill.

22. Hormone levels will be drawn and evaluated before therapy is started. This will include a FSH, estradiol, testosterone and free testosterone for women. Men need a PSA, estradiol, free estradiol, testosterone and possibly estrone prior to starting therapy. Levels will be reevaluated during hormone therapy at 4-6 weeks and again in 4-5 months. After the first years of therapy hormones levels are followed less frequently. The PSA in men is followed every 6-12 months.

23. Testosterone levels begin to decline in men beginning in their 30's. Most men maintain adequate levels of testosterone into their mid 40's to mid 50's, some into their late 70's early 80's. Men should be tested when they begin to show signs of testosterone deficiency. Even men in their 30's can be testosterone deficient and show signs of bone loss. Most men need to be tested around 50 years of age. It is never too late to benefit from hormone therapy.

24. The cost for the insertion of pellets is between $230 and $600 depending on the dose of the hormone and the number of pellets needed. Men need a much larger dose of testosterone than women and the cost is higher. Pellets need to be inserted 2 to 3 times a year depending on how rapidly a patient metabolizes hormones.

25. When compared to the cost of drugs to treat the individual symptoms of hormone decline, pellets are very cost effective. There is more data on pellets and bone density than any chemical drug on the market. This slide only addresses the cost of medications used for bone density. It is beyond the scope of this presentation to examine the cost of drugs used for insomnia, depression, sexual dysfunction, obesity, diabetes, hypertension and more.

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- Daily ibandronate was compared with placebo in 2,929 postmenopausal women with a prior vertebral fracture. (3) Treatment decreased the absolute risk of new, symptomatic, radiographically confirmed vertebral fracture from 5.3 to 2.8 percent over three years (absolute risk reduction 2.3 percent; number needed to treat = 43 for three years). (3) There was no difference in the likelihood of clinical nonvertebral fracture between placebo and ibandronate. The 2.5-mg daily and 150-mg monthly dosages of ibandronate were equivalent in terms of percent change in lumbar spine bone mineral density from baseline to one year. The effects of ibandronate on rates of hip fracture, death, and symptomatic vertebral fracture have not been assessed. (4) Data on the fracture prevention of ibandronate in patients with osteoporosis but without previous fracture are lacking. (5) No bisphosphonate has been compared with adequate doses of calcium and vitamin D. (5)

26. Some insurance companies cover the cost of pellets, others do not. Most physicians require payment for their services. Patients may want to contact their insurance companies to see if their costs will be reimbursed. Preventions is must more cost effective than disease.

27. In conclusion, estrogen and testosterone therapy by implantation of pellets is a safe and effective method of hormone therapy for both men and women. Long, continuous administration of hormones by pellets is convenient and economical for the patient. Pellet implantation has consistently proven more effective than oral, intramuscular, and topical hormone therapy with regard to bone density, sexual function, mood and cognitive function, urinary and vaginal complaints, breast health, lipid profiles, hormone ratios and metabolites)