Prairieland
Wellness Center

To Whom It May Concern:

Hormone replacement therapy by pellet implantation has been used with great success in the United States, Europe and Australia since 1938 and found to be superior to other methods of hormone delivery (Greenblatt 49, Mishnell 41, Stanczyk 88). It is not experimental. Pellets deliver consistent, physiologic levels of hormones and **avoid the fluctuations** of hormone levels seen with other methods of delivery (Greenblatt 49, Thom 81, Stanczyk 88).

Hormones delivered by the subcutaneous implants bypass the liver, do not affect clotting factors and do not increase the risk of thrombosis (Notelovitz 87, Seed 00). Bioidentical testosterone delivered subcutaneously by pellets is cardiac protective, unlike oral, synthetic testosterone (Sands 97, Worboys 00). Estradiol and testosterone delivered by pellet implantation, does not adversely affect blood pressure, lipid levels, glucose or liver functions (Burger 84, Barlow 86, Notelovitz 84, Stanczyk 88, Davis 95, 00, Sands 97, Seed 00, Cravioto 01).

Pellets are superior to oral and topical hormone therapy with respect to the relief of multiple hormonal symptoms (Staland 78, Cardoza 84). Estradiol and testosterone implants have **consistently** been shown to improve insomnia, sex drive, libido, hot flashes, palpitations, headaches, irritability, depression, aches, pains, and vaginal dryness (Staland 78, Thom 81, Brincat 84, Davis 95, 00, Cravioto 01).

Testosterone replacement therapy in men with subcutaneous implants (pellets) has been show to be extremely effective, convenient and safe (Handelsman 90, 92, 97, Kelleher 01, 04, Conway 88, Jockenhoval 96, Zacharin 03, Schubert 03, Dunning 04). Hormone replacement therapy with pellet implantation has an extremely **low** incidence of side effects (Cardoza 84, Barlow 86, Ganger 89, Pirwany 02) and high compliance rate (Gambrell 06).

Testosterone implants in women have been shown to improve lethargy, depression, loss of libido, hot flashes without attenuating the beneficial affects of estradiol on cardiac and lipid profiles (Sands 97, Seed 00). Testosterone delivered by subcutaneous implants does not increase the risk of breast cancer (Dimitrakakis 04, Tutera 06, Natrajan 02) as does oral, synthetic methyl-testosterone (Tamimi 06) or Prempro. In fact, studies show a **reduction** in the incidence of breast cancer with the implantation of testosterone pellets, with or without estradiol pellets (Dimitrakakis 04, Tutera 06). Hormone replacement therapy with a 20 mg estradiol pellet has been shown to have a lower risk of breast cancer than patients without hormone replacement therapy (Davelaar 91). Even after over 20 years of therapy with hormone implants, the risk of breast cancer is not increased (Gambrel 06). In breast cancer survivors, hormone replacement therapy with pellet implantation does **not** increase the risk of cancer recurrence or death (Natrajan 02) as does estrogens in combination with the synthetic progestins (Habits Trial 04).

FDA approval is required for 'drugs being marketed to the public'. Testopel® *is* an FDA approved pellet. However, it is only available in a 75 mg dose, which is often not optimal. Other dosages of pellets available in the United States are compounded and not 'marketed to the public', therefore do not require FDA approval. The testosterone used in the hormone implants is USP (United States Pharmacopeia) certified.

I hope this allays any concerns you have about what I feel is medically the best treatment for my patient. Prevention and treatment of disease with pellet implantation is the best and most cost effective therapy I am able to offer to my patients. I have been using hormone implants for over three years in clinical practice and treated many patients with pellets implants. The data clearly supports their clinical efficacy and safety.

Sincerely,

Bruce F. Weber, M.D.

Predetermination Request Information

Provider Data

Name of Provider: Bruce F. Weber, M.D.

Provider Type: Family Medicine

NPI Number: 1609870591

Tax ID: 27-0177833

Contact Name: Jennifer Swan

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Service Locations: 715 W. Broadway, Gillespie, IL 62033

Service Type: Outpatient (Non-Hospital)

NDC: Testosterone: 38779-2598-09

Documentation for Predetermination

- ☐ Letter of Medical Necessity (attached)
- ☐ CPT Procedure Codes: 11980, S0189, A4550
- ☐ ICD10 Diagnosis Codes:

  MALE: E29.1, R68.82, R53.83, R50.8

  FEMALE: N95.1, R68.82, R53.83, E34.9
- ☐ Labwork Results (upon request)
- ☐ Intake Forms/Symptoms Checklist (upon request)