The Clinical Need For Compounded Bio-identical Hormone Therapy

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Angela DeRosa, DO, MBA, CPE

- **Board Certified Internist**
  - Women's Health Specialist
- **Senior Medical Director**
  - Procter &Gamble Pharmaceuticals
    - Women's Health Lines
      - Osteoporosis
      - Female Sexual Health
- **MBA Amhurst Business College**
- **Founder and President of DeRosa Medical & DRM Integrative Health**
  - Treated over 20K patient using advanced BHRT and optimization
- **Clinical Assistant Professor**
  - Midwestern University, Arizona College of Osteopathic Medicine
- **Immediate Past President, Arizona Osteopathic Medical Association**
- **Founder and President of Hormonal Health Institute**
- **Medical Director**
  - Belmar Pharmacy & Belmar Select Outsourcing
- **20+ years in advanced BHRT therapy and hormone optimization**
- **Author, Lecturer and Published Researcher**

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- **Premature Ovarian Failure**
  - AGE of 35
- **Medical professional failed me**
- **Personal and Professional Journey**
- **Dedicated my career to understanding hormones and the effect they have on chronic illness and overall health and well being**
- **Guinea Pig of Research**

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Why is there a need for compounded products?

- **Personalization, customization and optimization that results in patient centered medical care**
  - Hormones by nature are idiosyncratic and providers need unique and customizable options
- **Current FDA products do not meet all the clinical needs of our patients**
  - E.g., Testosterone products for women
- **Patient specific needs:**
  - Allergies
  - Dosing options
  - Dose form changes
  - Prescriptive outages

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503A and 503B Pharmacies

- **Both provide clinicians the ability to provide customized products for patients via unique pathways and under different circumstances**
  - Office administration in time sensitive situations
  - Non-office (traditional) pharmacy

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503A vs. 503B Pharmacies

503A

- Patient specific customized compounded medications
- Not time sensitive
- Provided directly to patient

503B

- In office "Just in Time" clinical administration required
  - Pellets
- Patient procedure training
  - E.g., injections
    - ED meds

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A Provider-Patient Choice

When to use 503A versus 503B products:

Clinical Case Scenarios

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Patient Case JW

Patient is a 55 year old female with a past medical history of seasonal allergies, osteopenia and GERD. Patient reports having gone through “the menopause” at the age of 50. No medication allergies reported, however has a peanut allergy.

She struggles with hot flashes, night sweats, insomnia, moodiness, low libido, weight gain and fatigue. The patient has her uterus.

The patient tried an estrogen/progestin patch but claims that it made her breasts tender and gain weight. She felt that it only controlled her hot flashes and night sweats the first day she applied the patch, but not the other days in between the new patch application. The patch didn’t improve the majority of her symptoms.

She is seeking a second opinion at this time for management of her hormones.

Physical exam is unremarkable except low body temperature, thinning hair, & obese stature.

Patients labs confirm a diagnosis of estrogen and testosterone deficiency as well as a diagnosis of Autoimmune hypothyroidism. (Hashimoto’s)

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JW's Treatment Plan

- **Patient requires a hormonal treatment plan that includes:**
  - Estradiol
  - Testosterone
  - Progesterone (Patient has her uterus)
  - Thyroid
- **Consideration of her osteopenia diagnosis**
  - Indirect BHRT benefits
  - Vitamin D/Calcium

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Care Plan Discussion

- **Importance of therapy**
- **Product options available**
  - FDA approved
  - Compounds
- **Bio-identical versus synthetic**
  - Commercial
  - Compounded
- **Safety and tolerability of different products**
- **Efficacy of different modes of delivery**
- **Other**
  - Compliance concerns
  - Ease of use
  - Patient preference

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BHRT Treatment Choices For Women

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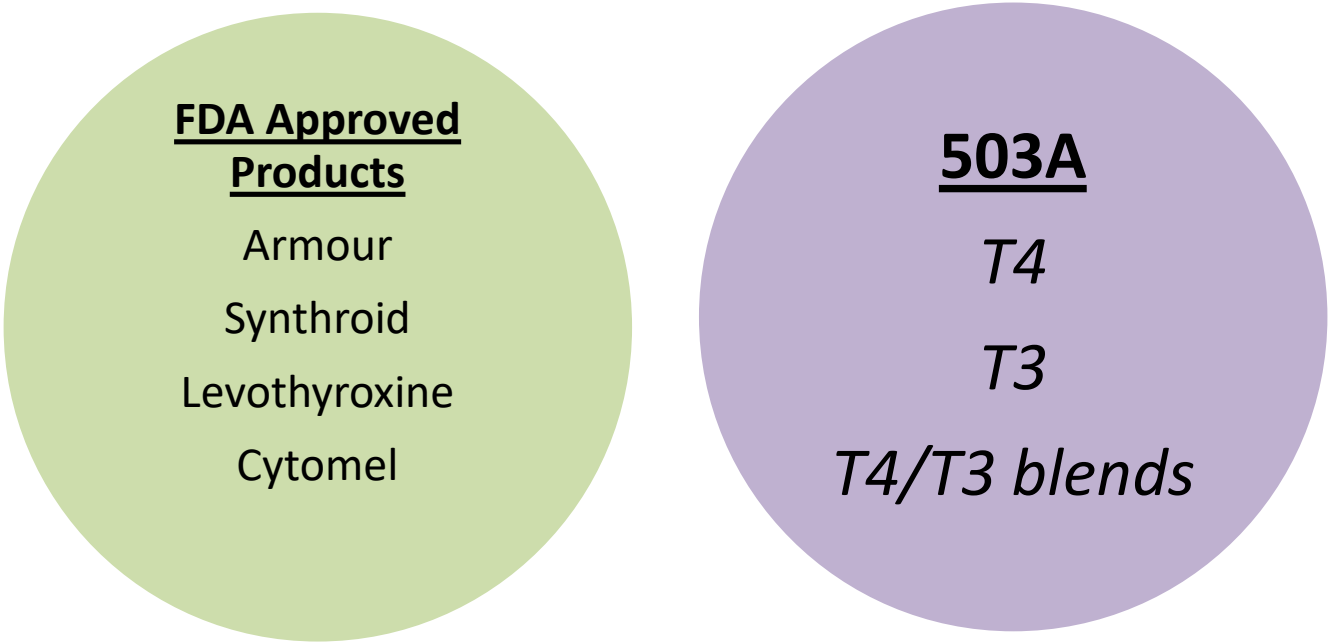
Thyroid Treatment Choices For Women



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Doctor-Patient Decision

- **Compounded oral Progesterone**
- **Pellet Therapy**
  - Estradiol
  - Testosterone
- ***Synthroid and Cytomel***
- Repeat DXA in 1-2 year

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Patient Case AH

Patient is a 62 year old male with a past medical history of HTN and erectile dysfunction; otherwise healthy. No medication allergies reported.

He struggles with fatigue, difficulty with muscle endurance and recovery from working out, irritability, low libido and inability to maintain an erection. He has tried Viagra with minimal improvement.

The patient is seeking a hormonal evaluation.

Physical exam including GU exam is unremarkable.

Patients labs confirm a severe testosterone deficiency.

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AH's Treatment Plan

- **Patient requires a hormonal treatment plan that includes:**
  - Testosterone
  - Erectile dysfunction medication?

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Care Plan Discussion

- **Importance of therapy**
- **Product options available**
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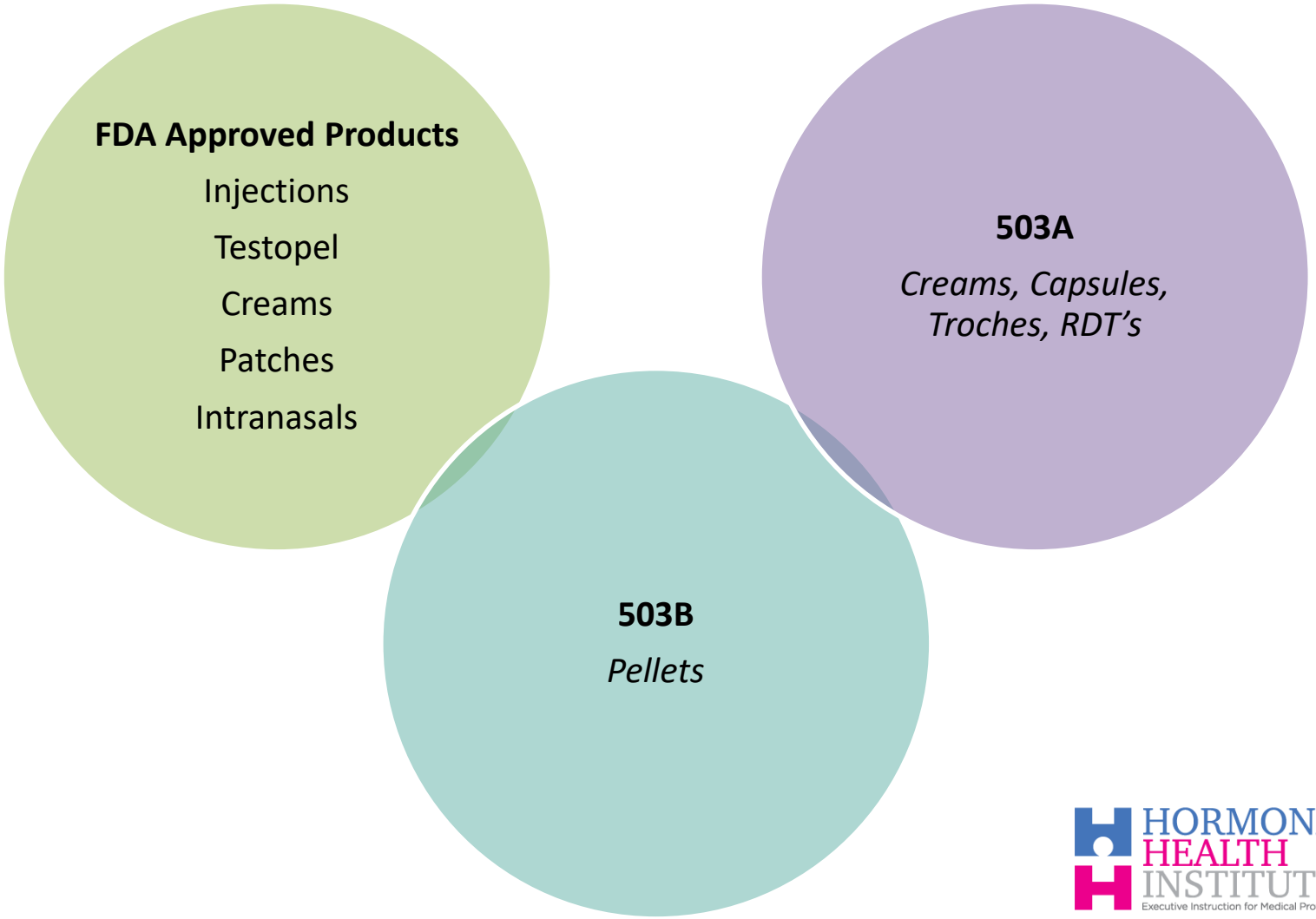
BHRT Treatment Choices For Men



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Doctor-Patient Decision

- **Testosterone pellets**
  - Testopel?
  - Compounded pellets
- ***Review need for other PDE5 inhibitors as well as penile injectables after assessing clinical response to Testosterone pellets***

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Conclusions

- Clinicians need a full “toolbox” to treat our patients.
- There are good FDA approved therapies to treat certain conditions in specific patients but there are significant gaps in the “tools” required to provide the best clinical outcomes.
- Having both FDA approved and compounded products allows clinicians to treat the unique needs of patients in a safe, customized, patient centered manner.

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Contact Information

Thank you so much for your time and efforts. I look forward to providing any further assistance in your pursuit of understanding the clinical need of compounded BHRT. Please do not hesitate to contact me

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