

# Current Topics in Hormone Replacement Therapy

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# Outline

- Why is this Important?
- Review Hormone Replacement Nomenclature
- Evaluate Current Indications for Therapies
- Discuss Proper Prescribing for Hormone Replacement Therapy

# Conflict of Interest Disclosures

- Speaker's Bureau: AMAG Pharmaceuticals, Valeant Pharmaceuticals

# What is Hormone Replacement Therapy?

- Hormone Replacement Therapy (HRT) is?
- A.) A means of restoring deficient hormone levels to physiologic values
- B.) A way to greatly improve patient's quality of life
- C.) A way to cause significant morbidity and/or mortality if not performed correct
- D.) All of the above

# Why is this Important?

- Public Confusion about HRT
  - Types, safety, etc
- Who could benefit from HRT?
  - Men, women, transgendered?
- Who should be prescribing HRT?
  - Physicians?
  - Chiropractors?
  - Dentists?
  - APRNs?
- Training in HRT?



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# Global Effects



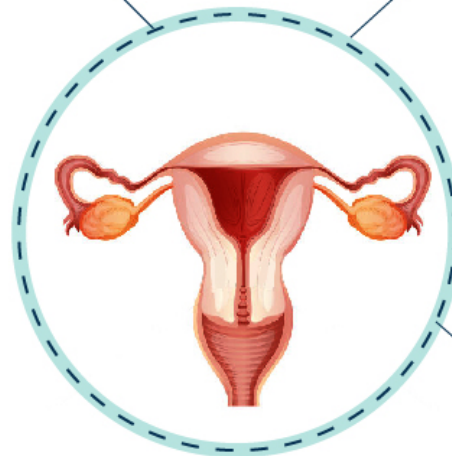
## The Global Hormone Replacement Therapy Market (MCP-6453) Trends, Drivers & Projections

May 2016



### Research Insights & Findings

- Lack of Proven, Effective Alternatives
- Rise in the Number of Women in Menopause
- Growing Demand for Transdermal HRT Products
- Increasing Sales of Approved Bioidentical Therapies
- Regulatory Controls Over Unapproved Bioidentical Drugs



### Sizing the Global Market

Global Market to Reach US\$3.5 Billion by 2022

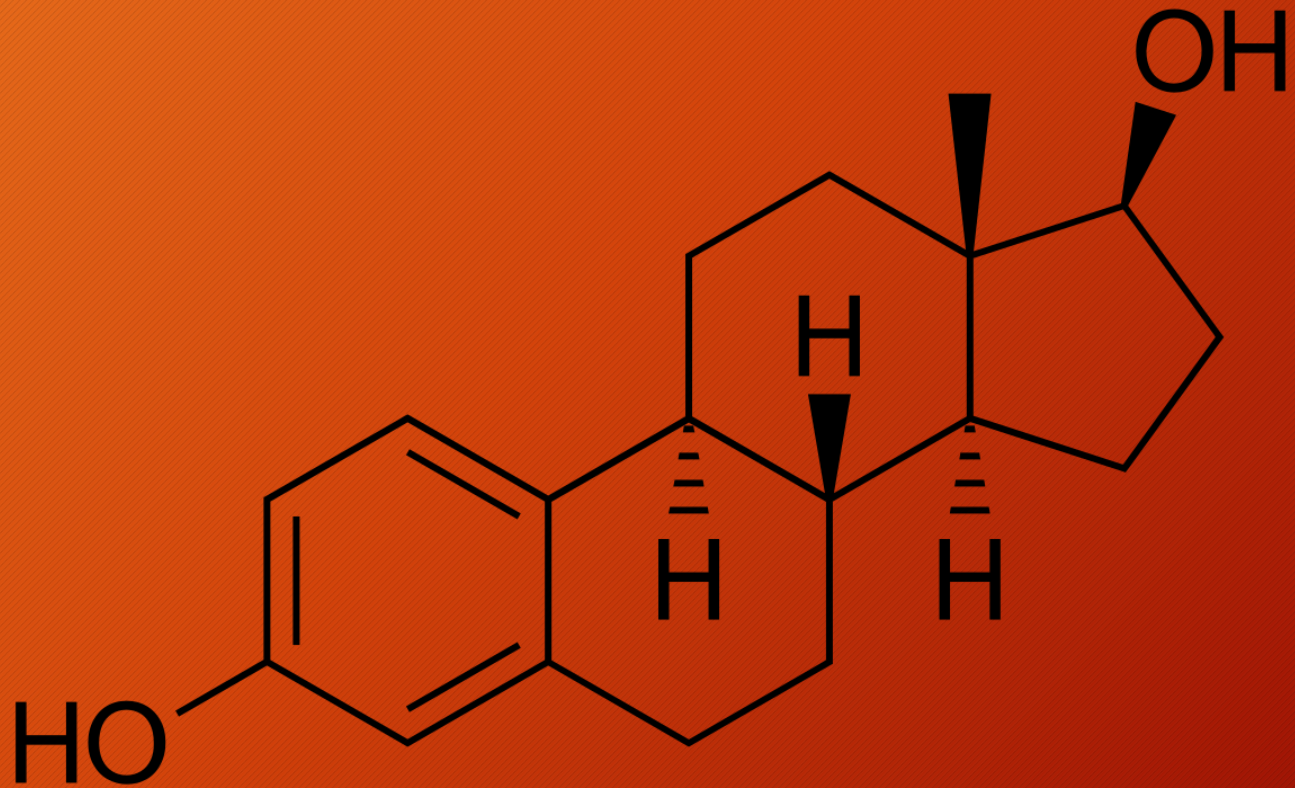


### Key Players





# Nomenclature



- FDA-Approved form of HRT
  - Only type studied in WHI
  - Lab-made compounds that are *similar* in structure to endogenous hormones
- “Synthetics”

- Examples:

- Conjugated Equine Estrogens, Ethinylestradiol
  - ex. Premarin, Tulane
- Medroxyprogesterone Acetate
  - ex. Provera

# “Bioidenticals Type 1”

- FDA-Approved form of HRT
- Lab-made compounds that are *identical* in structure to endogenous hormones
- Examples:
  - Estradiol, Estradiol Acetate
    - ex. Estrace, Climara, Femring
  - Micronized Progesterone
    - ex. Prometrium
- <https://www.health.harvard.edu/womens-health/fda-approved-bioidentical-hormones-for-menopausal-symptoms>

# “Bioidenticals Type 2”

- NOT FDA-Approved
- May be listed as nutritional supplements
- Multiple routes of delivery
- “Individualized Dosing”
- Often based off of salivary testing
- Examples:
  - BioTe
  - Multiple pharmacy formulations

# A Note about Bioidenticals...

- The term “bioidentical” is a marketing, not medical, term
- Coined by physicians John R. Lee and Jonathan Wright
  - Believed progesterone panacea
- Consumer scare of HRT from WHI lead to propagation of BHRT compounds
- Suzanne Somers popularized it in print form in 2006

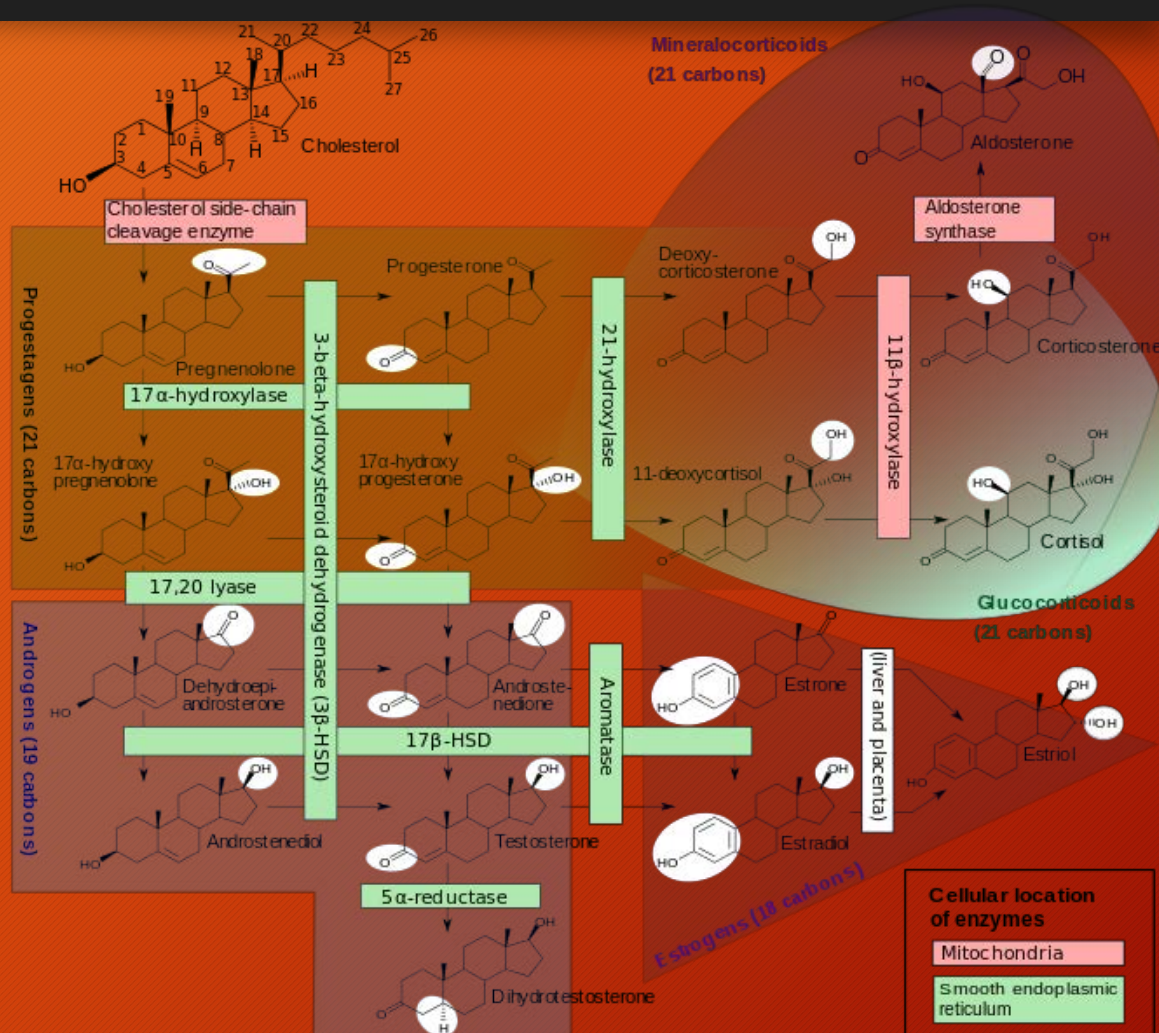
# From the FDA...

In January 2008, the FDA ordered seven compounding pharmacies...to stop making illegal claims about "bio-identical hormone replacement therapy (BHRT)" products. The companies were told that the FDA regards "bio-identical" as a marketing term that implies a benefit for which there is no medical or scientific basis [7]. Some were also making unsupportable claims that their drugs are better than FDA-approved menopausal hormone therapy drugs and can be used to prevent and treat serious diseases such as Alzheimer's disease, stroke, and various forms of cancer.

# A Little More Minutia...

- Sex Hormones are Cholesterol Based Steroids
  - Estrogens
    - 18-carbon ringed structures
    - Hydroxyl group vs. Ketone on C17
  - Progestogens
    - 20-carbon ringed structures
      - Progesterone MC type
    - Progestins are synthetic progestogens
  - Androgens
    - 19-carbon ringed structures
    - Testosterone precursor to Dihydrotestosterone

# You Knew This Was Coming...





# Current Indications for HRT

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# Indications Con't

- FDA-Approved (and NAMS codified) Indications for HRT in Women
  - Vasomotor Symptoms
    - Should be bothersome
  - Genitourinary Symptoms
    - VVA, recurrent UTI, dyspareunia
  - Prevention of Bone Loss
  - Premature Hypoestrogenism
    - Chemotherapy, POI, surgical menopause

# Would You Like to Know More?

- Menopause: The Journal of The North American Menopause Society
- Vol. 24, No. 7, pp. 728-753
- DOI: 10.1097/GME.0000000000000921
- © 2017 by The North American Menopause Society
- POSITION STATEMENT
- The 2017 hormone therapy position statement of The North American Menopause Society

# Indications Con't

- TRT in Men
  - From The Cleveland Clinic... "The indications, benefits, and risks of TRT are controversial, with current data lacking long-term follow-up and consistent biochemical target values. Treatment of low testosterone is not indicated at the present time in the absence of clinical symptoms"
  - For Symptomatic Men...
  - "Recommended for symptomatic men with low or borderline total testosterone or free testosterone (< 350 ng/dL or < 65 pg/mL)"

# Indications Con't

- Contraindications for TRT in men:
  - History of breast or prostate cancer, palpable prostate nodule or induration, or a prostate specific antigen (PSA) >4 ng/mL or PSA >3 ng/mL in men at high risk of prostate cancer, hematocrit >50%, severe lower urinary tract symptoms associated with benign prostatic hypertrophy (ie, AUA/IPSS score >19), uncontrolled or poorly controlled congestive heart failure, or uncontrolled severe obstructive sleep apnea.

# Indications Con't

- Testosterone in women?
  - No current FDA-approved formulations for Testosterone in women
  - Combination Estradiol/Testosterone pill does exist
    - Brand name Estratest
      - Enteric Testosterone poorly absorbed

# Indications Con't - Transgendered Peoples

- Determined by “goal” gender
  - Masculinizing therapies
    - Typically androgens
  - Feminizing therapies
    - Estrogens and antiandrogens
- May or may not be covered by insurance
- Requires knowledgeable practitioner
  - Some patients will self-medicate

# Proper Prescribing for HRT



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# Initial HRT Evaluation

- Key Points:
  - Symptoms
  - Indications
  - Contraindications
  - Desire for Therapy

# Case Study#1

- Joan is a 46 y/o G2P2 who presents to your office c/o hot flashes, insomnia, and increased vaginal dryness. She reports a cessation of menses approximately one year prior. She denies any other issues, and has a benign health history. She has heard about HRT, but is concerned that “it could cause cancer!”

# Case Study #1

- Symptoms: hot flashes, insomnia, vaginal dryness
- Indications: VMS, GSM
- Contraindications: None
- Desire for Therapy: Yes

# Case Study #1

- Key Points
  - Prior to initiation of HRT, discuss diet, exercise, sleep
  - VSM symptoms will often improve with environmental modalities
  - GSM is progressive disorder - will most likely require medication at some point
  - No demonstrable increase in CA in women using transdermal HRT within 10 years of menopause

# Case Study #2

- John is an overweight, 55 y/o male executive who presents complaining of low libido and erectile dysfunction. He is very interested in testosterone therapy. His health history is pertinent for BPH, and his last PSA was 6 ng/mL. Serum total/free testosterone shows levels are 200 ng/mL and 50 ng/mL.

# Case Study #2

- Symptoms: Low libido, ED
- Indications: Low serum F/T testosterone
- Contraindications: Elevated PSA
- Desire for Therapy: Yes

# Case Study #2

- Key Points

- Poor diet, lack of sleep, sedentary life can cause low T
- High cortisol = decreased androgens
  - Sympathetic response
- Testosterone should be AM draw
- Contraindications for HRT should be addressed

# Take Home Points

- Multiple FDA-approved formulations for HRT exist
- Multiple speciality societies express need for further investigation with longterm HRT
- HRT should only be prescribed if criteria are met
- Lifestyle modifications may reduce need for pharmacologic intervention
- Document, document, document



# Questions?

Call or email anytime

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