FDA Regulations Governing Hormone Replacement Therapy Supplements

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Class: NURS 648

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Objectives

What is Hormone Replacement Therapy (HRT)?
What is happening in the health care community?
Legal history.
Current law.
What does the future of HRT look like?
Recommendations for improvement.

What is Hormone Replacement Therapy (HRT)?

Treatment with hormones to replace natural hormones when the body does not make enough.

For example, hormone replacement therapy may be given when the thyroid gland does not make enough thyroid hormone or when the pituitary gland does not make enough growth hormone.

It may be given to women after menopause to replace the hormones (estrogen, progesterone, testosterone) that are no longer made by the body.

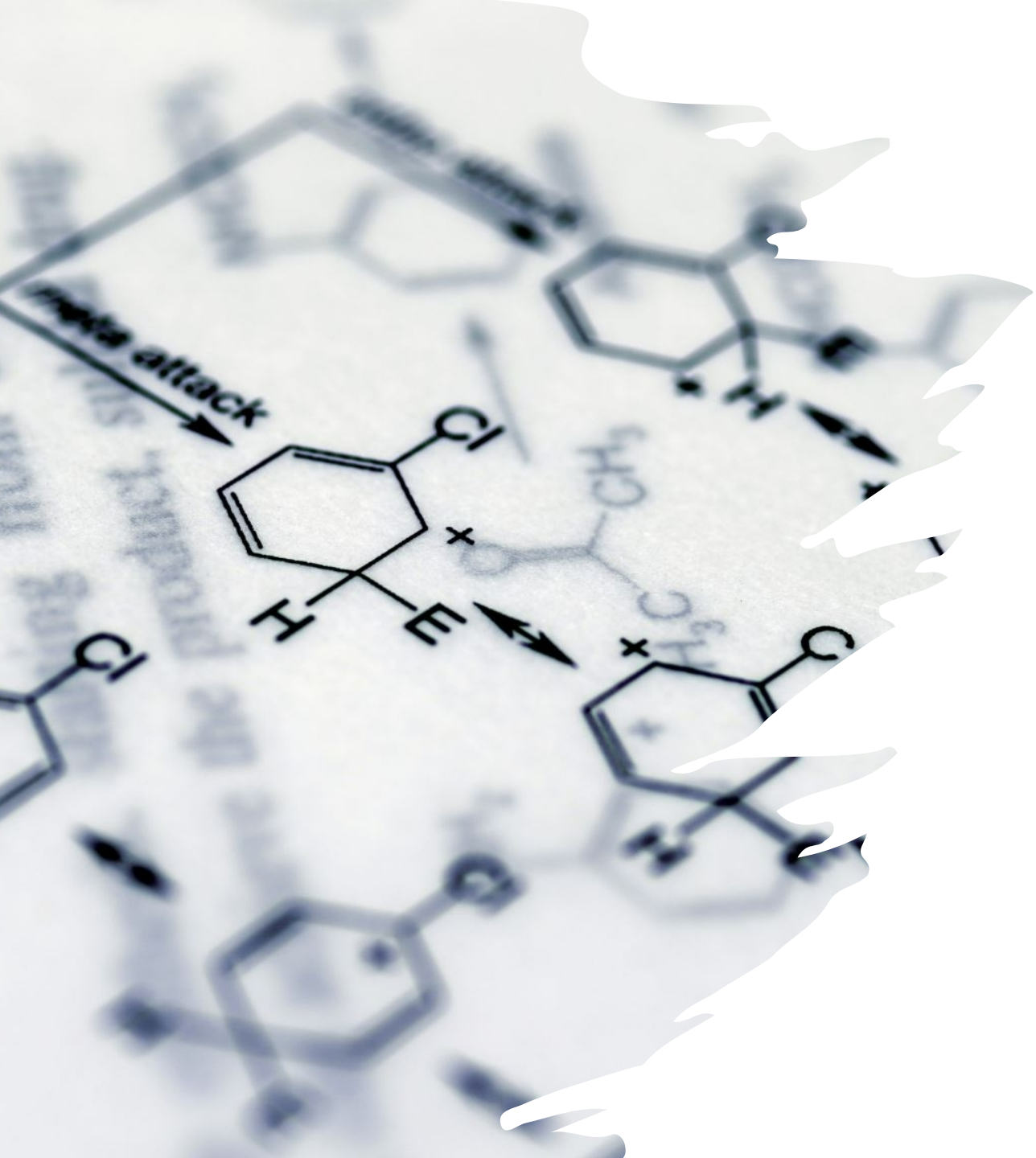
It replenishes women with ovarian hormones diminished during the natural menopausal transition to help with associated symptoms, like hot flashes and night sweats.

(Harper-Harrison et al., 2024; National Cancer Institute, n.d.)

Examples include:

- Estradiol creams or transdermal
- Estradiol/Norethindrone Acetate
- Testosterone undecanoate capsules or injections
- Testosterone gels
- Progesterone capsules or gels
- Leuprolide acetate (gonadotropin releasing hormone (GnRH) agonist)
- Somatropin-rDNA origin (recombinant growth hormone)
- Conjugated estrogens/medroxyprogesterone

(CenterWatch, n.d.)



Current Regulation

- Approved:
  - estrogen-based HRT for treating moderate to severe vasomotor symptoms associated with menopause.
  - Testosterone replacement therapy (TRT) for men with hypogonadism caused by certain medical conditions.
- Not approved:
  - Compounded bioidentical hormones

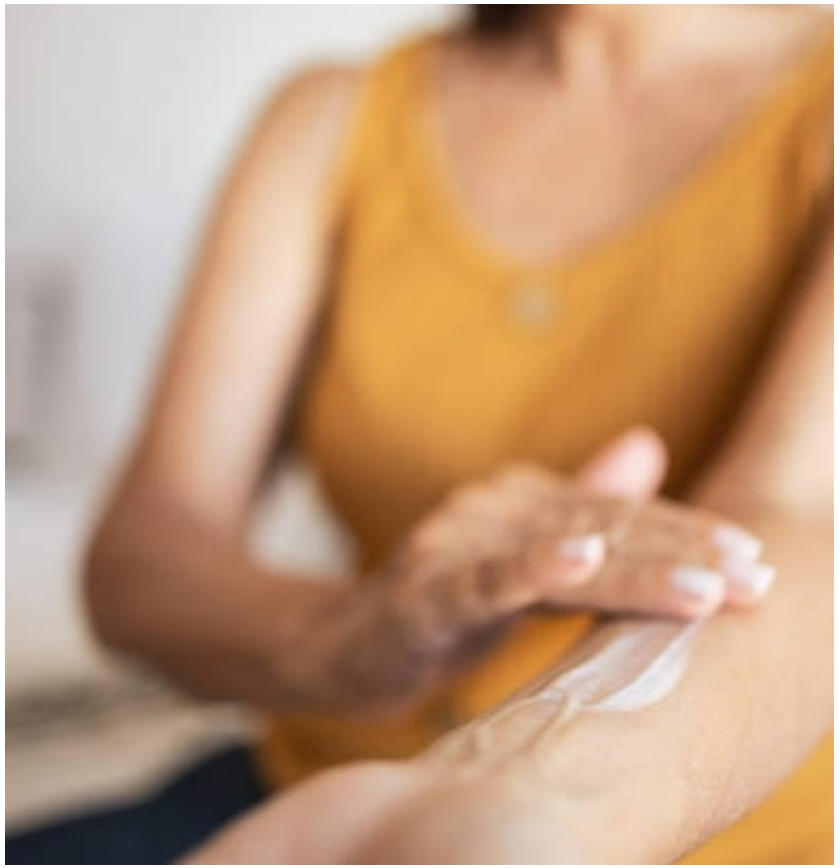
(Harper-Harrison et al., 2024)

Why is it important?

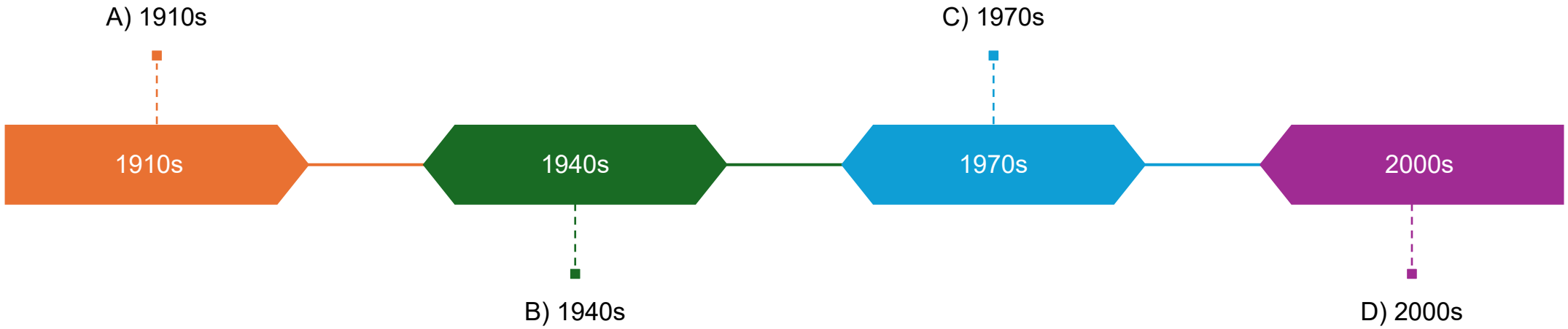
- Menopause is a natural biological process women will go through.
- Symptoms can have a significant impact on quality of life (QOL) for many women. Legalization of bioidentical methods could change QOL for millions of women.
- While commonly reported symptoms included hot flashes and mood changes, menopause can have an impact on all body systems
- Hormone depletion can lead to multiple co-morbidities including Alzheimer's disease, osteoporosis and heart disease (Bluming & Tavris, 2018).

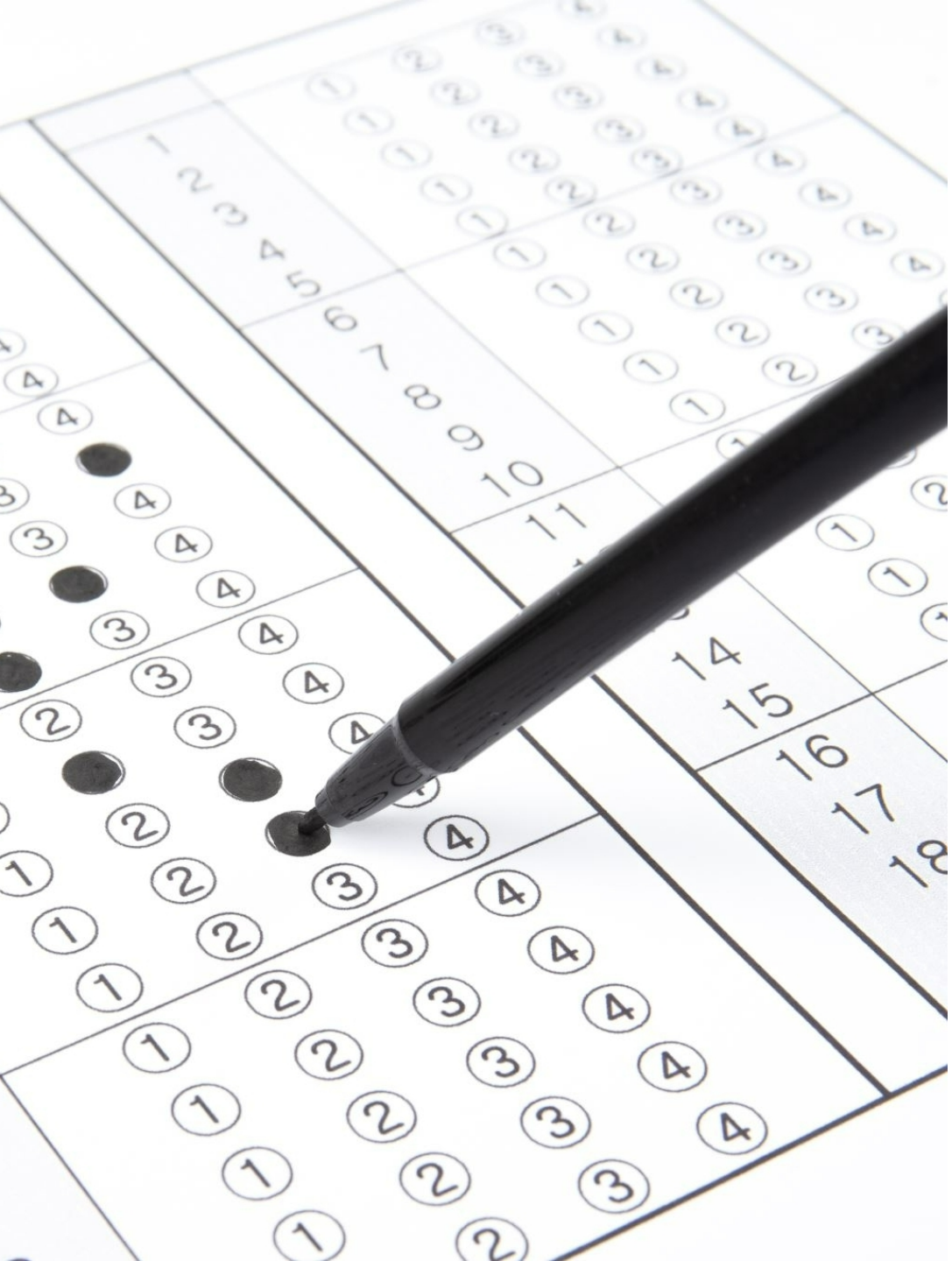
Why is it important?

- A growing movement to focus women's health and quality of life,
- Women are living longer, making HRT a key issue for improving their long-term health,
- HRT has been at the center of debate due to conflicting studies on the risks and benefits,
- The healthcare community is being pressured to find the right balance between symptom relief and minimizing risk (Haver, 2024). While also confined by legal limitations.



What year was HRT first approved by the FDA?





Answer

- B) 1940s

Legal History:

- First HRT Drug Approval by FDA
  - 1942
- Major Developments:
  - 1970s
- Other Advancements:
  - Menopause – 1997, 2003, 2013, 2023

(Federal Drug Administration, 2023; Glazier & Ko, 2023; McAninch & Bianco, 2016)

What HRT drug is not FDA approved?

Answer

- Transgender HRT Drugs

Current Law:

Not Approved by FDA:

Transgender HRT Medications

Current Legislature:

Transgender HRT Medications in Minors

Alternative Treatments and Fairness Act of 2011

Introduced to amend the XVIII (Medicare)of the Social Security Act to cover HRT for menopausal symptoms.

(American Speech Language Hearing Association, n.d.; Geffen et al., 2018; Library of Congress, n.d.)

What does the future hold?

The future of HRT

- Advances in Personalized Medicine
- Development of Safer Hormone Options
- Focus on Non-Hormonal Treatments
- Policy Changes and Workplace Support for Menopausal Women

What if nothing changes?

- Worsening Health and Quality-of-Life Outcomes
- Continued Misinformation and Stigma Around HRT
- Economic and Workplace Impact
- Disparities in Health Access and Gender Equality

Recommendations for Improvement

- Education to providers and patients.
- Individual patient assessment plans.
- Always consider lifestyle modifications.
- Education to patients on the risks and benefits of HRT.
- Ensure proper monitoring and follow-up of patients who are on HRT.
- Advocate for legalization of bioidentical HRT

Summary

- HRT is a treatment therapy with hormones to replace natural homes when the body does not make enough.
- Approved therapies are:
  - Estrogen-based HRT for treating moderate to severe vasomotor symptoms associated with menopause.
  - Testosterone replacement therapy (TRT) for men with hypogonadism caused by certain medical conditions.
- Continued advancement in medicine and technology is allowing for advancement in HRT delivery. Legal advancement should also follow.
- Evolving with the market and patient needs is essential to addressing health issues that affect the disease burden.

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Thank you!
You've been a great audience!

Any Questions!