


**LEGAL/ETHICAL DILEMMAS IN PHARMACY:
GENDER DYSPHORIA, MEDICAL ABORTION,
AND PHYSICIAN-ASSISTED SUICIDE**

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Through Pharmacy

2023 CPFI Annual Conference & National Student Retreat

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- I am receiving no compensation of any kind for my appearance here today, it is strictly voluntary.

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SESSION OVERVIEW

- Gender Dysphoria considerations
- Medical Abortion considerations
- Panel Questions
- Case Ethical Analysis Practice

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NORMATIVE ETHICS

- Beneficence
 - Use our knowledge to benefit our patients
- Nonmaleficence
 - First do no harm
- Confidentiality
 - Hold patient knowledge sacred
- Distributive justice
 - Treat all patients equally regardless of irrelevant factors
- Patient autonomy
 - Patients make informed decisions about their care

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GENDER DYSPHORIA

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Clinical Pharmacist Specialist and Clinical Ethicist

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Rodin - The Thinker

DESCARTES

"Cogito ergo sum."
-- 1640

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WORLDVIEWS

Judeo-Christian	Classical Gnosticism	Neo-Gnosticism
Come into existence at the moment of conception	Souls/spirit/light pre-exist in the ether	?
Mind-body-soul/spirit are created as one unified whole	Spirit-body dualism (soulmate)	Mind-body dualism
Spirit/soul continues after death	May reach a higher plane through knowledge (enlightenment) and reincarnated as higher being	Some believe in reincarnation, some believe we cease to exist, some believe in "heaven"

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- ## GENDER DYSPHORIA
- A. A strong and persistent cross-gender identification. In children, the disturbance is manifested by four (or more) of the following:
 1. repeatedly stated desire to be, or insistence that he or she is, the other sex
 2. preference for cross-dressing
 3. strong and persistent preferences for cross-sex roles in make-believe play or persistent fantasies of being the other sex
 4. intense desire to participate in the stereotypical games and pastimes
 5. strong preference for playmates of the other sex
 - B. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.
 - C. The disturbance is not concurrent with a physical intersex condition.
 - D. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

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- ## GENDER AFFIRMING CARE
- American Psychiatric Association: Gender Affirming Therapy is a therapeutic stance that focuses on affirming a patient's gender identity and does not try to "repair" it.
 - Core interventions include the following:
 - Gender affirmation
 - Space for processing and understanding
 - Linking to social supports, legal services, health care providers
 - Creating a safe zone
 - Allowing for diversity
 - Reflection and empathy
 - U.S. Dept. of Health and Human Services: "early gender affirming care is crucial to overall health and well-being"
 - Human Rights Campaign: "life-saving healthcare for transgender people of all ages"
 - American Medical Association: "medically-necessary, evidence-based care that improves the physical and mental health"
- There are NO randomized clinical trials showing effectiveness of gender affirming care.

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- ## GENDER AFFIRMING CARE
- Social affirmation
 - Legal affirmation
 - Medical affirmation
 - Surgical affirmation

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- ## BODY DYSMORPHIA
- A body-image disorder characterized by persistent and intrusive preoccupations with an imagined or slight defect in one's appearance.
 - Most often develops in adolescents and teens, and research shows that it affects men and women almost equally.
 - Occurs in about 2.5% in males, and in 2.2 % of females.
 - Often begins to occur in adolescents 12-13 years of age
- American Psychiatric Association, 2013

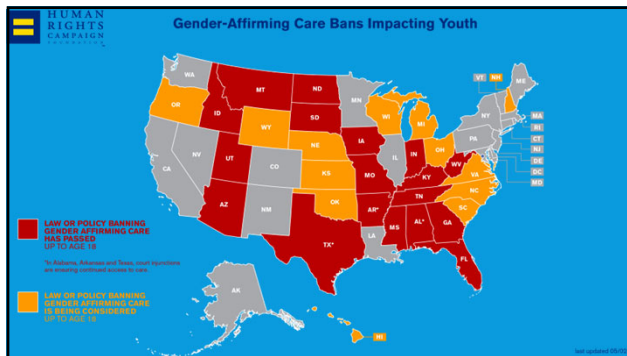
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- ## ANTISOCIAL PERSONALITY DISORDER
- A. There is a pervasive pattern of disregard for and violation of the rights of others occurring since age 15 years, as indicated by three (or more) of the following:
 1. failure to conform to social norms with respect to lawful behaviors as indicated by repeatedly performing acts that are grounds for arrest
 2. deceitfulness, as indicated by repeated lying, use of aliases, or conning others for personal profit or pleasure
 3. impulsivity or failure to plan ahead
 4. irritability and aggressiveness, as indicated by repeated physical fights or assaults
 5. reckless disregard for safety of self or others
 6. consistent irresponsibility, as indicated by repeated failure to sustain consistent work behavior or honor financial obligations
 7. lack of remorse, as indicated by being indifferent to or rationalizing having hurt, mistreated, or stolen from another.
 - B. The individual is at least age 18 years.
 - C. There is evidence of conduct disorder with onset before age 15 years.
 - D. The occurrence of antisocial behavior is not exclusively during the course of schizophrenia or a manic episode.
- Grandiosity, narcissism, predatory exploitativeness

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MEDICAL ABORTION

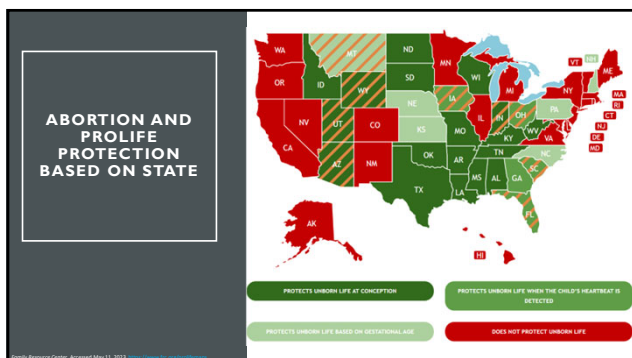
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DOBBS VS JACKSON

- US Supreme Court, June 2022
- Constitution does not confer a right to abortion
- Court does not decide what is a “right” referred to in the Fourteenth Amendment
- Reversal of Roe v. Wade (1973) and Planned Parenthood v. Casey (1992)
- Court unable to answer fundamental question of life
- Turned back to states to decide what is “potential life” and “preborn life”

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MIFEPRISTONE AVAILABILITY

- 2000 FDA approved for pregnancy termination through 49 days from female's last menstrual period, with restrictions
- Accelerated drug approval pathway – pregnancy as “illness” and “meaningful therapeutic benefit”
- Required 3 visits for dispensing
- 2011 - REMS from FDA Amendments Act of 2007
- Safety concerns (infection, hemorrhage/bleeding, ongoing pregnancy, requirement of surgery)
- ? Inadequate reporting structure with voluntary state reporting (including under-reported ER visits)

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MIFEPRISTONE AVAILABILITY

- 2016 FDA update label changed to 70 days and adjusted REMS:
 - Reduced visits to only 1 required with no follow-up
 - Removed data collection requirement for nonfatal adverse events
 - Increased adverse effects due to placenta and baby size
- 2021 FDA REMS change – in-person requirement removed (telehealth) due to “unnecessary restriction” – mifepristone can be mailed (states can still require in-person visit)
- 2023 FDA REMS change – available to be dispensed in certified pharmacies

Goodrich, J. et al. Health Care Access. 2022;14(1):1-10.
 Brennan, M. Health Care Access. 2022;14(1):1-10.
 Calton, J. BMC Women's Health. 2018;18(1):1-10.
 Hwang, M. Health Care Access. 2022;14(1):1-10.
 J. Pharm. Med. 2016;18(1):1-10.

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MIFEPRISTONE AVAILABILITY

- December 2022 US Justice Department ruled the mailing of mifepristone not unlawful
 - Based on adjustments to the 1873 Comstock Act (Sections 1461 and 1462 of title 18 of US Code)
 - The mailers “cannot know” what the recipients will do with the abortifacients
- Allowed to mail abortifacients to any state (including states with abortion restrictions)
 - Seller and USPS employees covered
 - Recipient covered “if she does not intend that they be used unlawfully”
 - Individual states can still require in-person visits for mifepristone

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MIFEPRISTONE AVAILABILITY – STILL?

- Texas Federal District Court – lawsuit against the FDA
 - Case made that FDA violated own procedures when authorizing mifepristone
 - Argument that improper approval of mifepristone puts women at risk
- Supreme Court expedited hearing – April 21
 - Procedural ruling to continue with appeals
 - Most likely will end up back at Supreme Court
- Appealed to Fifth Circuit – oral arguments begin 5/17

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CASE ETHICAL ANALYSIS

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