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# The Male Pill: Game Changer or Pipe Dream?

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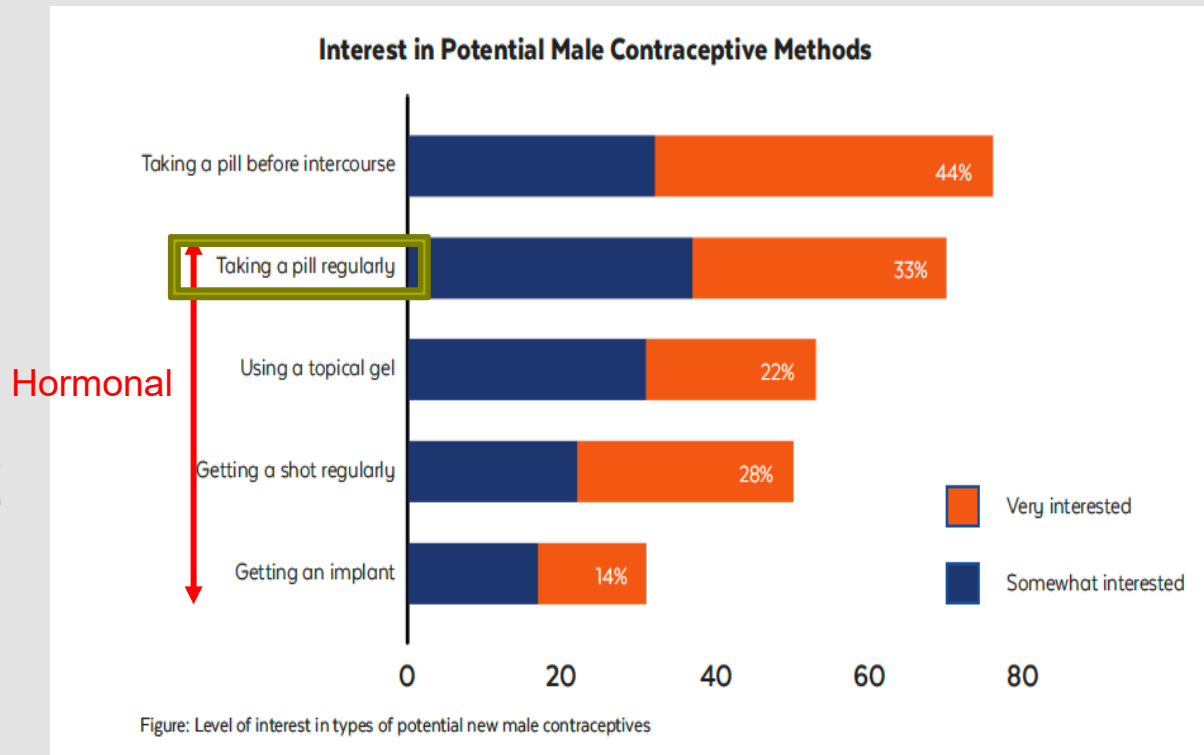


# Goals and Challenges of Male Hormonal Contraceptive Development

- Effective ✓
- Reversible ✓
- Minimal+/- Positive Side Effects ✓?
- Acceptable to both partners: ✓?
  - mode of delivery (injectable, pill)
- Accessible (costs, providers, policies)

# Male Contraceptive Initiative 2017 Survey: changing attitudes around male contraceptive responsibility

- 1500 men age 18-44
- 79% white
- 61% had no children
- < 50% married
- 85% wanted to prevent pregnancy and 60% noted shared responsibility as a motive to use



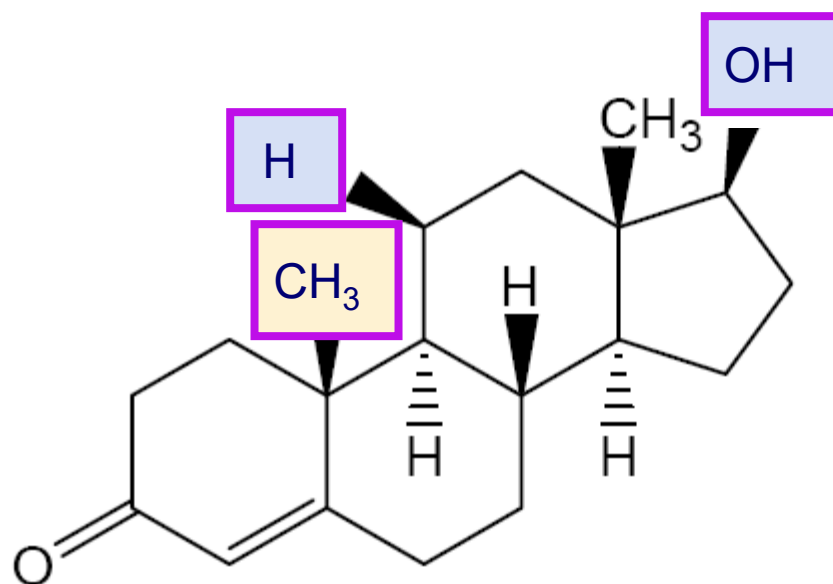
[https://www.malecontraceptive.org/uploads/1/3/1/9/131958006/mci\\_consumerresearchstudy.pdf](https://www.malecontraceptive.org/uploads/1/3/1/9/131958006/mci_consumerresearchstudy.pdf)

# Development of Novel Androgens: Optimization and Delivery

- Goal to combine androgen and progestin binding
- Oral and long-acting injectable formulations
- Possible selective androgen receptor modulators
- Compounds developed and patented by  
Contraceptive Development Branch (NICHD)
- Work done as part of NIH Contraceptive Clinical  
Trials Network



# Dimethandronolone undecanoate (DMAU): single agent male pill?



7 $\alpha$ , 11 $\beta$ -dimethyl-17 $\beta$ -hydroxy-estra-4-en-3-one 17 undecanoate

# Could DMAU or 11 $\beta$ -MNTDC become the Male Pill?



- Men had **VERY** low Testosterone, but had few symptoms of **Low T**
- No significant safety concerns were identified at any dose tested. Mild weight gain and cholesterol changes, ?libido  
**Next step: Longer study (3 months) to establish safety and sperm suppression**



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# The Male Pill: Conclusions

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- Once daily pill is desired by many men
- Oral delivery of androgens is challenging
- Novel androgens = “Male Pill” candidates are in Phase 2 with promising early safety and efficacy data
- “Bar” for side effects from a regulatory and user perspective unclear
- User demand is uncertain but acceptability of experimental regimens is high

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