

Optimizing Procedural Delivery Methods for a Novel Male Contraceptive Implant

The Scientific Repercussions of *Roe v. Wade* and the Uneven Burden of Contraception in American Culture

A Thesis Prospectus

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Prospectus

I. Introduction

Unplanned pregnancy is a growing public health crisis. Totaling 121 million each year, unintended pregnancies make up nearly half of all pregnancies globally (*UN Report, 2022*). Worldwide, 922 million women of reproductive age use contraceptive methods as a means of preventing unwanted pregnancies. Female sterilization and the oral contraceptive pill have been the leading contraceptive methods in the United States since 1982, together representing the choice of more than half of reproductive-age women who use contraception (*The Pill, Sterilization, and Condoms Top List of U.S. Birth Control Choices, n.d.*). On a global scale, female sterilization is similarly reported as the most common contraceptive method, accounting for nearly 24 percent of contraception use worldwide (United Nations, 2019a). Contraceptive methods that require men's direct participation – male sterilization, the male condom, and withdrawal – account for only 27.4 percent of contraceptive practice worldwide. Of these options, male sterilization represents the only long-term male contraceptive method and accounts for only two percent of contraceptive practice worldwide as reported by a 2019 United Nations Report (United Nations, 2019a).

Contraline is a local medical device start-up aimed at introducing a novel, long-lasting, and reversible contraception option for men. Their injectable hydrogel, ADAM™, is designed to physically occlude the vas deferens, the male reproductive duct responsible for transporting ejaculatory sperm from the scrotal sac. The technical portion of my thesis is aimed at developing an anatomically-accurate model of the vas deferens. Current models fail to mimic the distinct mechanical and physical properties of the sperm duct and, thus, oversimplify testing of the hydrogel delivery procedure. Without a realistic means of testing, Contraline has struggled to

effectively correct procedural pain points. The refined model will primarily serve as a tool to optimize current methods of hydrogel delivery. The second section of this prospectus examines my technical objectives in greater detail.

Reproductive equality is central to Contraline's mission. Their innovative technology aims to address a gaping hole in the landscape of male contraception, efforts which prove even more critical in a post-Roe era. The recent upheaval of *Roe v. Wade* – a landmark ruling which constitutionally protected a woman's right to abortion – has pushed the uneven burden of reproductive politics to the forefront of public debate. Together, the advent of the hormonal birth control pill and the legalization of abortion in the late-twentieth century inadvertently contributed to an emerging cultural narrative that the people who give birth must bear the burden of preventing and resolving pregnancies; this narrative may be partly responsible for the modern lag in male contraceptive development. With the STS portion of my thesis, I aim to explore the scientific repercussions of *Roe v. Wade* and the uneven burden of contraceptive responsibility in American culture. The third section of this prospectus demonstrates the significance of my central research question, identifies key stakeholders, and outlines a detailed plan to guide my research efforts.

II. Technical Topic

With the technical portion of my thesis, I aim to create and employ an anatomically-accurate model of the vas deferens to aid the development of a technological or procedural solution that ensures accurate, effective, and consistent delivery of the hydrogel into the vessel lumen. In the following sections of this prospectus, I will outline the background and significance of my technical research efforts.

The vasa deferentia (plural) are long, muscular tubes that connect the epididymis – sperm storage structures located on each testicle – to the ejaculatory duct in the male reproductive system. These vessels serve as channels for the transportation of sperm during ejaculation (*Vas Deferens*, n.d.). During a vasectomy, the vasa deferentia are surgically cut and sealed to obstruct the supply of sperm to the semen. This procedure represents the only long-term male contraceptive method and accounts for only two percent of contraceptive practice worldwide (United Nations, 2019a).

Contraline is a Charlottesville-based start-up working to develop a long-lasting, non-hormonal, and reversible male contraceptive. Their proprietary hydrogel, ADAM™, is designed to physically obstruct the transport of sperm from the testes by local injection into the lumen – or internal channel – of the vessel. Sperm cells blocked by the hydrogel barrier degrade naturally and, with time, are reabsorbed into the walls of the vessel. Further, at the end of its lifespan, the occlusive hydrogel liquifies, thus removing the barrier to sperm flow (*Contraline Product*, n.d.). By contrast, vasectomy procedures are not reliably reversible methods of contraception. The success rate of a vasectomy reversal is variable, ranging from 30 percent to 90 percent depending on a number of related factors including time since procedure, partner age, and underlying fertility issues (*Vasectomy Reversal - Mayo Clinic*, n.d.).

The average lumen of the vas deferens is less than two millimeters in diameter, providing only a narrow window for accurate cannulation and delivery of the hydrogel; this represented a significant pain point in Contraline’s first human trials. Operating urologists struggled to consistently and accurately cannulate the vas deferens for hydrogel injection. Current models of the male anatomy offer an unrealistic representation of *in vivo* conditions and, thus, oversimplify testing of the hydrogel delivery procedure. More specifically, most models are constructed from

silicon-based materials and fail to mimic the distinct anatomical properties of the vas deferens. These inaccuracies inhibit company-wide efforts to develop a procedural or technological solution that enables accurate and consistent placement of the catheter into the vessel lumen.

In order to refine the delivery process of the hydrogel-based contraceptive, an anatomically-accurate model must be developed using materials that closely mimic the physiological properties of vas deferens; this includes mechanical properties such as elasticity and tensile strength as well as physical characteristics such as vessel size and lumen-to-wall ratio. Research will be conducted to identify optimal materials and discover methods for molding or shaping selected materials into vessel-like structures. The refined model will primarily serve as a tool to optimize current methods of hydrogel delivery.

The solutions that emerge from this technical project will improve ease of use for practitioners, reduce time associated with hydrogel delivery, and ensure overall accuracy of the injection. Together, these improvements will aid Contraceptive in bringing the first long-term, readily-reversible male contraceptive option to market.

III. Science, Technology, and Society (STS) Topic

The 1973 Supreme Court ruling in *Roe v. Wade* constitutionally protected the right to an abortion on the basis of the Fourteenth Amendment and one's fundamental right to privacy. The recent struckown of this landmark decision has reversed fifty years of precedent and, in its wake, has yielded ripple effects with major social, political and technological implications. With the STS portion of my thesis project, I will investigate the scientific and technological repercussions of the *Roe v. Wade* ruling and the uneven burden of contraceptive responsibility in

American culture. In the following sections of this prospectus, I will establish the significance of my research, identify key stakeholders, and outline a detailed plan to guide my research efforts.

i. Background and Significance

The introduction of the hormonal birth control pill in 1960, in conjunction with the 1973 ruling in *Roe v. Wade*, ignited a sexual revolution which challenged culturally normative attitudes toward sexuality, morality, and interpersonal relationships. Newfound access to abortion and modern contraceptive technologies enabled the separation of sex from procreation by dramatically reducing the risk of pregnancy (“How the Sexual Revolution Unfolded,” 2017). Opinion polls conducted in the midst of this social movement highlight the liberal shift in cultural values: in 1965, 26 percent of all Americans opposed abortion, even when the pregnancy represented a serious risk to the woman's health; seven years later, this percentage fell to 8 percent (Luker, 1994). The 1973 ruling also yielded significant health benefits for women as the standard abortion procedure was transformed from an unsafe and secretive practice to one performed under safe medical conditions (*The Public Health Impact of Legal Abortion*, 2005).

From a technological standpoint, the introduction of the first hormonal birth control pill granted U.S. women unprecedented freedom over fertility, thus sparking a liberation movement which fundamentally changed the landscape of contraception in the United States. Female contraceptive technology was largely celebrated as an agent of liberation, freeing women from the obligation of motherhood (Bailey, 2006; *The Pill and the Women's Liberation Movement* | *American Experience* | PBS, n.d.). These sentiments prompted significant advancements in female contraceptive technology including the introduction of the intrauterine device and the contraceptive implant in 1968 and 1990, respectively (“A Brief History of Birth Control in the

U.S.,” n.d.). On the other hand, the landscape of male contraceptive technology remained largely unchanged by the sexual revolution. The first human vasectomy was performed in 1897; since then, technological options for men to actively prevent pregnancy have remained threefold: condoms, withdrawal, or a vasectomy procedure (United Nations, 2019b). Thus, the *Roe v. Wade* era marked a period of gender-biased innovation which contributed directly to a cultural narrative that women must bear the burden of preventing and resolving pregnancies.

The recent upheaval of the *Roe v. Wade* ruling has threatened women’s access to abortion services across the nation and, in turn, has exacerbated the uneven burden of contraceptive responsibility which has pervaded American culture since the late twentieth century. However, the consequences of this decision extend far beyond its social implications. Once the primary beneficiaries of the 1973 *Roe v. Wade* ruling, women will now disproportionately bear the burden of its reversal.

ii. Key Stakeholders

Reproductive-age women bear the brunt of contraceptive responsibility in American culture and, thus, represent primary stakeholders in my research efforts. My research will specifically establish women of color and low socioeconomic backgrounds as key stakeholders. Women of color and low socioeconomic status face a disproportionate risk of negative reproductive outcomes as a result of systemic inequalities including decreased access to educational and economic attainment, fewer neighborhood health services, less insurance coverage, and practitioner-level factors such as racial bias and stereotyping (*Racial and Ethnic Disparities in Reproductive Health Service... : Obstetrics & Gynecology*, n.d.). Racial and socioeconomic disparities are reflected in patterns of contraception use. The 2002 National

Survey of Family Growth found that the gaps in contraceptive use between poor and non-poor women and minority and White women increased between 1995 and 2022. Of women at risk for unintended pregnancy, 9 percent of Whites, 12 percent of Hispanics, and 15 percent of Blacks did not use contraception. With respect to income, 12 percent of women earning less than 150 percent of the federal poverty line (FPL) were not using contraception, compared to 9 percent of those earning more than 300 percent of the FPL (Dehlendorf et al., 2010). Exacerbating these disparities, marginalized women are commonly underrepresented in discussions of reproductive health. Research will be conducted to further explore the disparate health risks that these communities face.

The U.S. government also represents a critical stakeholder in my research. Variability in the judicial interpretation of the U.S. Constitution has resulted in inconsistent conclusions about a woman's right to an abortion. Further, policymakers play a central role in determining how rulings in the case of *Roe v. Wade* are enforced. Research will be conducted to explore how political climate shaped the opposing rulings in the *Roe v. Wade* case and the nature of the policies that emerged as a result.

Finally, health care and the medical technology industry represent another important stakeholder in my research. This industry is responsible for the development, testing, and marketing of new contraceptive technology. Despite its technological feasibility, modern male contraceptive technology has yet to be developed. Research will be conducted to determine the role of the medical industry in reinforcing the gender biases inherent to the contraceptive landscape.

iii. Research Methodology and STS Framework

The STS portion of my thesis project will utilize the feminist critique framework to guide research analysis. Feminist science and technology studies offer a framework for investigating the suppressive effects of science and technology and, similarly, challenging the hierarchies of knowledge production and patriarchal power structures. By exploring the intersection of gender and technical sciences, pioneers of feminist technoscience aim to understand how technology can be used to shape social relationships, gender roles, and power dynamics. Establishing a foundational understanding of the feminist critique framework represents the first critical step in my research timeline; this understanding will significantly shape my later approach to research collection and analysis (Adrian et al., 2018; Åsberg & Lykke, 2010; Wagman & Parks, 2021).

I aim to answer my central research question by conducting a comprehensive literature review. Through review and analysis of relevant texts, I will first gain a high-level understanding of the history surrounding reproductive politics and contraceptive technology. Next, I will explore the uneven burden of contraceptive responsibility in American culture. Specifically, I plan to investigate the relationship between contraceptive technology and the cultural narrative: which one shaped the other? Then, I will explore the scientific, political, and social implications of the *Roe v. Wade* reversal and its impact on each of my key stakeholders. Finally, I will investigate modern efforts to correct the gender biases inherent to contraceptive responsibility. The following section will introduce a number of key texts which will guide my research.

iv. Key Texts

In *Just Get on the Pill*, Krystale Littlejohn examines the uneven burden of reproductive politics—a phenomenon in which people who give birth are held accountable for preventing and

resolving pregnancies in gender-constrained ways. The book draws on first-hand accounts from hundreds of interviews, conducted through a joint study with Stanford and UC Berkeley, to document both the social history and urgent social implications of gendered compulsory birth control. Ultimately, Littlejohn aims to build the argument that the gender-biased approach to pregnancy prevention is counterproductive to feminist efforts to gain reproductive autonomy (*Just Get on the Pill* by Krystale E. Littlejohn - Paperback - University of California Press, n.d.; *The Gendered Burden to “Just Get on the Pill”*: “That Is Not Reproductive Freedom. It’s the Opposite” | *Salon.Com*, n.d.). *Just Get on the Pill* will serve as my primary text for exploring the gendered division of labor as it relates to pregnancy prevention and birth control. This resource will also be critical to uncovering how marginalized groups – such as trans, intersex, and gender nonconforming people – are overlooked and negatively impacted by reproductive politics.

Seizing the Means of Reproduction: Entanglements of Feminism, Health, and Technoscience by Michelle Murphy reexamines the women’s health movement of the 1970’s and 80’s through a feminist technoscience framework (Tunc, 2014). I aim to use Murphy’s work as a fundamental guide to my own analysis of reproductive politics through the feminist critique framework.

In *The Male Pill*, Nelly Oudshoorn explores the history of the male pill. The technical feasibility of a hormonal male contraceptive was demonstrated as early as the 1970’s, yet the technology has yet to be developed. Oudshoorn seeks to explain the stagnation of male pill initiatives by examining the cultural, scientific, and policy work that surrounded its development in the late twentieth century (Mamo, 2004; Oudshoorn, 2003). Through my analysis of *The Male Pill*, I aim to understand how technological innovation, specifically as it relates to birth control,

is shaped by historical context. Similarly, this resource may provide insights into the current state of male contraceptive initiatives.

In her book *Margaret Sangers' Eugenic Legacy*, Angela Franks seeks to draw modern connections between the eugenics movement and population control policy by examining the social and political agenda of Margaret Sanger, the founder of Planned Parenthood. Franks presents extensive research to suggest that the reproductive healthcare clinic was founded on eugenic principles and the desire to build a “better race” (*Margaret Sanger's Eugenic Legacy*, n.d.). In addition to offering a historical account of contraception accessibility in the United States, this book will provide an uncommon narrative about the origins of contraceptive technology and reproductive healthcare. I aim to use this text as a resource to further explore how these origins inform the modern applications of contraception.

Finally, David Garrow's *Liberty and Sexuality* is a definitive account of the legal and political struggles that created the right to privacy and won constitutional protection for a woman's right to choose abortion. The book delves into the earlier judicial battles, such as *Griswold v. Connecticut*, that set the stage for the landmark case of 1973 (*Liberty and Sexuality by David J. Garrow - Paperback - University of California Press*, n.d.). Garrow's work will offer insight into the political climate that surrounded the women's liberation movement of the late twentieth century.

IV. Conclusion

In summary, my thesis combines technical and social analyses to achieve a comprehensive understanding of contraceptive technology in the United States. By refining the common model of the vas deferens to more accurately mimic in vivo conditions, Contraline will

be better equipped to develop and test solutions to ensure accurate delivery of their hydrogel-based implant into the narrow lumen of the vas deferens. These improvements to procedural accuracy and reliability will, in turn, expedite the introduction of their novel contraceptive to market. Similarly, innovation in contraceptive technology will be broadly explored from a social perspective. By conducting an extensive literature review and applying the principles of the feminist critique framework, the STS portion of my thesis will examine the history of *Roe v. Wade* and its past and present role in driving gender-biased technological innovation and establishing an uneven balance of contraceptive responsibility in American culture.

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