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Drugs, gender, and profit: the continued absence of male contraceptive methods 60 years beyond the pill

Fiona Elizabeth Socolow
Vassar College

Drugs, Gender, and Profit:
The Continued Absence of Male Contraceptive Methods 60 Years Beyond the Pill

Fiona Elizabeth Socolow
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Advisors

Jill Schneiderman
Robert McAulay

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Note

I feel that it is important to recognize that because my thesis inherently revolves around individuals with biological reproductive capabilities that are consistent with their performed gender, this work necessarily focuses on cisgendered people. Moreover, I occasionally use the terms “woman” and “female,” and “man” and “male” interchangeably, though I try to be intentional about when I use each term, as biology and social identity are not one and the same.

Introduction

The introduction of effective family planning in the second half of the 20th century brought on profound and beneficial social changes, as well as significant improvements in public health outcomes. The Centers for Disease Control and Prevention (CDC) named family planning, including access to modern contraception, one of the 10 great public health achievements of the 20th century (1999). For evident reasons, women have long been the primary targets in the promotion of family planning, both in developed and developing countries. Effective contraceptive use has allowed women to space out and limit pregnancies to best fit their personal desires and financial resources. The freedom to effectively and independently control their own fertility has proven crucial to women's economic and social advancement, and continues to have a positive impact on education and workforce participation, as well as on subsequent outcomes related to income, family stability, mental health and happiness, and children's well-being.

However, despite the vast expansion of contraceptive access and choice, there continues to be a global unmet need for contraception. According to a 2015 United Nations report, 216 million married women worldwide want to delay or avoid pregnancy but are not using contraception. In the United States alone, there are 61 million women of reproductive age (15–44), of whom about 43 million, or 70%, are at risk of unintended pregnancy. That is, they are sexually active and do not want to become pregnant, but could become pregnant if they and their partners fail to use a contraceptive method correctly and consistently (Guttmacher Institute, 2018). Currently about 85 million unintended pregnancies occur annually worldwide, including approximately half of all pregnancies in the U.S., and up to one quarter of pregnancies worldwide end in induced abortion (Sedgh, Singh, & Hussain, 2014; Allen, Kaunitz, & Hickey,

2016; Guttmacher Institute, n.d.). Lowering the number of unintended pregnancies would improve quality of life for millions of adults, reduce abortion rates, and trim health care expenditures. This unmet need stems in part from issues of cost and accessibility, and in part from the fact that currently available female methods are not adequate for all women. Many methods entail significant side effects and associated health risks, have higher failure rates in actual use, may make demands on users that cannot in fact be met, or are inconsistent with the mores, practices, and deep-seated preferences of users or their sexual partners (Sedgh, Ashford, & Hussain, n.d.; National Research Council and Institute of Medicine, 1990). In order to begin to alleviate this issue, alternative solutions must be explored, and a large untapped user population must be recognized.

Globally, men tend to take a back seat in matters of contraception, so that the burden of birth control falls primarily on women. This disparity is based upon prevailing assumptions surrounding contraceptive responsibility and interests in family planning. However, increasing evidence suggests that new generations of men are willing to participate more actively in fertility control. While recognizing that reproductive issues more directly and profoundly impact the lives of women than men, men should have the ability to "demonstrate their identification with reproductive rights by taking responsibility for their own reproductive health and fertility control" (Solinger, 2013, p. 142).With this in mind, greater efforts to acknowledge and expand men's involvement in contraceptive decisions and behavior must be made. Broadening method choice to allow men and women the option to share family planning responsibilities has the potential to satisfy crucial individual and societal needs by helping to fill the current unmet

contraceptive need, and advancing gender equality by rectifying the current imbalance of contraceptive burden.

The description of contraception as a burden aims not to detract from its obvious virtues, but to reflect the various economic, emotional, psychological, and physical costs that women routinely tolerate for the sake of its benefits. Despite this reality, dissatisfaction with existing female methods remains a minimized issue in health care services and biomedical research, and is generally obscured by the sheer quantity of options. In the decades since the advent of the oral contraceptive pill in 1960, the number of reversible methods for women has expanded to include a wide variety of options, including intrauterine devices (IUDs), shots, patches, rings, implants, diaphragms, sponges, and cervical caps. Meanwhile, men continue to rely on the same few contraceptive options: vasectomy, condoms, and coitus interruptus, or withdrawal. Vasectomies, while highly effective, lack appeal due to their surgical nature, and are considered largely irreversible. Condoms, while important for protection against sexually transmitted infections, have limited user efficacy, with a failure rate between 13-18% with typical use, a statistic that indicates the percentage of women who will become pregnant within a year of method use (CDC, 2018; Guttmacher Institute, 2018; U.S. Department of Health and Human Services (HHS) Office on Women's Health, n.d.). Withdrawal, a lifestyle method rather than a technology, proves even less reliable with a failure rate of approximately 22% (CDC, n.d.). The significant drawbacks of existing methods reflect the failure of male contraceptive options to rival those available to women.

This discrepancy has long been recognized, yet little has changed in the field of male contraception for more than a century. Although research has been ongoing in many parts of the

world since the 1970s or earlier, commercial product development has stalled. One researcher lamented, “The joke in the field is: The male pill's been five to 10 years away for the last 30 years” (Watkins, 2012). Indeed, it is astonishing that after more than half a century of investigation, and despite huge medical advancements in many other fields, no new technology has emerged. The slow and seemingly fruitless trajectory of male contraceptive development thus requires a deeper examination of the social, cultural, political, and economic contexts in which scientific knowledge has been produced and technological artifacts have been created.

We tend to view technological entities merely as objects of use, often failing to realize that choices about our social order are fixed in the material we choose to create. Political theorist Langdon Winner suggests that we ask ourselves, “As we ‘make things work,’ what kind of world are we making?” He urges us to “pay attention not only to the making of physical instruments and processes, although that certainly remains important, but also to the production of psychological, social, and political conditions as a part of any significant technical change” (1986, p. 17). In order to do so, we must understand technology not only in terms of its physical function but in terms of social institutions, behaviors, symbolic means, formation of identities, and culturally rooted belief systems. We cannot think about technology only in the context of our individual interactions with artifacts, but also in the way that their design and arrangement build order in the world.

Technology does not merely aid human activity, but fundamentally shapes human activity and its meaning (Winner, 1986). It has the ability to update or reinforce pre-existing patterns, or to enable entirely new activities. It can moreover embody specific forms of power and organization. It can be “centralized or decentralized, egalitarian or inegalitarian, repressive

or liberating" (Winner, 1986, p. 29). The introduction of female birth control as contraceptive technology, in this case, was indisputably liberating and equalizing for women in myriad ways. For this reason, male birth control should not be considered a replacement but an added option. The possibility of a new male contraceptive should in no way detract from the monumentality of women's access to birth control, which remains a vital public health priority. Nevertheless, the continued imbalance of methods available to men and women has complicated the role of contraceptive technology in society. While female contraception has in many ways liberated womankind, the absence of a comparable male option has simultaneously contributed to the formation of repressive and inegalitarian systems of social organization in which women are regularly and automatically expected to bear this burden, regardless of the personal costs.

Indeed, the absence of technology proves just as significant as its presence. Professor and activist Betsy Hartmann wrote:

> "It is no accident that at the end of the twentieth century billions of dollars are spent every year on weapons of destruction and luxury goods, while technologies that could dramatically improve people's lives—nonpolluting energy sources, sustainable agricultural systems, basic health and sanitation measures--receive minimal funding at best. Those who hold the reins of power exercise power over technological choice." (Hartmann, 1995, p. 173).

The relationship between humans and technology is a reciprocal one. Technological innovations are not neutral—they embody the values of their creators. They are the products of social processes and social choices, and contraceptive technology is no exception. The continued absence of male birth control requires an examination of why some technologies succeed while

others fail, and illustrates how certain social issues and scientific aims are prioritized while others are neglected or actively silenced. In addition to examining the ways in which contraceptive technology shapes human activity and builds order in the world, we must examine the ways in which human actions and agendas shape the production, design, and distribution of technology. These processes are negotiated by relevant stakeholders and social groups, shaped by their interests, and driven by the relative power they possess. Those involved directly or indirectly in the pursuit of male birth control include researchers, clinicians, policy-makers, pharmaceutical industry leaders, nonprofit organizations, government agencies, potential users, and their partners, each with their own interpretations of what this technology would mean and what it could offer.

In chapter one, I use a historical lens to identify the confluence of social and scientific conditions that led to the development of the famed pill and the definitive shaping of contraception as a female arena. In chapter two, I examine how shifting or enduring norms in gender roles influence men's perceptions of contraceptive participation, responsibility, and acceptability. I use this analysis to gauge consumer interest and to evaluate the sociocultural feasibility of the male contraceptive objective. In chapter three, I discuss the technical feasibility of this goal, give an overview of previous and current scientific endeavors, and challenge the validity of the argument that biological limitations are the root of stagnation in this field of research. In chapter four, I explain the failure of promising research to be translated into a commercial product by identifying the difficulties of bringing new technology from laboratory to market. I identify the lack of pharmaceutical industry funding and the stringency of federal regulation as delaying the process, and discuss whether these factors reflect good market sense

and necessary safeguards or a continued gender bias in biomedical innovation. To accomplish this, I compare current events to the history of female contraceptive development and use.

I argue that given evidence of growing consumer interest and evolving sociocultural norms, as well as encouraging scientific work and abundant prospects for continued research, the greatest obstacles to male contraceptive development lie in the barriers to bringing promising technologies to market. I argue that as medicine has become increasingly commercialized, those with the greatest resources and influence have prioritized profit over public need. I moreover assert that while high standards and regulatory caution are justified given past errors in pharmaceutical development, marketing, and regulation, there exists a a fundamental, deeply ingrained double standard in our society's perception and treatment of the reproductive well-being of men and women. For these reasons, male contraception as an objective has lacked the attention, legitimacy, momentum, and resources needed to be brought to fruition.

Chapter 1: The Shaping of Contraception as a Female Arena

The Rise of Reproductive Medicine and Women as Objects of Medical Intervention

In order to envision a society in which the use of a new male contraceptive method could be normalized, we must first consider how and why contraception came to be recognized as an overwhelmingly female domain. This process began significantly before the rise of the pill, before even the recognition of contraception as a legitimate field of study. Female reproductive bodies have long been perceived as the natural objects of intervention (Oudshoorn, 2003). The field of gynecology was first established in the late 19th century as a new specialty in the biomedical sciences, the growth of which was not paralleled by the establishment of a complementary male-focused speciality for years to come. With the emergence of gynecology, women came to be identified as a "special group of patients" (Oudshoorn, 2003, p. 5). As reproductive sciences emerged in the beginning of the 20th century, concurrent progress in the field of hormone research led to studies of reproductive physiology (Watkins, 1998). With the development of sex endocrinology, or the study of sex hormones, in the 1930s, biologists for the first time "solved the riddle of the female reproductive cycle," demonstrating the effects of changes in hormonal levels on the physiology of reproductive structures in ways that proved fundamental to the subsequent development of hormonal contraception (Watkins, 1998, p. 22). With the emergence of these new disciplines, the field of medicine was newly provided with the tools to intervene in processes previously considered inaccessible and to transgress boundaries long thought to be natural. Furthermore, the existence of gynecology allowed this new science to focus almost exclusively on the female body (Oudshoorn, 2003, p. 5).

As the physiological processes of reproduction were brought into the domain of medical intervention for the first time, the female body became institutionalized in reproductive research and treatment. Andrology, a field devoted to the study and medical treatment of male reproductive bodies, did not emerge as a clinical science until the middle of the 20th century. The term was first coined in 1951 by a German gynecologist, but it was not until the last quarter of the century that the term gained real acceptance as an independent specialty, and the field remains marginal in comparison to that of gynecology, with reproductive scientists noting that the number of investigators interested in the former as opposed to the latter is "very small" (Basu, 2011; Oudshoorn, 2000, p. 131). The trajectory of reproductive science and medicine in the 20th century had two key consequences. First, the existence of obstetrical and gynecological clinics and the contrasting nonexistence of andrological clinics played a key role in the development of knowledge about human fertility (Clarke, 2000). Thus, when fertility control became an area of technological interest, scientists' knowledge of the female reproductive cycle provided more hints about rational approaches to contraception than did their knowledge of the male process. Second, as women increasingly became the focus of medical intervention, those with the power to intervene were overwhelmingly male: when the pill emerged in the 1960s, the overwhelming majority of American obstetricians and gynecologists were men (Djerassi, 1994). The emergence of female birth control methods thus coincided with changing attitudes within the medical profession that encouraged the medical management of reproductive health and increased male doctors' power over women's bodies (Tone, 2001).

The Pursuit of a Female Contraceptive

In the 1950s, the state of scientific knowledge, the passion and convictions of several key figures, and the public's faith in the ability of science and technology to solve social problems dictated the path of contraceptive research toward a female method in the mid-20th century. In the years following World War II, overpopulation became a growing public health concern (Oudshoorn, 2003; Gutmann, 2007). This era also saw the peak of American enthusiasm for technological development following the introduction of a succession of wonder drugs, including antibiotics, tranquilizers, and steroids. At this point in time, the confidence in and relevance of the contraceptive cause to multiple social groups provided the necessary impetus to push forward the agenda. The search for female birth control was pioneered primarily by activist and sex educator Margaret Sanger. Sanger's cause aligned advantageously with the social goals of other contemporary groups, including the Population Council, a nonprofit, private organization with an international focus on population control, as well as members of the eugenics movement. Sanger sought woman-controlled contraception to enhance women's sexual autonomy and to secure the rights and wellbeing of individual women. Meanwhile, population control advocates targeted women because "it is women who bear children and therefore women who, in their logics, should be controlled" (Clarke, 2000, p. 43). These goals worked in complementary fashion such that the terms "family planning," "birth control," and "population control" were used interchangeably in the 1950s and '60s. Therefore, when this project commenced, it elicited enough momentum and support to be brought to fruition (Tone, 2001; Watkins, 1998).

As these objectives came to the forefront of science in this era, a number of intellectual, economic, and sociocultural factors "conspired to preclude the development of a male

contraceptive" (Watkins, 1998, p. 20). The first of these factors were the interests and goals of Sanger and suffragist and millionaire heiress Katherine McCormick, who bankrolled Sanger's crusade. At the time, contraceptive research received no funding from pharmaceutical firms or from the government, and Planned Parenthood, the organization Sanger founded, lacked the financial resources to do so (May, 2010). Both Sanger and McCormick insisted on a method that could be controlled entirely by women, feeling that birth control should be their right and responsibility (Watkins, 1998). Sanger dreamed of female empowerment through women-oriented technologies, and believed that male-oriented technologies compromised this objective by placing women's procreative destiny in the hands of men (Tone, 2001). Sanger declared that "science must make woman the owner, the mistress of herself. Science, the only possible savior of mankind, must put it in the power of woman to decide for herself whether she will or will not become a mother" (May, 2010, p. 25). Consequently, this area received all of Sanger's attention and all of McCormick's financial backing.

Sanger required the scientific know-how and manpower to complete the project, and her call for scientists to take on this challenge was answered by Gregory Pincus, a biologist with relevant experience in both reproductive science and hormone research (Watkins, 1998). Aided by prior breakthroughs in steroid chemistry, "spurred by one determined feminist and sustained by another," Pincus used his professional experience to create a scientifically feasible and culturally appealing solution to the issue of family planning: the oral hormonal contraceptive (Watkins, 1998, p. 21). Once he had proven his success in developing the pill, the pharmaceutical company G.D. Searle & Co. made a serious fiscal commitment to the project (Watkins, 1998, p. 25). Thus, all of the necessary pieces fell into place: "Chemists had figured

out how to synthesize a more powerful analog of natural progesterone, and at least one company hoped to capitalize on the market. Pincus was both willing and eager to act as head scientist of the venture. McCormick contributed the necessary funds, and both she and Sanger provided the motivation for the project to move forward" (Watkins, 1998).

Pincus had originally been investigating hormonal contraception for men as well, yet that research never came to fruition once the female version was found to be successful. A focus on men provided several scientific obstacles. First was a matter of stigma: work on male contraceptives was a marginalized activity in the already marginalized reproductive sciences and contraceptive development worlds (Clarke, 2000). As R.J. Ericsson, an early pioneer in male reproductive research, complained, "Male contraceptive research has a dismal past. It is almost an illegitimate specialty within reproductive biology. For the most part, the brightest workers avoid it, and those who do work in the area are looked as rather strange fellows" (Hartmann, 1995, p. 179). Second was a matter of practicality: the task of inactivating the millions of sperm produced each day appeared daunting. This approach also presented more of a clinical challenge to scientists and clinicians, who could find a readier supply of women as guinea pigs for contraceptive research than of men: "women can be easily assembled for clinical studies through their association with Planned Parenthood clinics and individual obstetricians or gynecologists; there exists no simple mechanism for assembling similar groups of males for clinical experimentation" (Djerassi, 1994, p. 45). Third was a matter of demand: men at the time appeared to be averse to the idea of physical control of their reproductive systems. Pincus identified this contrast: "Male volunteers for fertility control studies may be numbered in the low hundreds, whereas women have volunteered for similar studies by the thousands….He has

psychological aversions to experimenting with sexual functions….Perhaps experimental studies of fertility control in men should be preceded by a thorough investigation of male attitudes" (Watkins, 1965, p. 194). Scientists involved in contraceptive research at the time justified the relative lack of attention to men by characterizing men's psychological frailty as a significant impediment to male contraceptive development (Tone, 2001). According to a professor of obstetrics and gynecology at the Harvard Medical School, man's "virility, sense of maleness, even his self-esteem are more closely allied to the sexual act than that of a woman...any method of contraception that diminished sperm count would create psychological problems for many men, leading to ego loss and impotence" (Kistner, 1969, p. 68). Consequently, a combination of scientific, social and cultural forces, as well as the contributions of several key figures, acted in concert to drive contraceptive research in the direction of a hormonal pill for women in the mid-20th century.

Contraception and Control

Women's enduring pursuit of a means to independently prevent pregnancy during the 20th century reflected the burden they had borne for centuries when their wishes about when and how many children to have were overridden or ignored by their male partners. The history of women's efforts to prevent unwanted pregnancies is riddled with strange and extreme measures that were often neither safe nor effective. As far back as 1850 B.C.E., recipes for contraceptive pessaries in ancient Egypt included honey, sodium carbonate, and crocodile dung. Around 900 B.C.E., Chinese women drank mercury to control their fertility, which often resulted in sterility or death. During the Middle Ages in Europe, women were advised to wear the testicles of a

weasel on their thighs or hang its amputated foot from around their necks (Planned Parenthood, 2015b). In the United States in the late 19th century IUDs became popular, yet many doctors refused to insert them unless there was "legitimate medical need," and at the turn of the century IUDs were the most painful and medically dangerous birth control method. They were bulky, large, and difficult to insert (Tone, 2001 p. 75). At a time when contraception remained largely illegal, such methods were neither easily accessible nor easily endured.

In the 1920s and '30s, a "grey" market for contraceptives flourished in the U.S. through the use of legal euphemisms. Devices and chemicals known to have contraceptive abilities such as such as douching syringes, antiseptic tampons, sponges, suppositories, and solutions were innocuously marketed as "feminine hygiene products." Before the Depression, condoms were the most popular commercial contraceptive in the U.S. By the late 1930s, sales of female contraceptive products outnumbered those of condoms five to one. Throughout this era, "contraceptives that would be almost 100 percent effective were unfathomable," and the dangers and deficiencies of these products were well known in the health community (Tone, 2001, p. 71). Manufacturers "preyed on and compounded women's fears of pregnancy to reap higher profits," and "manipulated women's anxieties to hawk goods that were useless as contraceptives and dangerous to women's health" (Tone, 2001, p. 157). Within this profitable and unfettered trade, desperate women became "the market's most reliable and, by extension, most exploited customers" (Tone, 1997, p. 213). By 1940, the commercial antiseptic douche had become the most popular birth control method in the country, and would remain the leading contraceptive until the introduction of the pill in 1960. Lysol, the most popular brand, did not prevent pregnancy, and contained ingredients which, when used in too high concentrations, caused

severe inflammation, burning, and even death (Tone, 2001). Thus, for centuries, many attempts at fertility control relied on folklore or faulty science, born out of hope and desperation. By contrast, the hormonal contraceptive technology developed in the 1950s was based upon an understanding of the physiology and biochemistry of reproduction. The advent of the pill in 1960 gave women a highly reliable way to control their own fertility for the first time in history.

Prior to 1960 and the emergence of modern, female-oriented birth control technology, other primary available methods—condoms, vasectomy, and withdrawal—were male-oriented. Though the rubber condom was first introduced in the 1850s, rudimentary versions of the condom date back thousands of years. Condoms transformed in efficacy over time with the invention of latex in the 1920s, design improvements in the 1950s, and the introduction of alternative materials in the 1990s (Khan et al., 2013). The use of vasectomy for human sterilization as part of eugenics programs dates back to the late 1890s, but the procedure came to be regarded as a method of consensual birth control during World War II (Leavesley, 1980). In general, because neither men nor women had many options prior to the pill, "no stabilized conventions existed concerning the relationships between gender identities and contraceptive use," despite the fact that those most reliable and least risky were male-controlled (Oudshoorn, 2003, p. 13). However, with the so-called "contraceptive revolution" of the 20th century primarily restricted to female methods, these relationships began to solidify (Saetnan, 2000).

The availability of higher-tech, more effective contraceptives for women qualitatively and quantitatively altered the set of alternatives from which couples could make their selections, effectively curtailing the decision-making process and altering the balance of male-female involvement in contraceptive use. Furthermore, contraceptive efforts before the pill were not

only often male-controlled, but generally had to be used at the time of intercourse or were related to the timing of intercourse. The advent of the pill, a method independent of intercourse that could be used without the knowledge, cooperation, or control of male partners irrevocably changed the link between sexuality and contraception and enabled greater user autonomy. The implementation and use of female hormonal contraceptives demonstrated that "as technologies are being built and put to use, significant alterations in patterns of human activity and human institutions are taking place" (Winner, 1986, p. 11). While the pill was liberating and empowering for women, giving them revolutionary control over their bodies and sexual lives, it simultaneously solidified contraception as a female burden and communicated to future generations of men that birth control is a responsibility outside their domain.

A Revolutionary Technology

The uniquely female desire for better fertility control was demonstrated by the rapid and widespread acceptance of the pill in the early 1960s. Within five years of approval, the pill had become the most popular form of birth control in the United States. Women rushed to their doctors actively requesting the pill, and by 1965, 6.5 million married women and hundreds of thousands of unmarried women had obtained prescriptions for oral contraceptives (Watkins, 1998). Since then, access to modern birth control has been revolutionary for women. The unprecedented ability to plan and space the birth of children has allowed them to take advantage of social, educational, and professional opportunities that unexpected pregnancies precluded, opportunities to which men already had greater access simply by virtue of being men. As Clare Boothe Luce, a renowned journalist, politician and playwright, wrote in 1969, "modern woman

is at last free, as a man is free, to dispose of her own body, to earn her living, to pursue the improvement of her mind, to try a successful career" (Marks, 2001, p. 183). Access to birth control has been tied to increased college enrollment, increases in the proportion of women in skilled careers, and increased earning power and narrowing of the gender gap in pay (Sonfield et al., 2013; Planned Parenthood, 2015a). By contrast, men's control over their own bodies, careers, and lives has never been at stake in the same way. For this reason, one potential obstacle to attracting men to new contraceptive options is that male birth control is unlikely to substantially improve a man's quality of life in the same way that it has for women.

The Male Objective

Male contraceptive efforts first emerged in the 1970s, catalyzed by two powerful social forces: the recognition of a dire need for population control in the developing world, and the feminist movement in the Western industrialized world advocating for gender equality (Oudshoorn, 2003). With regard to the former, the problem of overpopulation motivated and legitimized research into a male contraceptive just as it had done for the female pill (May, 2010). One scientist reasoned that "because of the immensity and seriousness of human population growth every avenue should continue to be explored and we should be unwise to neglect the male approach" (Oudshoorn, 2003, p. 19). This approach was advocated largely by government figures in China and India. Around the same time, women's health advocates in the U.S. vocalized the need to put men on the contraceptive agenda following criticisms of the female contraceptive pill as its health risks were publicized. The impetus to transform the contraceptive status quo thus involved two types of discourse: a population control discourse, and an

emancipation discourse. The objective was sustained by the World Health Organization (WHO), which created a special task force and formed coalitions with governments and international agencies to spur the exploratory phases of research in male contraception, with clinical trials initiated in culturally diverse populations (Waites, 2003). Interestingly, the advocates for male contraceptive development were governments, public sector agencies, and feminists—not men themselves. As Roy Greep, a leading reproductive biologist in the U.S. described, "It is the need for male contraceptives and not the demand that is expanding exponentially (Oudshoorn, 2000).

The inclusion of men in family planning policies and programs was more explicitly emphasized following the 1994 International Conference on Population and Development in Cairo and the UN's Fourth World Conference on Women in Beijing in 1995. The official policy of government agencies and nonprofit organizations around the world has since been to encourage men's involvement in birth control and safer sex practices in order the promote the rights of both women and men to regulate their fertility and have sexual relations free from fear of unwanted pregnancy (Gutmann, 2007; Solomon et al., 2007). However, despite the recognition of this issue, little headway has been made in significantly boosting men's participation in this realm.

The Forgotten 50% of Family Planning

Historically, family planning efforts and reproductive health initiatives have typically focused on women. In public health and in academic studies, the terms "reproductive health" and "reproductive rights" generally refer to the health and rights of women. By contrast, issues of men's reproductive health, when raised, usually refer to problems of the male organs or to

sexually transmitted infections. On the whole, the implicit assumption has been that men are neutral or begrudging partners in birth control utilization, "generally reluctant to share responsibility for preventing pregnancy from occuring during their few seconds of ejaculation," and for this reason have received minimal attention (Gutmann, 2007, p. 100). The absence of men from the history of family planning is customary in academic disciplines that have pioneered research in reproductive health. Men are moreover remarkably missing from reports and teaching materials produced by governments, international health agencies, and family planning associations. Through these systematic omissions, the formation of a "female contraceptive culture" and the expectation that men will not participate in family planning have "become a self-fulfilling prophecy" (Gutmann, 2007, p. 116; p. 101).

As the middlemen between producers and consumers, policymakers and service providers have played a key role in shaping fertility control as a woman's domain by facilitating the integration of contraceptive technologies into society and enforcing their use. By determining an existing product's availability to its potential user base, these "middlemen" are partially responsible for shaping user expectations and beliefs surrounding contraceptive use. Most obviously, policymakers and service providers control physical access to a method through public policy decisions, spread of information and education materials, and physical existence and location of services (Ringheim, 1993). Moreover, research in developing countries in particular has shown that the personal attitudes that service providers form through training can be passed on to clients, and can strongly influence perceptions of method acceptability (Ringheim, 1993). In general, the medical endorsement of female responsibility and innate male disinterest has encouraged the nearly exclusive targeting of women in professional guidance with

respect to birth control practices (Gutmann, 2007). Because women are systematically confronted by health personnel about birth control in ways that few men experience, unequal gender scripts are institutionally reinforced through these clinical encounters.

That being said, it is increasingly being recognized that in both developed and developing countries, the prevailing family planning emphasis on women as the key figures in contraceptive decision making often excludes men in a way that imposed burdens on both men and women. Family planning services and clinics have been largely set up to serve women, and men may find it difficult to utilize them. A free general health, birth control, and sexuality counseling center for men that opened in the 1970s in San Francisco was believed by its staff to be the only one of its kind in the United States at the time, and highlights the need for changes within healthcare infrastructure to accommodate evolving social demands. The director of the clinic's family planning program noted that she and other professionals had begun to notice more men accompanying their partners to family planning clinics, yet "there were no services provided for men—staff had more than enough to do taking care of women's concerns—and there was no literature for them to read while they waited….The men got left sitting out by the elevator looking uncomfortable" (Stix, 1977). While the focus on women in the promotion of family planning and reproductive health is warranted for a number of reasons which have I already identified, the complete neglect of men's roles in contraception represents a missed opportunity for the type of professional structure and guidance that could prove crucial to facilitating widespread use of a new male birth control method. Ringheim (1993) maintains that technological "failure should not be attributed to cultural bias until access to the method is observed to be easy, and appropriate education and information channels have been used to best

effect" (p. 88). As demonstrated by the lack of access to services and educational information for men, as well as the physical absence of spaces for male involvement, it is evident that the idea that men have both a right and a responsibility to participate in family planning is not yet widely accepted.

Changing the Dominant Cultural Narrative

The idea that women were responsible for contraception thus became the dominant cultural narrative as it materialized in available technologies, social movements, and public objectives during the 20th century. As a result, the emphasis on women has become embedded in the institutional frameworks of science, medicine, and pharmaceuticals. The potential introduction of new male contraceptive thus relies not only on technological capabilities but intentional efforts to reshape contraception as a shared domain, one which facilitates the inclusion of men in these conversations and practices. In the face of such a task, we must ask whether men are open to such an opportunity.

Chapter 2: Gender Roles and The Consumer Perspective

Gender Performance, Masculinity, and Contraceptive Norms

Through the continual use of technologies, our individual habits, concepts of self, perceptions of the world, and social relationships, are powerfully molded, becoming so deeply ingrained that the "recurring patterns of life's activity" that they facilitate "tend to become unconscious processes taken for granted" (Winner, 1986, p. 7). In the past century, the design and availability of contraceptive technologies have created a clear gender script, one which is now often taken for granted: responsibility for contraception and its risks is relegated primarily to women, not to men.

As we consider possibilities for technological change, we must pay attention to the ways in which this gender script can be written. This task entails the mutual adjustment of technologies and user identities: "without a technology there are no users, and there are no users without a technology" (Oudshoorn, 2003, p. 12). Ever since the demand for new male contraceptives was articulated, people have wondered whether men would use such a method if it became available. Indeed, technologies only work if they are accepted by users and assimilated into society. Some have argued that ensuring the success of a finished product is a more likely challenge than its initial creation: "there is nothing inherently difficult about finding chemicals to inhibit male reproductive capacities…[but] will they use it? Will men, even in a pill-popping society like ours, take to taking the pill?" (May, 2010, p. 111). In the process of developing a new technology, designers must therefore anticipate the motives, preferences, tastes, and competencies of potential users, and must inscribe the views and tendencies of these users into the design of the new product (Oudshoorn, 2003). In recognizing the cultural embeddedness of

technology, we must acknowledge the role of cultural norms in shaping the behaviors and expectations of technology-users, and in the case of contraceptives, those norms as they pertain to gender roles.

Considerations of the internalized expectations about what behaviors are appropriate for one's gender are crucial to include in anticipating the needs and behaviors of technology-users. To examine the relationship between technology and gender identities, philosopher Judith Butler's conceptualization of gender as performance provides a useful approach (1988). According to Butler and other feminist scholars, gender is not something we are, but rather something we do. In this view, gender is not predetermined or fixed, but rather reproduced through the "stylized repetition of acts" (p. 519). In other words, gender can be understood as "the mundane way in which bodily gestures, movements, and enactments of various kinds constitute the illusion of an abiding gendered self" (p. 519). Butler argues that a set of historically perpetuated and "punitively regulated cultural fictions" inscribe in us the belief in our own gender's naturalness (p. 522). Because we support these fictions with the choices we make on a daily basis, the ways that we as individuals conduct ourselves in society yield opportunities to either reproduce existing meanings of gender or create new meanings.

In the context of technological innovation, we must examine the ways in which technological artifacts and their uses play a role in stabilizing or destabilizing conventions of gender, and reinforcing or transforming gender performances. This being said, the relationship between technology and its users is a reciprocal one. Not only does the introduction of new technology have the potential to transform existing gender norms, but current gender norms play a pivotal role in determining what technology is produced in the first place, and further, whether

or not it will succeed. Thus, gender and technology can be viewed as mutually constitutive, or continually co-produced (Oudshoorn, 2003). In the case of contraceptive technology, the historical trajectory of technological development and the consequent socialization of reproductive behavior demonstrate the way in which technological innovation has the power to regulate and stabilize the gender performances to which Butler refers. As contraceptive responsibility became strongly aligned with traditional femininity, it simultaneously became excluded from the category of hegemonic masculinity. This notion has been perpetuated by subsequent efforts in contraceptive development, or rather the lack thereof.

The development of new contraceptives for men thus requires the destabilization of conventional understandings and performances of masculinity. Oudshoorn (2003) asserts that "the construction of masculinities is at the forefront of the design" of socially and culturally feasible contraceptive technologies (p. 16). This recognition is crucial, for a commonly cited justification for the scarcity of male contraceptive methods is an apparent lack of consumer demand, based on the perception that men are not interested in or willing to use such technology. Grady et al. (2010) suggest that traditional beliefs about sex roles within a heterosexual relationship may be associated with the division of decision-making power into male and female "spheres of influence," with contraception falling within the woman's decision-making domain. Much of the perception that men will not be interested in added contraceptive options relies on ideas about appropriate gender enactments in the context of sex, and the idea that broaching an issue generally perceived as a "women's topic" would violate traditional masculine sexual scripts. Sexual scripts, understood in psychology to be the cognitive schema for how sexual

interactions should unfold, are highly gendered, and mirror notions of traditional, hegemonic ideologies of femininity and masculinity (Masters, 2013).

According to the traditional masculine sexual script, men's bodies come preloaded with strong sexual urges that make them relatively unconcerned about risk and long-term consequences, tend to value sex more than relationships, and are more oriented toward sexual variety. The complementary traditional feminine sexual script suggests that women are less desiring, more concerned about risk, more relationship-oriented, and less interested in variety (Masters, 2016). Individuals typically subscribe to sex-role stereotypes and conform to the behavior dictated by them in order to affirm their own masculinity or femininity. Traits that are thought to conform to the stereotypical performance of masculinity include aggression, impulsivity, and phallic assertiveness in pursuit of sexual gratification, regardless of the consequences (Weinstein & Goebel, 1979). It has moreover been historically observed that men tend to be more pronatalist than women, though evidence is mixed with respect to this assumption, and modern data points to similarities in desired family size between men and women (Greene & Biddlecom, 2004; RamaRao et al., 2008).

According to this portrayal of masculinity, there seems to be no place for the behaviors and attitudes required to assume greater contraceptive responsibility. Effective fertility control requires "patience, punctuality, tolerance of adverse effects, and responsible behavior" (Ringheim, 1996). In family planning efforts in many countries, it has been assumed that men have to be "thwarted from their preordained natural tendencies" (Gutmann, 2007, p. 113). One survey of 150 men in the San Francisco Bay Area demonstrated the relationship between stereotypically masculine characteristics and contraceptive behaviors and attitudes (Gough,

1979). The results of this study, which took into account reports from men's spouses and interviewers, suggested that husbands who expressed doubts about using a male contraceptive pill were were seen by wives as forceful, dominant, and aggressive. They were more often characterized by interviewers as power-oriented, masculine in style and behavior, outspoken in giving advice and stating personal opinions, and moralistic in regard to values. By contrast, men who expressed greater willingness to use a male pill were less likely to show condescending behavior in relations with others, less dogmatic and less forceful in asserting beliefs and opinions, more open to change, more likely to appear to observers as introspective, and more attentive to the feelings and wishes of others.

Evidently, the construction of new gender norms that would be more conducive to male contraceptives cannot be accomplished without devoting greater attention to current male ideologies surrounding reproductive responsibility. It has been suggested that placing contraceptive control almost exclusively in the hands of women, despite its obvious benefits to women, may have also had some drawbacks in its cultural implications (Darroch, 2000). As women gained control of contraception, men were distanced from method choice and use. While some were likely glad not to bear the weight of this responsibility, others may have felt excluded by women who saw fertility control as their sole prerogative. Either way, men have come to be regarded as "important economically but as typically uninvolved in fertility except to provide sperm and to stand in the way of contraceptive use" (Greene & Biddlecom, 2004, p. 7). With continuing patterns of disproportionate maternal responsibility for child rearing,"men are typically less connected to and less likely to take responsibility for the health and safety of fetuses and children" (Solinger, 2013, p. 141). Consequently, some men appear unaware of the

extent to which their personal well-being is depends upon the contraceptive responsibilities regularly taken on by women. A recent national survey found that more than half of American men don't believe they have benefited personally from women having access to affordable birth control (PerryUndem, 2017). While this response was less common among younger age groups, this data suggests that a remaining obstacle to male involvement in contraception may be the failure for them to comprehend the full weight of women's current contraceptive burden and its direct significance to them as men.

This idea that fertility control is outside men's realm of control has moreover been perpetuated by the systematic neglect of men in reproductive research, as demonstrated by the fact that demographic studies have tended to focus on women alone. Indeed, most analyses of the contraceptive decision making in which couples engage are based on the reports of only one partner, usually the woman (Grady et al., 2010; Greene & Biddlecom, 2004; Gold & Berger, 1983). Because of their necessarily greater investment in fertility control, women's knowledge and use of contraceptives has been seen as more relevant than male knowledge and use (Hulton & Falkingham, 1996). Greene & Biddlecom (2004) argue that despite the increasing inclusion of men in fertility research, studies of their reproductive attitudes and behaviors are still dominated by an overly "problem-oriented approach," through which men are typically considered obstacles to women's reproductive health rather than potential assets (p. 20). This approach fails to recognize the presence of a growing population of men who would be receptive to greater participation in contraceptive decisions and practices.

Perceptions of Responsibility

Despite their relative neglect when compared to the vast body of female-focused research, a number of studies have been conducted to assess attitudes toward male contraceptive responsibility and interest in prospective technologies. These studies have, for the most part, pointed to changing perceptions of contraceptive roles as more egalitarian views gain prominence. Studies assessing theoretical interest in, as well as actual satisfaction with, experimental methods, have demonstrated that a majority of men believe contraception is a shared responsibility and a significant proportion in both developed and developing countries are receptive to assuming greater responsibility (Gough, 1979; WHO, 1982; Grady et al., 1996; Solomon et al., 2007; King et al., 2016; Ipsos, 2017; Male Contraceptive Initiative, 2019).

Prior historical shifts in gender expectations have already demonstrated that such norms are transient and are shaped by their contemporary cultural context. At the onset of the 20th century, for example, the Victorian ethos of male self-control yielded to new ideas and institutions that "took male sexual activity for granted" as an uncontrollable force (Tone, 2001, p. 106). The turn of the 21st century has likewise been accompanied by a gradual and generational shift in commonly held beliefs regarding the duties of men in marriage, childbearing, and rearing. Sociologists Marsiglio and Menaghan predicted several decades ago that this liberalization of gender role expectations would likely facilitate increased male involvement in contraceptive responsibility (1987).

Indeed, social scientists have noted a shift in men's attitudes and perceptions of the impact of their roles and behavior on their partner's health, particularly among young men (RamaRao et al., 2008; May, 2010). Merkh et al. (2009) concluded from an interview survey of

young men in heterosexual relationships that although these men believed birth control decisions were ultimately a woman's to make, they also viewed discussion of contraception as a potential relationship fortifier and a part of men's contribution to pregnancy prevention, suggesting an interest in greater participation. According to a recent online survey conducted by the global market research firm Ipsos, nearly nine in ten Americans who identify as heterosexual believe that men and women have equal responsibility for birth control in a healthy relationship. The vast majority of respondents (89%) disagreed that a man who takes a male contraceptive is "less of a man." However, a quarter of male respondents expressed concern that women would think less of them as men, and 29% stated that taking a male contraceptive would make them feel less masculine (2017). These results reflect that men's theoretical willingness is likely to be complicated by certain concerns surrounding method acceptability, which I will discuss in the following section.

Several studies have shown that more egalitarian sex-role beliefs are related to a greater likelihood of male pill usage (Marsiglio, 1985; Marsiglio and Menaghan, 1987). Moreover, demographic characteristics that have proven to be important predictors of a willingness to consider male contraceptive use include educational attainment, income level, and current use of contraception. Men who are younger, more affluent, more highly educated, and more familiar with comparable female methods appear most likely to believe that men should bear some contraceptive responsibility in a relationship and more willing to use a hormonal contraceptive (Heinemann et al., 2005; Martin et al., 2000; Weinstein & Goebel, 1979; Ipsos, 2017). However, one caveat of many of these studies is that these men's responses reflect ideology rather than true actions in their own relationships. That is, intention does not necessarily predict behavior. Thus,

men's apparent willingness to use a male hormonal contraceptive should be interpreted cautiously, given the commonly observed discrepancy between beliefs, attitudes, and intentions with respect to actual behavior (Marsiglio & Menaghan, 1987; Ringheim, 1993).

However, a number of men have lived up to their professed intentions through participation in any of the clinical trials that have intermittently emerged over the past several decades. Some simply consider themselves a more egalitarian breed of men, making statements such as: "I think men have been allowed to be lazy about all this"; "A man should have 50 per cent of the responsibility. This attitude is becoming more common. Women are not objects. They're the same as us. We're equals"; "My way of thinking is, once she's taken the risk for a few years, I'll take it...you halve the risk" (Ringheim, 1996, p. 87). Meanwhile, others seem motivated more by guilt than an intrinsic belief in equality. Ringheim (1996) interviewed one man whose clinical involvement was born out of a sense of obligation to relieve his partner from an evident burden:

> "Quite honestly, I never would have volunteered if my wife hadn't complained. My motto is: 'If it isn't broken, don't fix it.' I think most men are only too happy to have women use contraception. We know they have problems sometimes. Why would we want to share in that?" (p. 86)

Some in committed relationships may feel the need to make up for their own powerlessness in the face of their partner's suffering; the female partner of another trial participant noted that

> "He was very considerate when I used to have the migraines and I was banging my head against the bed. He said: "What can I do?" Just go away and leave me alone. I just want to die. He was always very sympathetic, but there was nothing he could do." (p. 81)

For men who express a willingness to take on greater contraceptive responsibility in preliminary studies, the motivations for doing so appear to vary, as evidenced by these interview samples.

Perceptions of Acceptability

In addition to perceptions of responsibility, acceptability plays a significant role in determining the likelihood of men's utilization of a new contraceptive method. Acceptability of a contraceptive method refers to how well, given existing choices, the method meets user preferences. Even if men theoretically hold egalitarian views of sex roles and agree that women should not bear the burden of contraception alone, their use of a technology in practice will be based on the acceptability of the method.

King et al. (2016) discuss the use of the health belief model (HBM), a psychological model that can be used to predict contraceptive behavior, and which provides a useful framework for anticipating men's attitudes toward a potential new male contraceptive method. The HBM is comprised of five primary constructs: perceived susceptibility, severity, benefits, barriers, and self-efficacy. The model posits that to be motivated to use contraception, an individual must consider himself to be susceptible to pregnancy (perceived susceptibility), believe that the pregnancy has potentially serious consequences (perceived severity), understand that the negative consequences of pregnancy are avoidable through effective use of contraception (perceived benefits), and believe that he is able to perform contraceptive behavior (self-efficacy). These factors are weighed against the costs of using contraception (perceived barriers) (King et al., 2016). Evaluation of the costs of contraception includes the convenience of obtaining and using a method and the safety and side effects associated with the method.

Personal convenience and physical satisfaction remain key considerations in the cost analysis of contraceptive acceptability for many men. Studies have found that a daily oral pill is commonly viewed by men as the most desirable method, followed by a monthly or several-monthly injection (WHO, 1980; Weston et al., 2002; Heinemann et al., 2005; Martin et al., 2000). Concerns about pain or the hassle of a regular regimen would thus be weighed against the downsides of condom use, of which the most commonly reported concerns include embarrassment and reduced sexual pleasure (Grady et al., 1993; Pleck et al., 1991; Institute of Medicine, 1995). One hormonal contraceptive trial participant explained his involvement as motivated by the lack of satisfactory alternatives: "[my partner] had an infection and then I sort of looked at the alternatives or rather the lack of alternatives, and thought, 'No, thank you,' because we were not using condoms, which you don't more often than you do, let's be honest" (Ringheim, 1996, p. 81). Such determinations are thus relative, conditional, and utility-driven, and men and women appear to employ different criteria for method acceptability in practice.

This remains particularly true with respect to weighing perceived costs against the perceived susceptibility and severity of pregnancy and its consequences. One edition of *Population Reports*, a Johns Hopkins University journal, recognized this inherent discrepancy, portraying a pregnant man with the text: "Would you be more careful if it was you that got pregnant?" (Gallen, Liskin, & Kok, 1986, p. 889). With the revolutionary control that modern contraceptives have given women over their bodies, women continue to make trade-offs for the sake of having the safe and independent sex life that men have generally been afforded. Moreover, aside from the clear social, economic, and health benefits of being able to choose whether and when to become pregnant, female hormonal contraceptives can provide

noncontraceptive benefits such as the improvement of menstrual patterns, alleviation of menstrual pain, and reduction of acne (American Society for Reproductive Medicine, 2011). Women are therefore often willing to tolerate the drawbacks of contraceptives.

By contrast, Brooks (1998) found in a survey that while a male pill was overwhelmingly ranked as the preferred choice for a new contraceptive method, over 70% of those questioned indicated that they would not tolerate any possible side effects. In the survey by Ipsos, which similarly demonstrated overwhelming male and female interest in a male contraceptive, women believed that men would be willing to tolerate minor side effects such as injection site pain, weight gain, and mood changes more than men reported themselves willing to be (2017). One male participant in a clinical trial stated: "Most of my male friends thought it was a good idea but when I actually told them what it involved—an injection once a week—they said: 'Well, she can stay on the bloody pill!'" (Ringheim, 1996, p. 87). These findings and personal accounts suggest that men are unlikely to tolerate the same drawbacks that women routinely do, for they lack that urgent need for better methods that once contributed to the rapid and widespread uptake of the female pill. One female editorialist highlighted this obstacle: "[a man] can already avoid unwanted pregnancies if his partner is on birth control; with his own he'd get the same advantages, except now he might have mood swings" (Beck, 2016). The historical record of contraceptive development has made clear the extent to which differences in acceptability are grounded in the different stakes of unintended pregnancy, which I will discuss later in greater detail.

Fertility, Virility, and Manhood

One of the central determinants of male contraceptive acceptability from the perspective of both users and researchers is a method's impact on male sexuality and sexual function, which factor heavily in historical and cultural expectations about what truly defines a man. Reluctance toward male contraception may in part be rooted in the corporeal association of manhood with virility and fertility. This association was recognized as an important consideration during the development of early hormonal contraceptives. One psychoanalyst warned in 1966 that a man's ability to impregnate unimpeded by technology was critical to his identity, stating that "for a lot of men, masculinity is a purely physical matter…[seen] in terms of what they can do to women" (Tone, 2001, p. 252). In 1968, a Merck researcher remarked that "the most difficult obstacle, perhaps, to a 'male' approach is the 'emotional-psychological' factor. The delicate male psyche equates virility with fertility, and it is believed that extensive education would be required to get men used to the idea of a 'male' contraceptive" (Tone, 2001, p. 252). From the initial stages of modern contraceptive design, assumptions about the innate value of male sexuality disqualified them from being able to "handle" hormonal contraception.

Conventional wisdom treats male sexuality as a "totemic illusion, such that male sexuality became naturalized as both a fixed entity and as something entirely distinct from female sexuality" (Gutmann, 2007, p. 131). Balswick (1972) similarly theorizes that some men may feel that tampering with their own reproductive system violates their sexuality more so than it does for women. He suggests that sterility in a man may be viewed subconsciously as a sign of feeble masculinity or virility, while in a female it is seen solely as an inability to conceive, and quite unrelated to her femininity. In the United States, for example, female sterilization is

currently twice as prevalent as vasectomy, despite the fact that vasectomies are equally effective, less invasive, and carry a lower risk of complications (United Nations, 2015b; Watkins, 2012; Caron, 2019). In a survey of the attitudes of lower-class men toward taking a male contraceptive pill, Balswick (1972) found that the second most common reason given for objecting to a male pill, after the fear of harmful effects, was that "it is against nature" (p. 197). This response suggests that a man's reluctance to hormonal manipulation may extend beyond reasoned objections and rely more upon an instinctual aversion to inference in his bodily integrity. One male contraceptive technology in the early stages of development is the so-called "clean sheets pill," a drug that would produce a semen-free orgasm, effectively eliminating the physicality of ejaculation. If the exhibition of fertility remains a crucial aspect of the masculine image, the cultural feasibility of methods such as this will have to be investigated. Considering such meanings, it is possible that tampering with a man's reproductive potential, despite its reversibility, may be viewed by some as emasculating.

It should be recognized that meanings of sexuality and masculine identity are not only performative but culturally specific, and their significance may differ between populations. For instance, Carl Djerassi, a chemist best known for his work in steroid chemistry, a key contribution to the development of oral contraceptive pills, suggested that in Latin America "the concept of 'machismo' and the preoccupation with potency would make it very unlikely that such a male Pill would find significant acceptance unless it could be claimed...that it also improved sexual performance" (1994, p. 69). Szasz (1998) reviewed a number of studies to explore this meaning among Mexican men, arguing that sexual prowess is viewed as a means to prove masculinity and the fathering of children has long been the emblem of manhood,

especially if a man lacks economic resources. Signs of sexuality such as “erections and penetration are considered the most valuable forms of male sexual expression; the male genitals represent courage, pride, arrogance, strength and well-being” (p. 97). Culturally, there exists a contempt for weakness and passivity, which is considered effeminate. Szasz posits that these meanings may contribute to low use of contraception. Balswick (1972) makes a similar point with regards to socioeconomic status, suggesting that fears of emasculation may be heightened in populations that have historically held a lower status, and that an individual might feel he was being “asked to deny a masculinity which he feels he has never had” (p. 198). Theories such as these suggest that acceptability of male contraception will likely differ between populations. Martin et al. (2000) conducted a multi-center study to assess men's attitudes to proposed novel hormonal methods, in which 44–83% of men in Edinburgh, Cape Town, Shanghai and Hong Kong stated that they would use a male contraceptive pill. This percentage range reflects the fact that method preference and willingness varied greatly between countries, similarly indicating that a culturally-specific lens must be applied when forming new visions of masculinity.

Researchers agree that for a potential male contraceptive method to be acceptable to men, it is essential to ensure that libido, an androgen-dependent phenomenon, is not impaired. Indeed, studies of acceptability of hormonal contraceptives have reported a consensus among potential users that noninterference with sexual functioning is an important factor, along with safety, efficacy, and reversibility (Davidson et al., 1985; Martin et al., 2000; Ipsos, 2017). Because hormonal contraception alters the secretion of male sex hormones responsible for such functioning, users’ concerns about sex drive and performance have been considered amply in design of contraceptive technology. The value placed on men’s sexual well-being has already

been made visible in the development of male condoms, which have been continually improved to maximize sensation and thus pleasure. The disproportionate attention paid to male sexuality in biomedicine was emphasized by the launch of Viagra in 1998 for erectile dysfunction, which, despite a sizeable list of potential side effects, was immediately and widely successful: "Apparently, a pill that enhances the potential for men to impregnate women is considerably more marketable than one that diminishes that possibility" (May, 2010, p. 116). The approval and success of Viagra in contrast to the absence of hormonal contraception indicates that in the field of reproductive medicine, priorities for men and women vastly differ.

Although hormonal manipulation has the capacity to affect sexual function in both men and women, this concern has merited significantly greater consideration in formulations for men than in those for women. Few studies have explored current female methods' effects on women's libido or enjoyment of sex. Current available data suggest that the pill may alternatively increase or decrease libido, although most women are not presented with this information (May, 2010). The inattention to how women's contraceptive methods affect female sexuality is striking when juxtaposed with the attention such an issue receives with regard to hormonal methods in development for men. This asymmetrical attention paid to sexuality may in part reflect the real and differing priorities of men and women in obtaining birth control. It has been observed that while men's concerns typically revolve around how it might affect sexuality and intercourse, women's concerns about hormonal contraception typically revolve around emotional and physiological side effects (RamaRao et al., 2008). Despite this, the hyper awareness of male sexuality in medical interventions in the male reproductive body, in contrast to the minimal

consideration given to the female body, is just one way in which prospective male hormonal contraceptives will face greater scrutiny than their female counterparts.

Partner Dynamics and the Influence of Trust

Contraceptive behaviors and decisions, however, can never be fully captured by characterizing the individual user alone. Studies have emphasized the importance of the attitudes and preferences of the female partner in contraceptive decision making. Real or anticipated endorsement by a female partner is a powerful predictor of male inclination to consider contraceptive use, and encouragement by female partners has been observed to positively influence men's willingness to volunteer for clinical trials (Martin et al., 2000; Ringheim, 1995). The degree of trust and the desire for personal reproductive control shape the ways in which contraceptive use is negotiated between partners. Because contraceptive failure has far greater personal consequences for women, method efficacy is generally of greater salience to them. Nevertheless, it has been observed that despite the greater risks associated with pregnancy and the greater personal investment, female compliance with daily oral contraceptive regimens, as well usage of other hormonal methods such as the hormonal vaginal ring, is “remarkably uneven,” which for many women reduces their contraceptive efficacy from 99% to approximately 91% (Planned Parenthood, n.d. (a)). This gap between theoretical and real protection in women’s typical birth control practices raises the question of whether compliance would be even worse among men, for whom the consequences are less direct (Potts, 1996).

Any discussion of the acceptability and use of a male hormonal contraceptive therefore necessitates consideration of whether women would trust their partners to use a method with a

rigid regime reliably, particularly a method that cannot be verified in the moment. For this reason, “prospects for new methods for men probably hinge as much, if not more so, on how they are perceived by women” (Ringheim, 1996). To address this factor, Glasier et al. (2000) surveyed nearly 2,000 women attending family planning clinics in Scotland, China, and South Africa, and found that a majority of women felt that the responsibility for contraception falls too much on women. Glasier et al. found that despite differing cultures, beliefs, and personal contraceptive experience, more than two-thirds of the women thought that male hormonal contraception was a good idea, and only 2% of respondents reported that they would not trust their partner to use hormonal contraception. It was concluded that “on the whole, many women have rather cynical views of men in general which do not reflect their views of individual men—especially their partner” (Glasier et al., 2000). In another questionnaire, women acknowledged that “in a trusting relationship, either partner can be counted on to use contraception,” however “You’d never trust trust a man that you’d just met. You’d laugh, wouldn’t you? ‘Show me your certificate or show me some documentation that you’re using contraception’” (Ringheim, 1996, p. 84-5). This distinction between the high level of trust between individual partners and the lack of confidence in men as a broader population challenges the popular assumption that women are not willing to share the responsibility, and that men cannot be trusted.

There does, however, appear to be some discrepancy in the confidence that men and women might feel in their partner in a situation of shared contraceptive responsibility. Eberhardt, van Wersch, & Meikle (2009) similarly assessed men's and women's attitudes toward the male contraceptive pill and their trust in the effective use of the male pill using a self-administered

questionnaire in England. They concluded that while both genders had favorable attitudes towards the male pill, women had a more positive attitude than men, but less trust that it would be used effectively by men. Interestingly, Ringheim (1996) interviewed some men who raised the issue of trust from an alternative perspective, suggesting that because a man could unwillingly and unknowingly impregnate a woman who took sole responsibility for reliable and effective contraceptive use, he might in fact prefer to rely on himself. Such an opportunity might be attractive to single or non-monogamous men seeking greater personal contraceptive control. Overall, however, studies have found that men in stable sexual relationships were generally more positive about the male pill than those in casual sexual relationships (Eberhardt, van Wersch, & Meikle 2009; Ipsos, 2017). The survey conducted by Ipsos indicated that many men and women believe that male contraceptives could enhance intimacy by reducing stress related to pregnancy risk (2017). The importance of trust in contraceptive use suggests that the target demographic for non-barrier male contraception would be men in stable, monogamous partnerships, for it remains questionable as to what extent women would be willing to rely on men's use of a systemic, undetectable method except in the context of a long-term committed relationship. The focus on this particular consumer base is further supported by the inability of hormonal contraception or other non-barrier methods to protect against sexually transmitted infections (Ringheim, 1993). The results of these studies overall confirm that gender, relationship type, and trust in the effective use of contraception influence attitudes towards a long-acting male contraceptive.

Beyond Social Transformation

As demonstrated in studies conducted over multiple decades around the world, there is mounting evidence that men are willing to play a more active role in in contraceptive efforts than that assigned to them in traditional family planning schemas, whether motivated by a belief in gender equality and fertility control as a shared responsibility, a sense of obligation to lift the burden from their partners, or a desire for control over their own reproductive body. While general reluctance appears to be declining, it should be acknowledged that not all men can be expected to support such a shift, and those who express theoretical interest may not be willing to venture far beyond their comfort zone. However, Ringheim (1996) points out that, as with all instances of social change, the "early adopters" of a technological innovation are a select group, and may not represent the population as a whole, "yet their motivations, interest and enthusiasm may portend a broader social revolution" (p. 80). In order to foster the cultural conditions in which a new male contraceptive is viewed as a potentially viable and worthwhile objective by those who can create such a product, we must ensure that consumer interest is vocalized.

Moreover, in order to foster the cultural conditions in which such a technology would succeed, we must encourage the gradual shifts that have been taking place in recent decades. Solomon et al. (2007) suggest that efforts to bring men into the contraceptive world on a broad scale through the restructuring of gender norms may benefit from the language of "male transformation" rather than "male involvement," as this terminology challenges men to drastically reorient their understandings of their masculinity (p. 3). This may be slowly working. In the wake of the feminist challenge to traditional gender norms, "a new concept of manhood that includes qualities of caring and taking responsibility has eroded earlier attitudes that equated

masculinity with sexual conquest" (May, 2010, p. 112). Moreover, a greater emphasis on the importance of male participation in fertility control has the potential to erode reluctance surrounding the personal inconveniences of contraceptive use, for a "strong motivation to limit fertility increases the willingness of individuals to use a method; the weakly motivated are more difficult to satisfy" (Ringheim, 1993, p. 93).

However, while the transformation of sociocultural norms will prove essential to the integration of a new male contraceptive, consumer interest must be matched by a viable product. Currently, men have limited options for greater participation, and have relatively little knowledge of what could potentially be made available. We must therefore assess the possibilities for turning this demand into a reality by examining the scientific feasibility of this task.

Chapter 3: Scientific Feasibility and The State of Research

Inherent Biological Challenges?

Some researchers and other key figures have invoked biological rather than psychological explanations for the asymmetry in available contraceptive methods, and the preponderance of female methods has been attributed to "nature," rather than to a "male conspiracy" (Tone, 2001, p. 253). It has been argued that due to fundamental differences between male and female bodies, the male reproductive system by nature is more resistant to intervention than that of women. While medical and philosophical ideas that the female body is closer to nature have been propagated in various forms for centuries, scientific understandings of the male body have identified certain physiological challenges. Several general approaches to male contraception have so far guided research in the field: Research has focused on alternatively inhibiting sperm production, interfering with sperm maturation, or inactivating or blocking sperm once it is produced. Substantially more work has been done on the first approach, primarily through hormonal interventions analogous to those employed in female hormonal contraceptives. However, several key differences between the male and female reproductive body present unique challenges in translating the techniques utilized in female reproductive technology to a viable male version.

To begin with, the constancy as well as the sheer volume of sperm production appear to make it a daunting target for intervention in comparison to the cyclical and limited nature of the female reproductive process. A woman is born with a finite number of immature eggs, of which the vast majority will decline in quality over her lifetime. By the onset of puberty, only about 300,000 remain, of which only approximately 400 will ever mature and be released during a

woman's reproductive lifetime ("Female Reproductive System," 2012). Female hormonal contraception works primarily by inhibiting ovulation, which occurs once a month and entails the release of a single egg. Oral contraceptives contain synthetic sex hormones, either a combination of estrogen and progestin or progestin alone. The administration of synthetic hormones works to stabilize hormone levels within the female body, preventing the spike in estrogen that usually occurs midway through the menstrual cycle and sets off a chain of signals that lead to ovulation. Without this spike, ovulation is prevented and no egg is released to be fertilized. The hormones additionally thicken the cervical mucus, incapacitating sperm within the female body. The birth control patch, vaginal ring, implant, shot, and hormonal intrauterine device all function in similar ways, delivering low doses of hormones over time. These methods may be used for years at a time, with fertility in women generally ceasing around the age of 45 (CDC, 2017).

By contrast, contraception in men requires intervention in the production of large numbers of sperm cells that are produced daily throughout a man's lifespan, with no period during which sperm production stops. The average male produces 1,000 sperm per second, and will produce more than 500 billion sperm cells over a lifetime (White et al., 2013). On average, men release about 180 million sperm every time they ejaculate, and it takes a single sperm to fertilize an egg (SciShow, 2018). Some reproductive scientists argue that it is much easier to control a single monthly event such as ovulation than to prevent the constant mass production of sperm. Interestingly, the same biological insights have been used to justify opposing viewpoints. Others have argued that the very qualities that seem to present challenges may in fact make the male reproductive system easier to manipulate:

> "There is no evidence that it is more difficult to prevent 'billions' of sperm from being produced, or acting, than one egg. The difference is not the numbers produced, but the discontinuity of egg production in the female and the continuity in the male. In many ways, it is easier to target a continuous process" (Schwartz, n.d.).

However, an argument on the basis of numbers does not fully hold up, for the thresholds of contraceptive efficacy differ greatly in male and female bodies. In male bodies, with densities above 15 million sperm per milliliter of ejaculate considered to be normal, the current consensus is that lowering the sperm count below one million per milliliter, still seemingly a large amount, is a significant enough inhibition spermatogenesis to provide reliable contraceptive efficacy, reducing fertility by 99% (Mayo Clinic, 2018; Kean, 2012).

In addition to key differences in quantity of production, some have highlighted variations in the stages of each process, explaining that "the number of 'vulnerable links' in the female chain of reproductive events was greater, rendering the woman a more suitable subject of contraceptive research" (Tone, 2001, p. 253). In this view, the male reproductive system is less complex yet more difficult to suspend:

> "Is the failure thus far to find a new male method comparable to the pill indicative of male disinterest in women's well-being? I don't think so. The simple fact is that the number of targets...is far more limited in males than females….Even the forces of women's liberation cannot change the fact that the reproductive analogies between male and female end with sperm transport and egg transport, and that all subsequent events potentially subject to controlled interference occur only in the female." (Segal, 1972, p. 21-22)

If male and female reproductive processes function so differently, it must be asked why we continue to pursue a male pill to mimic the activity of the existing female pill. Some of these views have become antiquated as endocrinology advances, and biologists have pointed to similarities in the hormonal regulation of the reproductive system in males and females, identifying similar potential targets of intervention. In addition, these contradictory views on the feasibility of contraceptive mechanisms illustrate the interpretive flexibility of biological facts, as a result of which the same biological phenomena may be interpreted as either facilitating or constraining the possibilities for intervention in the male reproductive system.

If the constant production of sperm can successfully be inhibited, the delayed effect of such inhibition presents a remaining issue. Spermatogenesis is an approximately 70-day process, with the result that male hormonal contraceptive would take several months to become effective, with a similarly long period needed to regain sperm function after ceasing the method. It has been recognized that such a delay would likely be deemed inconvenient and disfavored in comparison to the relative expediency of female contraception (Taylor, Aldad, & McVeigh, 2012). It is, by contrast, fairly easy to use a low dose of hormones to fool a woman's ovaries into believing she is pregnant: the prevention of ovulation can be achieved within a week of hormone treatment. Yet while these differences could represent obstacles to widespread acceptability and utility, they do not appear to create insurmountable challenges.

The Hormonal Approach

Despite the recognized physiological challenges, the sequence of events leading up to fertilization affords many potential sites for contraceptive action, which have been explored via a

variety of approaches in preclinical and clinical studies over the course of decades. As previously stated, suppression of sperm production through hormonal intervention has received disproportionate attention. Decades of research have culminated in a more advanced understanding of hormonal manipulation of the male body: that male fertility may be temporarily interrupted by interference with hormonal control of the testes. Sperm are produced in the testes, where testosterone is also produced. Testosterone levels in the testes are 25 to 125 times higher than in the blood; these high concentrations are required for sperm production (Amory, 2017). Suppression of sperm production using both male and female sex hormones has been demonstrated since the middle of the 20th century (Heller et al., 1950). Operating on the same principle as female oral contraceptives, these early studies aimed to artificially raise sex hormone levels in order to trick the body into shutting down endogenous production of the hormones required to produce sperm. When exogenous testosterone is administered in the male body, artificially raising its levels, the brain and pituitary gland sense that systemic levels are high enough and halt production in the testes, causing concentrations in the testes to drop and consequently inhibiting spermatogenesis (Moudgal & Suresh, 1995).

Clinical trials of hormonal contraceptives for men in various dosages and combinations began in the 1970s, as mentioned previously. The International Committee for Contraception Research (ICCR) began testing various types of progestins, synthetic hormones that exert action similar to the female sex hormone progesterone (Schearer, 1978). Because these hormones were already in widespread use for more than a decade in oral contraceptives for women, a fair amount was already known about their pharmacological properties. Despite their moderate efficacy in suppressing sperm count, many dosage regimens were reported to cause side effects

such as loss of libido, liver toxicity, moderate weight gain, and "symptoms of femininity" such as gynecomastia, or the development of breasts (Schearer, 1978). Schearer hypothesized in one review of existing research that some cases of decreased libido constituted psychological reactions caused by apprehensiveness about the treatment rather than pharmacological side effects produced by the hormones tested (1978). Studies of androgens, or male sex hormones, which are responsible for various "masculine" characteristics, resulted in similar efficacy rates and similarly unacceptable side effects. One 1981 study found that in some men, a daily hormonal injection caused a loss of sex drive and "momentary increases in body temperature, or so-called hot flashes, such as those experienced by women after menopause" ("Male Contraceptive is Tested," 1981). For reasons discussed previously, these downsides were repeatedly found threatening enough either to personal health or to personal confidence to disqualify such compounds or combinations. Most early study regimens presented additional practical challenges: time to efficacy and return to fertility were both significantly delayed: ranging from six to 20 weeks and 12-18 months, respectively (Schearer, 1978). From a technical standpoint, the hormonal research conducted in the latter part of the 20th century proved that this approach had promise, yet required further refinement in order to eliminate adverse effects and inconsistencies in efficacy.

Despite decades of experimentation and alteration, investigators maintain that a product that satisfies principles of safety, efficacy, reversibility, and acceptability is yet to be met with success. A combination of both testosterone and progestin is now believed to be the most promising formulation. When administered together, the two hormones appear to increase the rate and extent of suppression, while the exogenous testosterone serves the additional purpose of

preserving libido and male sex characteristics. However, common side effects of hormonal trials continued to include acne, mood changes, weight gain, and injection-site pain (Kopf, 2016; Christensen, 2000). Moreover, researchers have encountered fairly high nonresponder rates to hormonal treatments, as well as unexplained differences between races: one study found that Asian men maintained a suppressed sperm count with greater frequency than Caucasians (Goodman, 2008).

Researchers have additionally faced technical difficulties establishing a safe and convenient delivery method. Oral testosterone clears the body too quickly for once-daily dosing, and would instead require two doses a day to maintain high enough levels (Kean, 2012). A further concern is that available oral forms of testosterone may cause liver inflammation (Endocrine Society, 2018). Clinical attempts have therefore explored alternative methods of delivery, including weekly or monthly injections, twice-a-year synthetic implants in the arm, and daily topical gels (Osborn et al., 2003; Seppa, 2012; "NIH to evaluate effectiveness," 2018). According to preference ratings gathered in surveys, periodic injections are generally deemed less convenient than a daily pill that can be taken at home and thus may face greater scrutiny with regard to common use (Kean, 2012). In this regard, a topical gel may provide a viable alternative: in early tests of one combination gel, 89% of men achieved sperm counts below one million—a low level of sperm production indicating comparable contraceptive efficacy to that of the female contraceptive pill (Ilani et al., 2012). Importantly, most study participants reported that they were satisfied with the regimen and would use it if it became commercially available, and the product has progressed to larger clinical trials (Roth et al., 2014).

More recently, a new hormonal compound has shown promise in bypassing the delivery issues associated with oral testosterone. The work on dimethandrolone undecanoate, or DMAU, was first presented in 2018 by the National Institute of Child Health and Human Development (NICHD). The compound, which is receiving considerable attention, has a different structure than testosterone that slows clearance and allows it to remain in the body for longer, which keeps levels steady enough to be taken once a day. The compound binds to the same hormone receptors as do testosterone and progestin throughout the body. It can be administered via injection or pill, and similarly tricks the body into producing less testosterone, thus reducing concentrations in the testes and inhibiting sperm production. The compound has worked well in animals, and is now in the preliminary stage of clinical trials. Researchers had 83 men between the ages of 18 and 50 take DMAU in pill form daily for 28 days. At the highest dose tested, subjects showed "marked suppression" of testosterone levels. Sperm count itself was not measured, as this study was primarily conducted to assess the pill's safety. Despite their low levels of circulating testosterone, few subjects reported symptoms consistent with testosterone deficiency, including changes in sex drive and sexual function. Furthermore, all subjects passed the safety tests, including markers of liver and kidney function, although participants did experience mild weight gain and slight decreases in HDL ("good") cholesterol. The team expects to begin another study soon that will follow men taking the pill for a longer period of time, in which semen samples will be collected to measure levels of sperm production (Endocrine Society, 2018). Another hormonal pill, 11-Beta-MNTDC, considered a "sister compound" to DMAU, very recently passed Phase I tests of safety and tolerability when healthy men used it daily for a month, and similarly produced hormone responses consistent with effective contraception without causing severe

adverse effects. These results suggest that these compounds will decrease sperm production while preserving libido (Endocrine Society, 2019). Thus, current work, while still in its early stages, represents a promising step forward in the development of a commercially viable hormonal method.

Non-Hormonal Approaches

In response to various past challenges posed by hormonal methods, the attention of the research community has also shifted to expand its net to include promising non-hormonal methods. These include several drugs that disrupt the process of sperm maturation, rendering them incapable of fertilization. While several new compounds have shown efficacy in animal testing, none have yet been tested in humans. These include Adjudin, a compound that breaks the adhesion of immature sperm to the cells that "nurse" them and would likely be administered by patch or implant (Mok et al., 2011). Before it can be studied in humans, researchers must find an effective and affordable way to inhibit an autoimmune response to the compound (Amory & Bremner, 2016). H2-Gamendazole, which would be taken orally, is a compound that inhibits growth of the head and tail of the spermatozoon. These immature sperm fragments would then be reabsorbed into the body. Researchers are currently investigating potential tissue toxicity, as well as the physiological impact on the female partner if the compound remains in the semen (Tash et al., 2008).

Andrologist John Amory at the University of Washington School of Medicine is currently exploring another novel non-hormonal approach: inhibition of the conversion of retinol (vitamin A) to retinoic acid, a process necessary for spermatogenesis. The vitamin A that we ingest is

converted by a family of enzymes into retinoic acid within the body, and one of these enzymes is found exclusively in the testes. The blockade of this enzyme with an antagonist would deprive the testes of retinoic acid, thus preventing sperm production without affecting the function of vitamin A elsewhere in the body. This approach has been tested in animals, and Amory reports that he hopes to test it in humans soon (Hogarth, Amory, & Griswold, 2011).

Thermal techniques represent another approach that has proven worthy of exploration over time. Fahim et al. (1975) initially researched the potential for heat as a means of male contraception, and showed that a short treatment with ultrasound caused infertility in rats. Fahim hoped to interest electronic companies in creating an ultrasonic device that could be bought and used at home. He also explored the design of a contraption similar to a heated undergarment that could be worn temporarily (May, 2010). Tsuruta et al. (2012) conducted a recent study to continue this work, aiming to determine whether a commercially available therapeutic ultrasound device could be used as a male contraceptive. The non-surgical and non-pharmacological nature of ultrasound could make it and similar heat-based methods promising candidates for a male contraceptive. The team of researchers concluded that further studies must be conducted to confirm its efficacy, verify its reversibility, and track any potential long-term detrimental effects.

Phenoxybenzamine, known as the “clean sheets pill,” is a fast-acting drug meant to produce a semen-free orgasm and represents another exciting non-hormonal candidate. The drug, which is currently used to treat high blood pressure, acts by relaxing muscles in the vas deferens to prevent transport of sperm and ejaculation without affecting the male orgasm. This drug moreover provides a unique advantage in its potential to prevent STI/HIV transmission in addition to pregnancy. Although its ability to cause aspermia has been known for decades,

exploration of the drug as a contraceptive agent remains in its early stages for reasons I will address later (Homonnai, Shilon, & Paz, 1984; Parsemus Foundation, n.d. (b)).

One of the most promising current projects is a long-acting, non-hormonal method called Vasalgel that functions like a reversible, non-surgical vasectomy. In vasectomies, the vas deferens, the tube that transports sperm from the testicle, is the site for contraceptive intervention: the tube is cut and tied, preventing the flow of sperm. Vasalgel is a polymer material that is injected with a syringe into the vas deferens, where it remains in a soft gel-like state that filters out sperm while allowing the passage of other seminal fluids (Revolution Contraceptives, n.d.). Sperm are unable to reach and fertilize an egg, and neither sperm production nor male hormone levels are affected. The procedure takes approximately 15 minutes with local anesthetic, and once injected, the gel could be effective for up to 10 years. The process can be reversed at any time with a second injection that breaks down the polymer gel and flushes it out, allowing sperm to pass through the vas deferens normally. Vasalgel has been in development since 2010 by the Parsemus Foundation, a U.S.-based nonprofit organization with a stated mission to "[advance] innovative and neglected medical research" (Parsemus Foundation, n.d.).

Vasalgel was inspired by a technique called RISUG, or reversible inhibition of sperm under guidance, which was originally developed in India in the 1970s by Sujoy Guha, a biomedical engineer at the Indian Institute of Technology. RISUG works by causing an electrical charge disturbance. The gel coats the walls of the vas deferens, and the positive charge of the gel results in rupturing of the negatively charged sperm membranes, damaging the sperm and rendering them nonviable (Sen, 2002). The technique uses a similar formulation to Vasalgel, but

lacks the chemical stability required by FDA standards. RISUG has been developed and tested over multiple decades: Phase I clinical trials were conducted in the early 1990s, and advanced Phase III clinical trials are presently underway in India, where over 500 men have received the injection as of 2017 (Sen, 2002; Altstedter, 2017). The procedure has been shown to be 98% effective at preventing pregnancy with no major side effects, according to R. S. Sharma, head of reproductive biology and maternal health at the Indian Council of Medical Research (Altstedter, 2017). Unlike the pill and condoms, which have a real-life efficacy rate lower than that associated with the "perfect use" scenarios advertised, this contraceptive injection, like an IUD, leaves virtually no room for human error.

Although human trials of RISUG in India are currently restricted to locals, Guha licensed the technology to the Parsemus Foundation in 2010 to help establish a market for the technology outside of India. The foundation chose to pursue its own variant, which it feels has a better chance of making it to market in the U.S. While Vasalgel has yet to be tested in human trials, preclinical animal studies have proven successful, with tests of Vasalgel in a rabbit model resulting in rapid and durable efficacy of the contraceptive. The study demonstrated that rabbits had no sperm in their semen as early as 29 days post-injection and the contraceptive effect was sustained throughout the 12-month study (Waller et al., 2016). Preclinical studies of reversibility were similarly promising, showing rapid restoration of sperm flow in all rabbits (Waller et al., 2017). Further, a recently completed study in 16 adult male monkeys showed that Vasalgel was successful in preventing pregnancies after the primates fraternized with females for 1-2 breeding seasons (Colagross-Schouten, 2017). However, reversibility of the contraceptive effect has not yet been demonstrated in these primates, and research is ongoing to clarify any issues and

optimize the procedure. While these results warrant continued development of the product, initial human trials will solely enroll men interested in a permanent contraceptive effect until reversibility of the contraceptive is proven in humans (Berry & Lissner, 2017).

Beyond the Laboratory

The chemical compounds and procedures highlighted in this chapter represent a handful of the dozens of male contraceptive methods under investigation, and demonstrate that current and ongoing projects show much promise. With such an abundance of prospects for further research, we must ask why research has progressed so slowly since such efforts were set in motion in the 1970s. In some ways, it seems that the history of the second half of the 20th century became one of an ever-widening gap between the insights of reproductive physiologists and their real-world application to fertility control. To be sure, as time passes and scientific insights and technological capabilities advance, possibilities in research gradually expand. Many promising compounds remain novel, and may require years to overcome key technical issues prior to their use by humans. However, other candidates appear ready for testing in humans, yet remain stalled in the laboratory. Still other candidates have been tested in humans, yet have not progressed to the stage of approval by the U.S. Food and Drug Administration (FDA). The state of male contraceptive research illustrates that the scientific community does not lack promising leads; instead, there remains a stubborn gap between laboratory discoveries and their conversion into a practical and acceptable products.

Chapter 4: From Laboratory to Market

The Contraceptive Development Process

The failure of any of the aforementioned experimental drugs and technologies to be translated into commercially viable products following decades of promising research, and the glacial pace at which such processes are now occurring for newer options, can be attributed primarily to regulatory and financial obstacles that have proven fundamentally intertwined. Heightened scrutiny of new pharmaceuticals born out of past mishaps has made it increasingly costly and time-consuming to bring new contraceptive methods to market (May, 2010). With the cost of new drug development hovering in the hundreds of millions of dollars, there are few options for adequate funding except from the pharmaceutical industry (Hartmann, 1995). However, innovation in the field of male contraceptive technology has been absent from the research and development (R&D) agenda of the industry for a long time.

The willingness of pharmaceutical companies to invest in new product development is determined by the perceived presence of a market, potential profits, and risk of litigation. With uncertain forecasts of market demand and the risk of commercial failure weighed against the soaring costs of R&D and clinical trials, extraordinary safety and efficacy regulatory hurdles, and liability concerns, the pharmaceutical industry has all but abandoned the field of male contraceptive research over the past decade or so, leaving government agencies, nonprofit organizations, and start-up companies to pursue this objective and to procure funding with more difficulty. As a result, much past or current male contraceptive research has fallen victim to the drug development "valley of death," a nickname for the gulf between laboratory success and the exponentially more costly human trials. Furthermore, the drugs that have made it to the clinical

trial stage without industry involvement have faced additional challenges as heightened scrutiny of adverse effects and ingrained double standards in gendered contraceptive development obstruct the testing and approval process.

The drug development process in the United States is stringently regulated by the FDA. This process is even more rigorous when it comes to new contraceptive drugs and devices, which pleases some and frustrates others: “the balance between allowing ample opportunity to develop useful new products and protecting the safety of consumers is at the heart of the debate about the FDA's safety and efficacy requirements for new drugs generally and for contraceptives in particular” (NRCIM, 1990). Some believe that these requirements have driven up the cost of drug research and development and delayed drug innovation, and regard the FDA as a significant barrier to better contraceptive methods and therefore to fewer unwanted pregnancies and abortions. Others view the requirements as necessary to protect the public from unsafe or ineffective drugs. With the increasing commercialization of medicine and other therapeutic products, the FDA “must protect the consumer from harm and fraud, it must maintain and enforce appropriate analytical standards, and it must generally assume the function of policeman or watchdog” (Djerassi, 1994, p. 48). Still others view FDA standards as not rigorous enough and too easily influenced by pressures from private industry (NRCIM, 1990).

For those who undertake the task of new drug development, the process is long, arduous, and resource-intensive. Pharmaceutical companies, government agencies, academic institutions, or nonprofit research groups must first conduct preliminary research, which includes finding promising drug candidates and studying their properties. Potential agents are tested in several rounds of preclinical animal studies to demonstrate proof of concept and safety. Since the

introduction of the first oral contraceptives in the 1960s, the FDA's requirements for toxicological testing of proposed contraceptive drugs have become more demanding than its requirements for the testing of other drugs. In the 1970s, the U.S. Food and Drug Administration (FDA) added a requirement that, prior to the initiation of human clinical trials, two-year toxicity studies in rats, dogs, and monkeys be completed (NRCIM, 1990). Clinical trials usually occur in three phases. In Phase I, the drug is given to a small number of usually healthy volunteers to establish safe dosage levels and to study its metabolism and side effects. Phase II, which involves up to several hundred patients, evaluates the efficacy of the drug. Phase III studies evaluate safety and efficacy in much larger numbers of patients, ranging from several hundred to several thousand, and may last for several years (Angell, 2004). Vasalgel, for example, after its demonstrated success in primates, is now required to pass these three rounds, meaning that it will If clinical trials are successful, results are submitted to the FDA for approval.

Few drug candidates survive this scrutinizing process. According to estimates by Big Pharma, the umbrella term used to refer to the conglomerate of the world's largest and most powerful pharmaceutical companies, only one in 5,000 candidate drugs make it to market: one in 1,000 survive preclinical testing, and of those, only one in five make it to clinical testing (Angell, 2005, p. 23). Indeed, many contraceptive drug formulations are discarded during the development process because of concerns about safety, efficacy, feasibility of delivery, or marketability. One study found that between 1963 and 1976, of 20 new chemical entities identified as potential contraceptive agents, 17 were placed into human trials, only three were submitted to the FDA for approval, and only two went on to be approved (NRCIM, 1990). Overall, the total time from the beginning of preclinical testing of a candidate drug to its coming

to market ranges from approximately six to ten years; for new contraceptive drugs, that number may jump to 10 to 17 years (Angell, 2005; Hartmann, 1995).

Contraceptive drugs and devices face particularly stringent clinical trial requirements from the FDA because, unlike most treatments, they are intended for potentially long-term use by millions of healthy people. Some argue that these requirements reflect a "demand for proof of safety that applies to all drugs but is, perhaps, uniquely burdensome to sponsors of contraceptives" (NRCIM, 1990). However, given the assumed pattern of use, rigorous requirements to ensure a high degree of safety are justified. Contraceptives may be used for the majority of a person's reproductive years, which for women generally span several decades, and for men even longer:

> "The single greatest objection to the oral contraceptives now being used is the essentially continuous administration of a potent agent to fertile women for many years. Clearly even greater objection would be raised in the case of a male contraceptive pill if it had to be taken day after day by fertile males for many years, possibly 40 or more." (Djerassi, 1994, p. 46)

The unique pattern of use associated with contraceptives thus sets them apart from other medicines in the risk-benefit analysis upon which FDA approval is contingent. If a drug demonstrably offers unique and dramatic benefits—if, for example, it saves lives or cures a severely disabling disease for which there are no comparable treatment options—it is fairly easy to conclude that this risk of the unknown is worth taking (FDA, n.d.). By contrast, a multitude of effective, fairly well-understood female birth control methods exist, diminishing the urgency of the approval process of a new technology and making the risk of attempting the unknown less

compelling. In the face of such risk, it is often preferable to “treat sick people with the hopes of curing them than healthy people with the hopes of not making them sick” (Beaton, 2017).

All active drugs cause adverse effects in some users. If safety were understood as the total absence of adverse effects, then no drug could truly be called “safe.” Thus, the safety of a drug is conceived by regulators as a ratio of benefits to risks for the population of users as a whole. The value of the medical benefits provided by a drug is typically a matter of technical, quantifiable medical judgment, such as the lowering of blood pressure or the shrinking of tumors, as are the associated risks. However, the value of some benefits transcends a professional or quantifiable judgment, particularly in the case of contraceptive technology. While few disagree that the ability to determine the number and spacing of one's children can significantly influence a person’s health and economic well-being, scientists and physicians have difficulty assessing the value of avoiding an unwanted pregnancy or of the nonmedical aspects of a particular means of contraception because the criteria are less clear or are challenging to measure. The societal and personal costs of an undesired pregnancy are simply not equated by the public and by regulatory bodies to the immediately evident health consequences of a disease such as measles, cancer, or AIDS (NRCIM, 1990). Despite this distinction, the oral contraceptive pill has been recognized by the WHO as an “essential medicine,” one that meets “the priority health care needs of the population” because of its “public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness” (Watkins, 2012; WHO, 2017). Fertility control is thus of great value to women and men, and that value, even though unquantifiable, must be recognized in risk-benefit analyses.

With regard to users' risk-benefit analyses, expectations are understood to differ based upon the seriousness of their need and the presence or absence of alternative treatment options. The choice to take on potential health risks is a much less straightforward calculation for a medication that improves quality of life than one that provides a direct and tangible remedy to illness. Demonstrating that a male contraceptive is as safe and beneficial as existing female methods will prove even more difficult because its risks and costs cannot be similarly weighed against the risks and costs of pregnancy, making any risk at all difficult to justify to users, to the industry, and to the FDA. This challenge is further complicated by the generally indirect means by which men have been emotionally and economically linked to pregnancy and childbearing and rearing in society, with the result that improvement in quality of life is even less directly evident.

Profit and Innovation in the Pharmaceutical Industry

Although selective drug approval and rigorous safety standards are justified in the field of contraceptive development, the time, costs, and data required to gain approval of a new product have reduced the incentive to undertake innovative research because they detract from the profitability of new products, which remains the primary objective for pharmaceutical firms. Developers of new contraceptives protect their investment in research and development by securing patents, which grant inventors a number of years during which they have exclusive rights to manufacture and sell their products. Patentability thus influences corporate decisions to pursue new product development, and is especially valuable in the pharmaceutical industry. However, FDA requirements for data on a contraceptive product's safety and efficacy and the

wait time for approval have contributed to a reduction in its effective patent life, making investment in R&D less attractive (NRCIM, 1990). Pitted against this loss, new contraceptives are not viewed as worthy ventures: one researcher lamented that "contraceptives are a retail business—it's a matter of selling a lot, and profit is low" (Extance, 2016).

Moreover, since the early 2000s, industry leaders, observers, and policy makers have been reporting an "innovation crisis" in pharmaceutical research. Claims have been made throughout the industry that the productivity of its research and development expenditures has been declining. In 2010, the investment bank Morgan Stanley recommended that, following "a decade of dismal R&D returns," the major companies shift away from in-house research investment—essentially, that they stop attempting to discover new drugs and buy into discoveries by others (Light & Lexchin, 2012). However, according to Light and Lexchin (2012), data indicate that the widely touted innovation crisis in pharmaceuticals is a myth with most research and development at large pharmaceutical companies directed at developing minor variations on existing drugs rather than finding better drugs for unmet needs. This strategy is not specific to contraceptive drugs, but applies to the pharmaceutical market at large.

In general, the few innovative drugs that do come to market nearly always come from publicly supported research, almost all of which is sponsored by the National Institutes of Health (NIH) and carried out at universities, small biotech companies, or the NIH itself (Angell, 2004). This work is often then patented and licensed to drug companies to market (Angell, 2012). Thus, many of Big Pharma's drugs are now acquired from outside sources, and while "companies are delighted when research breakthroughs occur...they do not depend on them" (Light & Lexchin, 2012). Moreover, physician and author Marcia Angell argues that R&D is a relatively small part

of the budgets of the big drug companies, and is “dwarfed by their vast expenditures for marketing and administration” (2012, p. xxiii). With the deep ties between industry and healthcare in the United States in particular, “pharmaceutical value has increasingly become a marketing proposition, not a scientific one” (Applbaum, 2009, p. 16). Angell argues that “drug company profits are so large that one would hope the companies would be willing to make less profitable but vital drugs as a social service….But that is not the way this industry works. It all comes down to dollars and cents” (2012, p. 92). With the increasing commercialization of medicine, the pharmaceutical business model is one that regularly prioritizes profits over public health objectives.

This trend has been observed in contraceptive development. While birth control remains a basic health care need for persons of reproductive age, pharmaceutical companies have found little incentive for investing in the innovation of new methods. When the success of the first contraceptive pill became apparent, other pharmaceutical companies rushed to bring their own versions of an oral contraceptive to market. Eager to capitalize on the early success of oral hormonal contraception, researchers additionally sought other ways to deliver the hormones into women's bodies (Watkins, 2012). In the 1970s and ’80s, major manufacturers began to spend more money on modifications to formulations of existing steroidal contraceptives than on new methods (Tone, 2001). Meanwhile, nonprofit organizations undertook much of the research, development, and testing of alternative delivery systems for hormonal contraception (Watkins, 2012). Chemist Carl Djerassi made a prediction in 1989 based on the trajectory of research at the time:

> "All we can expect well into the beginning of the 21st century are minor modifications of existing methods: different delivery systems for steroids, possible improvements in sterilization techniques and barrier methods, more precise indications of the safe interval, and possibly a more realistic reconsideration of the IUD option. Such modest developments will extend contraceptive use patterns, but they will not affect our total dependence on conventional 19th and 20th century approaches to birth control."

This remains an accurate reflection of the current birth control landscape. Although there are two general types of oral contraceptives (combination and progestin-only) dozens of brand name variations of these pills exist today. With regards to efficacy, "no brand of pill has been shown to be more effective than any other" ("Which Birth Control Pill," 2017). For pharmaceutical firms focused on profit, the safer bet continues to be to stick with current product lines, making occasional changes to the formulations without making any major innovations.

A key reason for the pharmaceutical industry to avoid investment in male contraceptive research is the notion that such an avenue would provide limited opportunities for growth and for profits because the market was already saturated with existing products. In 2015, the global contraceptive market was worth $18.35 billion, according to a report by the global market research firm Transparency Market Research (Altstedter, 2017). Today more than 100 million women use the pill worldwide (Christin-Maitre, 2013). In fact, oral contraceptives are the most common form of reversible contraception in most developed economies of the world, including Western Europe, the U.S., Canada, and Australia. Because they have existed and been tinkered with for decades, they are fairly well understood. Pharmaceutical companies have moreover expanded their marketing of existing female contraceptive products beyond the function of

fertility control, advertising them for acne treatment or regulation of menstrual symptoms (Watkins, 2012). Female contraceptive technologies thus constitute a lucrative and well-established market.

With such a reliable base, new male contraceptives are not regarded as potential blockbusters. Diana Blithe, a program director at the NICHD, which funds male contraceptive research, suspects that some companies view contraceptives as a zero-sum game in which every dollar spent by consumers on male contraceptives would mean one less dollar spent on female contraceptives (Kean, 2012). In particular, cost-effective and long-acting treatments might undermine profits from daily methods such as the pill or expensive methods such as the IUD, which typically lasts for 3-5 years and for which costs may exceed $1,000 (Planned Parenthood, n.d. (b)). The Vasalgel injection, for example, does not have the ability to make large sums of money because it is a one-time procedure that lasts for up to a decade and uses materials that are relatively inexpensive to make and distribute (Parsemus Foundation, n.d. (a)). Yet the economic dimensions of male hormonal contraception have previously been studied by independent parties, suggesting a large potential market for profit. According to one 2012 estimate, assuming a market size of 10 million men in the U.S. and 50 million men worldwide, the market value of a new male contraceptive method could be worth $40 to $200 billion (Dorman & Bishai). This estimate suggests the existence of multiple conflicting interpretations of the potential commercial viability of a male contraceptive product.

Industry Involvement in Contraceptive Research

The unwillingness to invest in the costly pursuit of a new male contraceptive is thus primarily a result of monetary cost-benefit analyses. While one fear is that new male contraceptives would disturb the profits reaped from the multitude of female products that permeate the market, an alternative is that they would not attract enough users to be profitable, and would fail in the marketplace. Similar hesitancies surrounding consumer demand existed surrounding the development of the first female pill. During the initial years of contraceptive research and development in the 1950s, the pharmaceutical industry shied away from funding such activities. Companies feared negative publicity that might be generated by attempting to market a product that challenged the anti-contraceptive laws still in place in some states, and feared boycotts of their other products by Roman Catholic citizens, who opposed contraception and who made up 25% of the American population at the time (Watkins, 1998). Despite supplying the materials for clinical trials, G. D. Searle & Co., the company that went on to market the first contraceptive pill, Enovid, remained cautious about any association with a contraceptive drug. It was not until high initial sales of Enovid under the guise of treatment for menstrual disorders demonstrated its profitability that the company showed true interest in this endeavor. Searle's public relations director later recalled: "we had underestimated the receptivity of the product. We got quite a surprise" (Tone, 2001, p. 225).

Today, any perception of lack of consumer demand has more to do with gender norms and user preferences than with political or religious controversy. Many major pharmaceutical companies remain skeptical that men would embrace a male contraceptive with the accompanying inconvenience and potential side effects, or that male compliance with hormonal

regimens would be successful. Christensen (2000) remarked that “even in clinical studies, men sometimes find the complicated schedule of pills and patches or injections difficult to handle.” Despite weak support for this reasoning, such doubts provide the basis for the pharmaceutical industry’s general agreement that such an endeavor is simply not worth the investment of time and resources.

The last major attempt by Big Pharma to create a male hormonal contraceptive occurred when Dutch company Organon and Germany company Schering AG teamed up in 2002, reporting that they were “optimistic to fill this gap” (Flynn, 2018). The two pharmaceutical giants joined forces to start a phase II multicenter clinical trial to test the reliability and acceptability of two hormones in combination which were known to have a suppressive effect on sperm production based on the results of earlier studies. The trial, however, was cancelled in 2006 when the two companies dissolved the partnership, claiming that they would continue research efforts separately. The companies described the collaboration as constructive, with contraceptive efficacy demonstrated in approximately 90% of the men and post-treatment recovery of normal fertility. However the reported adverse events were deemed intolerable. Although the men experienced dramatic drops in sperm counts, they also experienced side effects such as acne, weight gain, and mood issues. It was moreover concluded that the administration route investigated in the trial, which combined an annual implant with three-monthly injections, was unlikely to result in a product that would be found acceptable for widespread use. The firms’ proclaimed individual efforts were dropped soon after: Schering’s research and development activities surrounding male fertility control was halted in 2007 when it was acquired by Bayer, one of the largest pharmaceutical companies in the world, and one of the

top sellers of female birth control (Sifferlin, 2018). Bayer concluded that men would consider the regimen, in the words of a spokesperson, "not as convenient as a woman taking a pill once a day" (Khazan, 2015). Organon's program ended soon after, when it was acquired by Schering-Plough and subsequently Merck & Co. in 2009 (Flynn, 2018). A Merck spokesperson said only, "It is not a priority area" (Kean, 2012).

An examination of why certain projects are prioritized while others are neglected must look beyond profit to consider the identity makeup of those involved in making these decisions. Significantly, there is a continued paucity of gender diversity within the pharmaceutical industry, particularly at the highest levels of leadership. Estimates indicate that only approximately 7-9% of chief executive roles in the industry are filled by women, despite the fact that women enter the field at a higher rate than men (Ramsey, 2017). Herjan Coelingh Bennink, who helped develop the female contraceptives Implanon and Cerazette as the head of Research and Development in Women's Health for Organon International for more than a decade, emphasized that "the big companies are run by white, middle-aged males who have the same feeling—that they would never do it….If those companies were run by women, it would be totally different" (Altstedter, 2017). Such assumptions, made from positions of power, have consequently translated into broader and seemingly more antiquated perceptions of cultural gender expectations and, resulted in the industry's failure to recognize the shifting of consumer attitudes.

Liability Concerns

In addition to potentially gender-biased perceptions of consumer disinterest and an unwillingness to disturb an already lucrative hold on the contraceptive market, fears of liability

have contributed to pharmaceutical companies' abandonment of new contraceptive development. The industry at large has an extensive and continuing record of litigation surrounding female contraception. In 2014, the pharmaceutical giant Merck & Co. agreed to pay $100 million to resolve all U.S. product liability lawsuits alleging it downplayed serious health risks involving its intrauterine contraceptive device NuvaRing, including blood clots, strokes, and heart attacks. These cases addressed the experiences of approximately 3,800 women, including 83 reported deaths. Despite the legal action and ensuing settlement, the NuvaRing remained on the market, and in that same year, Merck made $723 million in profit from sales of it (Langhart, 2015). Merck's settlement was not unusual; it came in the wake of similar lawsuits against female contraceptive makers. Its competitor, German pharmaceutical company Bayer AG paid $1.6 billion over the prior two years to claimants against its oral contraceptive pills, Yaz and Yazmin, because of similar cardiovascular issues (Stanley, 2014). These recent settlements indicate that Pharma is willing to shell out money to keep its female contraceptives on the market, while simultaneously shying away from male contraceptive research for fear of similar legal troubles and financial risks. Moreover, although package inserts and company websites have been updated to contain adequate precautions, the continued acceptability of marketing products with such serious and demonstrated risks must be questioned, particularly in comparison to the delicate and wary treatment of male contraceptive candidates.

A Double Standard

Experimental male contraceptive compounds indeed have historically received considerably more caution in response to adverse effects. Pincus, while working on the female

pill in the 1950s, conducted a small-scale study testing the effects of Enovid on male patients in a mental hospital. Although now recognized as ethically questionable, this research demonstrated that Enovid had a "sterilizing" effect on the men. However, the men suffered severe side effects, including shrunken testicles. A similar clinical trial in the late 1950s was conducted on male prisoners with a combination of Enovid and testosterone preparations. Although the compounds fully inhibited sperm production, the subjects lost sexual desire and had difficulty getting erections and producing seminal fluid, and the attempt was deemed unsuccessful (May, 2010). While these adverse effects were justifiably unacceptable for widespread use, the immediate acknowledgment of these side effects stands in stark contrast to the skepticism with which Pincus treated women who reported equally unpleasant side effects during the testing of Enovid, which I will discuss shortly in greater detail.

In the early 1960s, scientists tested a potential contraceptive drug known as WIN 18,446 in male prisoners. The compound, which is now understood to suppress spermatogenesis in the same way that Dr. Amory is now attempting to do, was found to lower sperm counts in the prisoner population without affecting libido (Amory & Bremner, 2016). The study's promising results made national news (Tone, 2001). However, when clinical trials shifted to the general population, men experienced vomiting, sweating, headaches, and blurry vision (Kean, 2012). The drug was found to interfere with alcohol metabolism, causing men who drank alcohol to become violently ill, and was subsequently abandoned. Kean argues that "WIN 18,446 is a perfect example of why creating the male pill is so hard. It stopped sperm production in everyone who took it -- and it was reversible...Yet it failed anyway as a drug because of an arguably minor side effect" (2012). While it could be reasonably argued that this was more than a minor side

effect and would almost certainly have negatively impacted the drug's acceptability to its prospective user population, negative alcohol interaction is in fact a common side effect in hundreds of modern medications used to treat dozens of conditions (NIAAA, n.d.). Addyi, a drug described as the female equivalent of Viagra that was approved by the FDA in 2015, has been shown to severely lower blood pressure in patients when drinking alcohol, possibly leading to loss of consciousness (Harrison, 2015). Thus, while the categorization of alcohol intolerance as a minor side effect may be debatable to some, it is not an uncommon one, nor has it prevented the regulatory approval of drugs such as Addyi. The rapid abandonment of WIN 18,446 suggested early on that male contraceptives would be held to high standards, in part because the calculus for male- and female-specific medication differs.

Hormonal agents in particular, despite high levels of contraceptive success in a multitude of studies, have faced repeated challenges due to the presence of side effects deemed intolerable. A high-profile study led by the U.S. nonprofit group CONRAD and co-sponsored by the WHO was discontinued in 2011 despite promising data because "the risks to the study participants outweighed the potential benefits." The study aimed to suppress spermatogenesis using coadministered injections of progestogen and testosterone every eight weeks in healthy men, aged 18-45 years. Behre et al. (2016) demonstrated reversible suppression of spermatogenesis in 96% of continuing users, indicating a relatively high contraceptive efficacy in comparison with other reversible methods available for men, and even with hormonal methods for women. However, the study was terminated early following the recommendation of an external safety review committee monitoring the trial due to side effects deemed too severe to continue the therapy. Twenty out of the 320 participants had withdrawn from the study prior to its

termination. The adverse effects of concern to the committee were reports of pain at the injection site, increased libido, and a "relatively high" frequency of mood disorders. Additionally, one participant was diagnosed with depression (assessed by the researchers as probably related to the study regimen), one experienced an irregular heartbeat (assessed as possibly related), and one committed suicide (assessed as unrelated). Overall, more than a third of the adverse effects reported were concluded to be unrelated to the therapy, and 91% of adverse effects were classified as mild, while 99% were considered mild or moderate. Despite the side effects, feedback from the participants and their female partners demonstrated high rates of satisfaction, and more than 75% of participants said they would be willing to use the method if it came to market (Behre et al., 2016). Despite these high levels of efficacy and acceptability, recruitment of volunteers and administration of treatment were halted (Flynn, 2018).

The early termination of this study proved to be inflammatory, sparking a feminist backlash and media uproar over perceived double standards in the development of contraceptives. The side effects reported in this study were noted to be similar to those that women experience on current forms of hormonal birth control. Fifty years after the original version of the pill was approved, current formulations of hormonal birth control use far fewer hormones than early versions, yet are still accompanied by a multitude of side effects which continue to be routinely tolerated in exchange for sexual and reproductive freedom. Possible side effects of the pill include nausea, headaches, breast pain, weight gain, mood changes, and changes in libido. Common side effects of the NuvaRing, a hormonal vaginal ring with 91% efficacy with typical use, include many of those associated with the pill, in addition to vaginal infections, discomfort, irritation, abdominal and menstrual pain, changes in hair growth, issues

with contact lenses, and decreased sex drive, among others (Planned Parenthood. (n.d. (c)). The seeming difference in the acceptability of side effects suggests that the burdens women must bear in exchange for their reproductive freedom are generally considered too much to expect men to deal with, whether or not men themselves would be willing to do so.

Whereas mood disorders were one of the primary subjects of concern in this study, the relationship between available female hormonal contraception and mood disorders remains contested both in the scientific world and among the general public. While female users have reported mood-related symptoms for years, a definitive link has proven difficult to establish. Recently, a Danish study found a correlation between the use of hormonal birth control and diagnosis with clinical depression, suggesting a small but real increased risk (Skovlund et al., 2016). The study has been praised as finally giving credibility to the lived experiences of women, although it has been critiqued by others. Jeffrey Jensen, a professor of Reproductive & Developmental Sciences at Oregon Health & Science University, contended that "women are more skeptical of using hormonal therapy than ever before. It's a tragedy of the riches. If you really want to be depressed, have an unintended pregnancy" (Haelle, 2016). This justification for the continued societal disregard for risks to women's mental health stands in stark contrast to the concern shown in response to the male contraceptive study led by CONRAD. It reinforces the expectation that when it comes to a cost-benefit analysis between pregnancy and other drawbacks, women will make these trade-offs because they must.

Some feminists thus maintain that male hormonal contraceptives with demonstrably high efficacy have been shelved at various stages of development and testing due to the continued existence of a gender bias toward standards of acceptability. Although many women are able to

use hormonal birth control without experiencing any significant issues, dissatisfaction with available methods is apparent from the rates at which women discontinue their use of these methods. The pill is the most common female contraceptive method in the United States, yet nearly a third of American users are so dissatisfied that they abandon it within the first year, usually because they are unable to tolerate the side effects (Khazan, 2015).

Yet the abandonment of one method often only signifies the continued search for something more tolerable. In fact, nearly a third of women report having used five or more birth control methods (Daniels, Mosher, & Jones, 2013). The wide range of available female methods ensures that women who experience difficulties or complications are simply transitioned between drugs and devices:

> "I had a very difficult time with contraception. I found the coil horrendous--discontinued after 3 months due to heavy bleeding. I've tried 7 or 8 different brands of pills, but had to stop because they found pre-cancerous cells that required laser surgery. I was told I couldn't use Norplant or injections either because of problems I'd had with the pill...so I became pregnant. Later I developed thrush from the cap." (p. 82)

The pill alone exists in a great enough variety that some women must go through a lengthy and difficult process of trial and error:

> "I went to my doctor each time with a problem with the pill, and each time she would give me another pill to try….She would say: 'That's all right. I know the answer. This one is much better.'" (Ringheim, 1996, p. 85)

Some women are thus kept on a prolonged rotation of medications, or are left settling for physically and mentally tolling regimens. More than two decades later, women are still recounting such experiences:

> "The cycle was always the same. Suffer on it for three months. Go to the doctor. Try something else. Every time I probed the doctors for more answers about how these drugs were different, they had zilch to say to me…. At 16, I realized for the first time that I was a complete hormonal guinea pig…. I'm sick of women being treated like lab rats. There's no way men would put up with trial and error when it comes to their hormones." (Gould, 2019)

With such practices occurring regularly in reproductive health care, the repeated failure of studies such as that led by CONRAD may feel disheartening to many. However, while medical regulators have demonstrated a lower tolerance for adverse effects caused by experimental male contraceptives, a distinction must be made between minor side effects and serious complications.

Safety and Regulation of Female Contraceptives

The differences in the bar for what men and women are willing to or expected to tolerate, and the differences in the risk-benefit analysis for each, can be further examined by comparing current safety and acceptability standards in male contraceptive development to those used for early female oral contraceptives. The first birth control pill, marketed under the name Enovid, was approved by the FDA for contraceptive use in 1960. The gravity of its side effects, which became apparent in early testing of the drug, was minimized by both scientists and physicians for an extended period of time (Watkins, 1998). Seventeen percent of women in the first cohort of

the first large-scale clinical trials of Enovid, which took place in Puerto Rico, experienced significantly unpleasant side effects, causing a number of them to withdraw from the trials. Moreover, one woman died from congestive heart failure and another developed pulmonary tuberculosis, but researchers confidently concluded that "none of these effects could in any way be attributed" to the pill (Hartmann, 1995, p. 190). Dr. Edris Rice-Wray, who oversaw the trials, concluded that although the pill provided nearly 100% protection against unintended pregnancy, it caused "too many side reactions to be generally acceptable" (Tone, 2001, p. 223). Yet Pincus had little clinical empathy for what he regarded as hypochondria among the women in the trials, and dismissed her concerns (Planned Parenthood, 2015b). Claiming that many of the women's symptoms were psychosomatic, he asserted that "most of them happen because women expect them to happen" (Tone, 2001, p. 233). When problems with the pill later gained attention, some expressed suspicions that "men's scientific objectivity had been compromised by their sex" (Tone, 2001, p. 204). Indeed, Pincus's response reflects an underlying disregard for the concerns of female patients that has never been uncommon in medicine. His response moreover illustrates that compromises were to be made to satisfy the exigent demands for a working female method.

The willingness to make compromises for the sake of a reliable birth control method, both on the part of its makers and users, was demonstrated by the public response to the pill, particularly in the United States. Enovid was immediately embraced by hundreds of thousands of women as a marvel. As the Los Angeles Times wrote in 1967, "rarely in history has a change in mass behavior come so swifty. And never in history have so many healthy people taken such potent drugs month after month, year after year." Yet, as was demonstrated in early trials, the benefits of the pill were double-edged. Some users experienced dizziness, weight gain,

headaches, mood changes, stomach pain, nausea, and vomiting. For some, the reactions were enough to discontinue the medication, while others found themselves willing to tolerate side effects in exchange for the ability to enjoy sex without constant worry about consequences, particularly at a time when abortion was either illegal or difficult to obtain (Marks, 2001). As one official of a New York clinic explained in 1967, "our patients are so glad to have something to keep them from getting pregnant that they rarely complain" (Los Angeles Times). From the start, the uniqueness of the female burden and the utter lack of alternative options inherently lowered the bar for what was deemed permissible.

Lofty scientific, technological, and feminist ambitions may be used to explain the creation of an imperfect product, and the desperate need for a reliable contraceptive may be used to explain its mass acceptance among users. However, the subsequent and prolonged minimization of its considerable flaws remains difficult to justify. Enovid began its commercial life as a massive overdose, with 10 times the amount of hormones needed for effective contraception. The original high doses increased the likelihood and severity of side effects and the potential for rare but serious and occasionally fatal health problems such as blood clots, heart attack, and stroke. By 1962, Searle had received reports of several hundred cases of thrombosis and embolism associated with use of the pill, resulting in 11 deaths (Hartmann, 1995). However, in evaluating the pill's safety, regulators were most concerned about its ability to prevent pregnancy because pregnancy and childbirth were inherently medically risky. In fact, the risk of thrombosis is higher among pregnant women than among combination hormonal contraceptive users. The FDA held that even if the pill caused these adverse events, the rate of them—1.3 out of 100,000 users—was much lower than the rate of women who would die from pregnancy

complications —36.9 out of 100,000 pregnant women (Planned Parenthood, 2015b). Other common pregnancy complications further include high blood pressure, preeclampsia, gestational diabetes, and depression (HHS Office on Women's Health, n.d.). This judgment demonstrates once again the ways in which the cost-benefit analysis with regard to pregnancy that is unique to women has demanded that they assume certain risks, and has moreover qualified those risks as acceptable.

Similar demands are made of today's pill users, who continue to run a greater risk of circulatory disorders than nonusers. This risk is higher among women who smoke and are over the age of 35. The pill has moreover been found to increase a woman's risk of breast cancer and liver tumors (Planned Parenthood, n.d. (a)). The NuvaRing may cause high blood sugar and high lipid levels in the blood (Merck & Co., Inc., n.d.). Rare but severe risks associated with the modern IUD include pelvic inflammatory disease, which can lead to infertility, and perforation of the uterus, which can potentially damage internal organs and require surgical removal. Pregnancy with an IUD, in its rare cases, is more likely to be an ectopic pregnancy, which implants outside of the uterus and can threaten the life of the mother (Planned Parenthood (n.d. (b)). Yet women routinely assume these health risks, and are permitted by their physicians to do so, because to many, the alternative is worse. Women's bodies are the ones destined to endure the physical consequences if birth control fails. Thus, the cost-benefit analysis nearly always leans favorably toward the use of contraception, particularly with regard to temporal urgency. Low but actual risks of cancer or other chronic conditions might rationally be accepted by a woman for whom effective contraception is of great present value because of the health risks associated with pregnancy, labor, and delivery, or because of the personal, economic, and social

ramifications of an unwanted pregnancy. Some women may simply view this trade-off as an inevitable reality, whereas men face no similar dangers, no counterbalancing risk. The personal calculus of choice inherently differs between genders: preventing a pregnancy may be important to a man for a number of reasons, but not for his personal health or bodily integrity.

It required nearly a decade after the pill's initial approval, and uptake by millions of users, for scientists to prove the statistical link between thromboembolism and oral contraceptives, and to learn that much lower doses were just as effective at preventing pregnancy. Even then, the FDA was slow to act, concluding in 1969—after this link was established—that the pill's benefits sufficiently outweighed the risks (Hartmann, 1995). In 1970, the U.S. Senate held hearings on the safety of the pill and the lack of adequate information on the relative risks and benefits of its use, during which not a single woman was asked to testify before the all-male committee. It was not until 1978 that the FDA required manufacturers to include a comprehensive informational pamphlet in every contraceptive package. Over time, lower-dose formulations were brought to market, yet it was not until 1988, after pressure from the FDA, that manufacturers removed high-dose oral contraceptives from the market (Watkins, 1998).

The slow regulatory and industry responses to the early pill's flaws fostered growing concerns among women's health advocates about the standards used to judge the safety of products under development, as well as the role of science and technology organizations and pharmaceutical companies in women's bodies and rights. As women were forced to balance the freedom from pregnancy against the risks the pill posed to their health, "the swallowing of a pill represented not so much a liberty as the imposition of a control over their bodies by the medical profession and the pharmaceutical industry" (Marks, 2001, p. 186). The power of the pill as a

liberating technology was diminished as women began to question why men controlled these fields, and why women's health interests were suffering as a result. Some wrote letters to Pincus, asking him to direct attention toward men instead (Tone, 2001). The public response to the injustices of the pill became as much a general indictment of sexism in American society as it was an increased scrutiny of the medical and scientific establishments.

Yet while some women became increasingly disillusioned with the pill, it remained a powerful and popular technology throughout this period of medical uncertainty. After a brief drop in users following the Senate hearings in 1970, prescription rates for oral contraceptives rebounded in the U.S. and the number of users continued to rise. In many ways this has always been the relationship between women and contraceptive technology. One pill user reported: "I don't care if you promise me cancer in five years, I'm staying on the pill. At least I'll enjoy the five years I have left" (Tone, 2001, p. 245). The coexisting views of contraceptive technologies as "among the great liberators of our time" and "among the great oppressors of our time" aptly illustrate the complexity of their meaning in our society. As Ann Saetnan asks, "How can a single technological artifact...have such manifold and contradictory impacts?" (2000, p. 2). These complexities must be kept in mind when envisioning the integration of something new.

Still, from the perspective of the 21st century, it is difficult to imagine how and why the original formulation of Enovid was kept on the market for so long. The extreme lapse in regulatory judgment that allowed the extended use of a drug for which red flags had been so blatantly raised can, in part, be explained by putting it in the context of its time. The pill arrived at a time before several major crises shook public faith in medicine, a time when "it seemed that medical research could do no wrong," when new drugs were rapidly being introduced:

"pharmaceutical companies, the media, and the public proclaimed and accepted the benefits of the postwar chemotherapeutic revolution. Every problem, be it a medical one or a social one...seemed amenable to a 'technological fix'" (May, 2010, p. 126; Djerassi, 1994, p. 102). The development of the pill moreover preceded a vast overhaul of FDA regulation that led to stricter standards of safety and more rigorous clinical trial requirements. At the time of Enovid's approval, the scope of FDA authority had not changed since the passage of the 1938 Food, Drug, and Cosmetic Act, which had imposed the first requirement of safety on drug development in order to regulate the medical market. Ethical standards in research also differed from those established today, and the use of human subjects was poorly regulated. In the 1950s, there were no fixed rules as to what constituted an appropriate sample size to test a new drug, and trials of the pill generally adhered to the standards of the time. In the wake of the "pill crisis," the FDA imposed tougher standards, requiring larger data samples and better regulation of experimentation on human subjects (Tone, 2001).

After the introduction of Enovid, another medical disaster contributed to the end of the postwar faith in medical technology and a growing suspicion of the pharmaceutical industry. In the early 1970s, the Dalkon Shield IUD became another example of a product through which women were exposed to unnecessary risks in the name of corporate profit, and to which the regulatory response was appallingly absent. At this point, the FDA still had limited authority over the medical device industry. The pharmaceutical company A. H. Robins aggressively advertised its IUD for several years while downplaying or ignoring user reports of terrible complications. The device caused over 200,000 infections, miscarriages, septic abortions, and hysterectomies, led to an untold number of birth defects, and was tied to at least 18 deaths (Tone,

2001). Hundreds of thousands of women sued the makers for knowingly marketing a product that increased the potential of life-threatening complications, eventually bankrupting the company in 1985 (Tone, 2001). The case caused considerable negative media attention and public skepticism about IUDs, casting a shadow over subsequent research in the field and catalyzing legislation authorizing the FDA to regulate medical devices ranging from IUDs to pacemakers (Beaton, 2017). Pharmaceutical disasters such as the Dalkon Shield and thalidomide, a sedative that was marketed in the 1950s and early 1960s as treatment for morning sickness in pregnant women and caused the births of thousands of babies with debilitating malformations, contributed significantly to the increased stringency of drug and device regulation in the decades following (Vargesson, 2015).

Because of the major changes that have occurred between the introduction of the pill and the current generation of products under development, it is difficult to compare standards across time. In some ways, the lessons learned from the turbulent history of female oral contraception changed the process of future contraceptive endeavors for the better, ensuring that more stringent standards were established and allowing for the more cautious approval process that exists today. Additionally, as the field progresses, the more that is understood about the human reproductive system and about hormonal manipulation, the more there is to account for. Djerassi argues that the special requirements that have been imposed in the case of drugs used for fertility control are "understandable and justified," as "a response to our gradually increasing knowledge of human reproductive physiology in general, our accumulated experience with oral contraceptives in particular, and especially the surprisingly rapid acceptance by so many women of these new birth

control agents" (1994, p. 41). The benefit of past experience with female methods has raised demands for safety and testing of side effects.

However, at the same time, it is possible that excessive scrutiny of male alternatives has become a constraint on progress. While caution is necessary, "no drug can be totally effective and completely safe, and no agency of government can guarantee that it will be" (Djerassi, 1994, p. 49). Past experiences, as Darroch suggests, have also "hopefully lowered expectations that a new method will be 'perfect' and suitable for everyone throughout their reproductive lives" (2000). Darroch's point highlights a key challenge faced by researchers and feminists alike in judging the acceptability of male methods in which safety is prioritized and standards are realistic. Djerassi worries that the risks and costs of developing such agents have escalated to such an extent that it is unlikely that the traditional course of drug development will lead rapidly to the creation of fundamentally new contraceptive agents: "if the present climate and requirements had prevailed in 1955, oral contraceptive steroids would still have been a laboratory curiosity in 1970" (1994, p. 41).

The Funding Dilemma

The medical mishaps of the 1960s and 1970s changed the landscape of pharmaceutical development. Carl Djerassi identified three reasons for Big Pharma's flight from contraceptive research: (1) increased regulatory stringency, which greatly expanded the time and expense of developing new products; (2) a negative portrayal of the industry by the media in the wake of inquiries into the safety of the pill and the subsequent Dalkon Shield IUD disaster; and (3) the increasingly litigious nature of American society, as the courts became the place to seek

restitution for injuries or diseases attributed to drugs, medical devices, and other substances (Watkins, 2012). Leading scientists left the field, accompanied by a growing "estrangement of of academic and government scientists from those who work in industrial laboratories" (Djerassi, 1994, p. 70). Pharmaceutical firms scrapped or tabled promising projects as they swapped birth control initiatives for less risky ventures. In 1970, 13 major drug firms were actively pursuing contraceptive research and development, of which nine were American; by 1987, there were only four, with just one in the U.S. (Watkins, 2012). As was demonstrated by the history of the female oral contraceptive, a drug's side effects may take years to materialize to their full extent, and long-term safety cannot be put beyond doubt prior to its entrance into the market. Due to an acquired wariness of risk, pharmaceutical leaders have thus begun to shy away from such ventures, shifting their focus to less controversial projects.

Without the backing or resources of the powerful pharmaceutical industry, researchers have been left to find other sources of funding. Male contraceptive research continues to be funded by government agencies and by nonprofit organizations such as the Bill & Melinda Gates Foundation. Yet the industry absence is still felt, for it possesses a "unique ability to organize, stimulate, and finance multidisciplinary R&D covering the entire gamut of the scientific disciplines required in converting a laboratory discovery into an practical drug" (Djerassi, 1994, p. 41). Indeed, the power afforded to Big Pharma by virtue of its wealth should not be underestimated. In 2017, the top 10 global pharmaceutical companies all generated more than $20 billion in pharmaceutical revenue alone, with the top company earning more than $52 billion (Statista, 2019). While "ideas for innovative drugs may come from outside the industry….Universities can't put pills in bottles and sell them" (Angell, 2004, p. 71).

Small biotechnology enterprises have begun to pick up the slack in this field, yet lack the resources of larger companies. When the hormonal study led by CONRAD was terminated early, the research team did not have adequate funding to test another formulation (Flynn, 2018). The "clean sheets pill," project has similarly been stalled in the past several years due to lack of funding for continued research (Parsemus Foundation, n.d. (b)). The Parsemus Foundation is developing Vasalgel as a social venture, and is committed to making the treatment affordable and widely available (Parsemus Foundation, 2018). The foundation plans to sell Vasalgel for close to cost in low-income countries, and make it affordable to those at every income level in the U.S. The product could potentially be sold at $10 to $20 per person in low- and middle-income countries, and $400 to $600 per person in wealthier markets, according to Elaine Lissner, the foundation's founder (Altstedter, 2017). However, the foundation states that it does not have enough funding to finish the project. It has conducted fundraising campaigns and sought wealthy "social investors" to help support the preclinical animal studies that are paving the way for the first human trial. Lissner estimates that should the FDA permit clinical trials to take place in humans, this next step will cost millions of dollars (Parsemus Foundation, (n.d. (a)). However, Lissner has lamented that the response from representatives of the Bill & Melinda Gates Foundation has been lukewarm, as its primary focus has instead been on contraceptive options for women in developing countries. In 2016, the foundation gave $600,000 worth of awards for research into male birth control. By comparison, it spent $147.9 million on family planning efforts aimed at women (Mullin, 2017). While these efforts remain crucial to meeting unmet need, particularly in developing countries, this imbalance in the distribution of resources

reflects the perpetuation of ingrained social priorities in which we fail to recognize areas of great potential to expand overall involvement in and access to family planning.

Changing The Market Mentality

In many ways, marketing decisions, rather than scientific innovations, have guided the development and availability of next-generation contraceptive products. The body of knowledge in the reproductive sciences is fairly expansive, and promising technologies are in development, but the continued testing and subsequent availability of these technologies have been delayed by the failure to commit sufficient monetary resources. Pharmaceutical companies have intimated that they require greater assurance that such a technology will succeed—that is, that it will work and that men will use it. However, The continued efforts of non-industry scientists and benefactors suggests that while Big Pharma has been discouraged by heightened scrutiny of new pharmaceuticals and uncertainty of profit, there remain a number of groups championing the male contraceptive objective. The scientists behind the DMAU pill trial, for example, have worked in the field for years and note welcome and unprecedented energy around this research today, with public interest providing a positive momentum that did not seem to exist 15 years ago (Sifferlin, 2018). However, while great strides have been made within the past decade, even the most advanced of these options is likely at least a decade away from commercial availability.

Conclusion

Both women and men think of reproduction in terms of women's bodies and of birth control as a woman's responsibility, and this idea has been perpetuated by social and cultural beliefs and materialized in available technologies. Modern female contraception has provided an important tool for millions of women to effectively control their own fertility, freeing them from fears of pregnancy and constant childbearing and enabling them to take advantage of expanding opportunities for education, employment, and participation in public life. Although modern contraceptive formulations reflect improvements from more than half a century of extensive research, the trade-offs associated with available female contraceptives indicate that there still exists demand for better and alternative options, and serve to highlight the need for new male contraceptives. To this end, the introduction of more sophisticated and varied options for male contraception must become a more prominent objective in research, policy-making, and the commercial realm.

As I have demonstrated, the relative neglect of this objective is the product of a great number of social, cultural, scientific, and economic factors, some more direct and intentional, others more underlying or incidental. However, "to recognize the political dimensions in the shapes of technology does not require that we look for conscious conspiracies or malicious intentions" (Winner, 1986, p. 25). To understand why the development of contraceptive technology has unfolded as it has, and to envision ways to change its course, it is essential to recognize the reciprocal ways in which this technology has shaped our world, and in which the the world it created has dictated the subsequent trajectory of its development. Winner describes the production of technology as "an ongoing social process in which scientific knowledge,

technological invention, and corporate profit reinforce each other in deeply entrenched patterns, patterns that bear the unmistakable stamp of political and economic power" (1986, p. 27). In recognizing those deeply entrenched patterns, in identifying the sources of power, we can hope to dismantle those patterns and harness the necessary power.

The birth of the pill and the subsequent history of female contraceptives reveal much about the negotiations involved in bringing technological ambitions to fruition, and how the use and meaning of new technology are negotiated in society. The pill generated great interest among the medical profession, pharmaceutical industry, federal government, family planning organizations, feminist advocates, the media, and the public. The missions of these groups sometimes conflicted as their interpretations of the meaning of the pill differed, yet ultimately the amalgamation of their enthusiasm, power, and resources provided the impetus necessary to make modern female contraception a technological reality. By contrast, the search for male birth control has thus far lacked attention, social impetus, legitimacy, or resources comparable to those that propelled forward the creation of the pill.

In some ways the absence of male contraceptives is a sustained response to the history of female contraception. The pill played a key role in the movement for reproductive rights, the achievement of standards in medical research and drug development, and establishment of requirements surrounding consumer safety and access to knowledge of pharmaceutical risks and side effects. However, the gains made laboriously through the creation and gradual improvement of female contraceptives have perhaps simultaneously hindered any hopes for a male alternative. Perhaps, in part, we fail to recognize just how powerful the backlash against the pill was in in shaping future research and popular conceptions of drug safety. Yet there does appear to exist an

fundamental double standard in the ways in which male and female health is envisioned and valued in society. Female suffering has been consistently overlooked or minimized; male dignity has been grounded in the preservation of male bodily function in a way that is not for females; and the women have been saddled with the burdens of pregnancy in a way that men have never been, so that the expectation of physical sacrifice in the use of contraceptive technology differs wildly for each.

The slow progress of male contraceptive efforts highlights the importance of recognizing what is scientifically feasible and approaching continued challenges realistically, particularly if pharmaceutical firms are to be convinced that this technology has the ability to attract the proper social and market interests. With this in mind, discussions surrounding the widespread introduction of male contraception and success among potential users must address the need for a balance between shaping technology and its users' expectations. Ringheim (1993) suggests that while "it is more desirable (and easier) to modify technology to suit people than to attempt to modify people to suit technology...flexibility must come from both sides" (p. 93). He argues further that "while biomedical scientists have been convinced that development of an unacceptable method is pointless, potential users, service providers, and policymakers have realized at the same time the unlikelihood that science will produce an 'ideal' contraceptive that is...free of all side effects and 100 percent effective" (Ringheim, 1993, p. 93). It will therefore be necessary to adjust producer and consumer expectations of a perfect contraceptive method, with an emphasis on comparison to the historical and current contraceptive experiences of women.

Effective adoption of a new male contraceptive will have as much to do with reorienting cultural definitions of masculinity as with fashioning and disseminating the product itself. It must

also entail the reconstruction of social and institutional frameworks that encourage gender-specific contraceptive roles. The prevailing assumption has been that family planning is both a woman's right and responsibility, and that men are not interested in further involvement. There are good reasons why family planning programs and reproductive health initiatives have focused on women, but the exclusion of men from these efforts has not only impaired men's ability to participate more actively in contraception, it has ultimately hindered the goals of gender equality.

Long-acting, reversible male contraception has the potential to be a disruptive technology, one which could radically change society. Ultimately, this objective is achievable, yet it faces a number of extra-scientific obstacles. The continued lack of male contraceptive technology has much to do with the insidious consequences of both the patriarchal and capitalistic ideologies that prevail in our society. Progress has been hindered by regulatory hesitance, motivations of profit, and the misguided notion that we live in a society in which current practices and ideas are too ingrained to be conducive to technological change. The failure of this technology to emerge is a result of conflicting interpretations of both the importance and viability of such a technology, such that new male contraceptives have simply not been prioritized.

Technology succeeds with viable networks of collaboration, and with social impetus generated through perceived social need. We must create new models of collaboration in which all parties view their engagement and investment as winning propositions. This represents one of the greatest challenges to bringing a new male contraceptive method from laboratory to market. The fulfillment of this objective requires partnerships between government, academia,

family-planning services, non-profits, and industry to identify the best candidates for testing, approval, marketing, implementation, and accessibility. It moreover requires small- and large-scale advocacy, new educational focuses, and more frequent dialogues in an effort to promote the interest in and need for new male contraceptive options. There is great potential to be unlocked.

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