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‘Female Viagra’ and the intersection of medicine, gender, and desire: reinforcing misconceptions of female sexuality in the sexopharmaceutical era

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‘Female Viagra’ and the intersection of medicine, gender, and desire: Reinforcing misconceptions of female sexuality in the sexopharmaceutical era

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INTRODUCTION. DESIGNING A 'FEMALE VIAGRA'

Technology is inherently political and its creation and execution "is 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" (Winner, 1986, p. 27).

In a 2007 lecture titled "The marketing of Female Sexual Dysfunction (FSD): Illuminating current issues in sexuality and public health," activist Leonore Tiefer discusses the implications of the way our society studies female sexuality and sexual issues. Tiefer asks the audience to think about whether sexology, the scientific study of human sexuality, more closely resembles studies on digestion or studies on music and dance. Although sexuality is both a cultural and biological matter, sexology uses language that denotes "normal" and "healthy" behavior in a way that one would not ever expect to find in literature about music or dance. The emphasis on biological research to address social phenomena strengthens medical and expert power, often at the expense of socio-cultural research. The sexual norms embedded within interactions between the medical field and female sexuality work to standardize and regulate sexual behavior, expectations, and frustrations. In this thesis, I aim to explore how medical and pharmaceutical attempts to study and treat female sexual issues reinforce misconceptions of female sexuality and reproduce conventional social norms. The failure to interrogate the social construction and the role of context in the female sexual experience has hindered the development of a successful 'female Viagra'. The introduction of Addyi, the first FDA-approved pharmaceutical treatment for Female Sexual Dysfunction, provides a backdrop for which to observe the implications of operating within the male-dominated paradigm of sexual dysfunction.

Through the medicalization of female sexuality, sexual issues become matters of health and disorder. A medical framework is adopted to understand a problem, and a medical intervention is used to treat it (Conrad, 2000). This privileges scientific power through directing efforts into finding 'cures' rather than investigating the complex interplay of socio-cultural, environmental, relational, and personal contexts that contribute to sexual experience. The classification of Female Sexual Dysfunction is an example of medicalization working to define normal and natural sexual behavior as informed by an essentialist framework. Sexual essentialism, the idea that sex is a biological, asocial drive, is constantly reproduced in the medical discourse on sexuality (Rubin, 2011). In perpetuating the idea of an innate "sex drive," the implication is that a lack or absence of sexual desire is unhealthy. Standardizing sexuality as an inherent property of human identity resists the exploration of social forces that influence an individual's sexual desire. Pharmaceuticals play an active role in perpetuating this resistance by prioritizing and legitimizing sexual medicine.

Sexual essentialist discussion privileges certain bodies and sexualities and fails to acknowledge natural sexual variation. Human sexual response is conceptualized as a uniform, linear process culminating in orgasm, which creates a narrow barometer for sexual normalcy. This dominant notion upholds biological and physiological aspects of sexual response, but it is also necessary to understand how sex is shaped by and gives meaning to social forces. Anne Fausto-Sterling suggests the metaphor of the Russian nesting doll to illustrate both the process by which gender is materialized within the body and the process by which gendered knowledge about the body is simultaneously produced (Fausto-Sterling, 2000). The Russian doll represents the layers of sexuality and the sources of knowledge within them, whether relating to the

historical, cultural, social, psychological, individual, or cellular. What is important is not each layer in isolation, but rather the doll's disassembling and reassembling process. Sexual medicine such as Addyi ignores all of the non-biological layers that contribute to human sexuality and thereby discourages a deeper, more comprehensive understanding of female desire. The shortcomings of Addyi will demonstrate the impossibility of finding a pharmaceutical "cure" for female sexual problems, as the complexity of the construction of female sexuality inherently prevents a psycho-pharmaceutical intervention to be as lucrative as the blockbuster Viagra.

Addyi targets Hypoactive Sexual Desire Disorder (HSDD), a female sexual dysfunction that focuses on the absence or lack of sexual desire or fantasy. Coined in the 1970s, HSDD is part of a long history of female sexual disorders. The first chapter focuses on the historical context of Addyi's development by exploring the evolution of female sexual disorders in 20th and 21st century America, as exemplified in the editions of the Diagnostic Statistical Manual (DSM). The framework of DSM revisions illustrates how the medical field grappled with female sexuality and upheld strict, heterosexual, and gendered norms through the gravitation towards a more clinical, biological understanding of sex. The DSM editions show how the addition of more specific criteria and subtypes in the classification of female sexual dysfunction functions not to avoid overdiagnosis, but rather to legitimize the disorder and expand its manifestations to potentially broaden the prevalence of those affected.

The emergence of Viagra in 1998 was revolutionary in its influence on interactions between the medical field, the pharmaceutical industry, and the study of sexual issues. The quick-fix drug's massive success inaugurated the "sexopharmaceutical era", characterized by a new paradigm in sexual medicine which promoted drug intervention as the solution to sexual

issues (Tiefer, 2006). Viagra shaped the methods by which the pharmaceutical industry approached female sexual dysfunction, spurring immediate efforts to find a 'female Viagra'. The second chapter dives into the "Viagra Phenomenon" to illustrate the drug's role in Addyi's design and the stark contrast in the development and FDA approval process between the two drugs. While Viagra was fast-tracked through the FDA approval process soon after its discovery, Addyi's multiple rejections became the topic of widespread controversy primarily in the feminist community. I will unpack the positions and rhetoric of the competing feminist campaigns that sprouted up both for and against the drug's approval to direct attention to both the lack of consensus and the prevalent social ambivalence towards female sexual issues.

Chapter 3 describes Addyi's timeline after FDA approval, focusing on the challenges faced in its introduction to the market. Addyi is situated at the intersection of corporate interest, sexuality, and feminism. I will explore the implications of the gendered messages embedded within its marketing, primarily employed by the CEO of Sprout Pharmaceuticals Cindy Eckert. Promotional messages frame Addyi as a tool for female empowerment, applying a corporate feminist framework to increase profit. The story of Addyi's initial introduction to the market in 2015 and its relaunch in 2018, spearheaded by Cindy Eckert's very pink media presence, provides the backdrop for my analysis of the inability of the medical field to develop a successful 'female Viagra.'

As low sexual desire is the most common presenting sexual complaint in women, female desire or lack thereof has been the focus of popular, clinical, and scholarly attention (Hayes et al., 2006). The concept of desire is central to HSDD classification, yet the lack of consensus on its varying definitions and models persists. While dominant frameworks for sexual response

continue to focus on biology over context, to ignore variation in women's relationship to their sexuality, and to equate male and female bodies, alternative models are gaining traction in the field. Chapter 4 provides an overview of one such model, the Dual Control Model (DCM), as it provides a more comprehensive approach to female sexual issues that centers women's experiences. It challenges the way sexology and sexual medicine reduce and medicalize sexual issues through a reconceptualization of sexual normalcy. Looking at sexual behavior through the lense of the DCM gives insight into why the efforts to design a pharmaceutical solution to female sexual dysfunction have not proved successful, and why it is important to promote meaningful shifts in sex research.

This thesis does not attempt to argue that this drug hasn't helped certain women, that there are not biological underpinnings for low desire, or that Addyi is inherently bad. Rather it serves to illuminate what is ignored through prioritizing and marketing this drug as the solution to low female sexual desire. Addyi is said to empower women through providing the choice to regain control of their sexual lives and reclaim their pleasure. But is this drug truly the key to sexual empowerment? Is developing a female equivalent to Viagra a win for women, or does Addyi act as a continuation of the history of medicalizing female sexuality?

I want to point out that my thesis explores the heterosexual matrix in which sexual medicine, namely Addyi, is created. I often use the terms "woman" and "female," and "man" and "male" interchangeably. This is a reflection of the language used in discussions of sexual medicine occurring in medical and scientific literature, in the popular press, in the marketing of Addyi, and by Addyi resistors and users. I acknowledge the difference between sex and gender, and that not all individuals assigned female at birth identify as women and not all individuals

assigned male at birth identify as men. For the purpose of this thesis, I want to make it clear that my use of "woman" and "man" denote cisgendered individuals. When exploring female sexual desire, I am discussing women who were assigned female at birth, raised as girls, and identify as women. The research on sexual dysfunction experienced by genderqueer and transgender individuals is limited and not within the bounds of this thesis, therefore I did not extend the conclusions and observations regarding the medicalization of cisgender women's low desire to this demographic. I hope to highlight in this thesis how the heteronormative, conventional models dominant in sexology operate under a limited understanding of sexuality and gender that fails to be inclusive.

CHAPTER I. THE HISTORY OF THE DISORDER AND THE DRUG

"Nowadays, if a woman lacks the desire for sex, and is bothered by it, she could be diagnosed with a disorder of low libido. That's just one of the four main disorders of female sexual dysfunction described in one of the leading manuals of diseases. The others include disorders of arousal, orgasm, and pain. As the evidence plainly shows, forces are fast-amassing to tell you, and your doctor, that close to one in every two women suffers from some form of this new medical condition." (Mintzes & Moynihan, 2010, p. 2)

Addyi came onto the scene in 2015 as the first pharmaceutical drug to address Hypoactive Sexual Desire Disorder (HSDD), but it emerged out of a long history of pathologizing female sexual issues. Female sexual disorders as we understand them should not be accepted as biological and certain, but rather as the product of interactions between the medical field and female sexuality. They are defined by certain behaviors and characteristics that are deemed outside of the realm of contemporary ideas of what a normal sexual response should be. The history of sexual dysfunction and disorder can be traced many centuries back, but for the purposes of understanding HSDD and the context for the emergence of Addyi, the focus of this chapter will be on clinical and medical descriptions of sexual disorders in North America over the course of the 20th and 21st centuries. The evolution of the Diagnostic and Statistical Manual (DSM) will form the foundation of the historical timeline, as this body of work is representative of the contemporary professional consensus on sexual disorders. This history is not necessarily a linear one; though the DSM is used in psychiatric practice, each edition has faced severe criticism and pushback. The American Psychiatric Association, medical practitioners, feminists and women's organizations, the press, and the public have all wrestled with perceptions of sexuality and desire, with the disorders that exist to diagnose sexual issues, and with the treatments developed to address them. The negotiations encouraged by critiques of the DSM's

classification of disorders contributed and continue to contribute to changes in the medical approach taken to address female sexual disorders. Through the revisions of the DSM and the prevailing models of sexual response, I aim to contextualize the significance of the discovery and approval of Addyi as it relates to the history of the medicalization of female sexuality. New models continue to evolve that challenge or alter dominant models of sexual response, but this chapter works to ground Addyi in the context in which it was developed.

The Frigid Woman

The female sexual disorder that dominated the medical field in the earlier half of the 20th century was frigidity, although the disorder dates back to at least the 13th century (Cryle & Moore, 2011). An exploration of frigidity illustrates the history of the medical field grappling with low desire. Here we will focus on the disorder as it relates to medical texts in North America in the 20th century, emerging in the medical language alongside growing anxiety about the changing and fragile role of women in society. Frigidity acted as an umbrella term to encompass a variety of situations relating to women's unsatisfactory sexual functioning including vaginismus, orgasmic dysfunction, and a lack of sexual arousal or interest (Faulk, 1973). Due to the long timeline of frigidity and the varied and changing meanings ascribed to it, it would be impossible to characterize it as a singular concept.

Frigidity was given very loose and differing definitions over the course of the century; for some it was defined simply as a lack of satisfaction (Devensky, 1952), but for most it was defined in relation to a woman's ability to orgasm (Caprio, 1953; Hitchsman & Bergler, 1936). American psychiatry, professionalized and medicalized early on in the 20th century, was

dominated by psychoanalysis towards the 1930s (Angel, 2010). This set the stage for Freud's far-reaching writings on female sexuality which placed a great emphasis on a woman's ability to orgasm with vaginal stimulation over clitorial stimulation (Wallen & Lloyd, 2011). Reviews and guidelines on the causes and treatment of frigidity perpetuated the idea that the vaginal orgasm was the key to sexual fulfillment and reinforced its definition as the inability to experience vaginal orgasm (Hitchsman & Bergler, 1936).

As vaginal stimulation was associated with heterosexual intercourse, the "frigid woman" was defined in relation to her male partner. In the early 20th century there was a growing emphasis on the importance of sexual pleasure for maintaining a healthy marriage (Angel, 2010), and frigidity became seen as a barrier to being a good partner and wife (Caprio, 1953). A very popular 1959 study by New York psychiatrist Marie N. Robinson put out the bold claim that 40% of married women suffer from frigidity, defined as the lack of a "true" orgasm (Robinson, 1962). A woman deemed frigid was often seen as less feminine, possessing traits or behaviors associated with masculinity such as aggression (Caprio, 1953) and likely to rebel against traditional roles of womanhood through feminism and lesbianism (Ussher, 1997). In this way, the disorder worked to reinforce strict rules as to what constituted normal sex and uphold norms of femininity within heterosexual relationships simultaneously.

The first edition of the APA's Diagnostic and Statistical Manual (DSM) was published in 1952, at a time when frigidity was still the clearest parallel to what would become the umbrella term Female Sexual Dysfunction (FSD). The existence of frigidity in the DSM-I suggests that it was very common in psychiatry in the U.S. at this time, but it was not universally accepted. One of the most influential individuals in the study of sexuality in the 20th century was Alfred

Kinsey, who published his landmark study *Sexual Behavior in the Human Female* the year following the publication of the first DSM. Kinsey and his team at Indiana University interviewed more than 10,000 people and used the results to publish two editions, one regarding male sexuality and the other regarding female sexuality. Kinsey directly rejected frigidity as the universal term to describe a woman's inability to function sexually, as the interviews revealed a great gap between the medical norms of the time and women's self-reported sexual preferences and behaviors (Kinsey et al., 1998). He found that an assessment of female sexuality and pleasure based on clitorial stimulation and on vaginal stimulation produced very different results and argued for a better understanding of the biological sexual response. Kinsey's work did not create a dramatic shift away from the myth of the vaginal orgasm nor a rejection of frigidity, as frigidity remained the most common female sexual disorder in the in the DSM-II published in the 1960s. However it did mark a slight and gradual gravitation towards broadening the parameters of normalcy and pleasure.

Bringing sex into the lab

The second edition of the DSM was published just two years after Masters and Johnson's landmark study the *Human Sexual Response*, but would not reflect its influence until the publication of the third edition. The Masters and Johnson study was a breakthrough in that it brought discussions of sexuality into a laboratory setting, pushing sexuality studies in a biological direction and replacing the term "frigidity" with the term "dysfunction" (Masters & Johnson, 1966). By filming hundreds of people engaging in sexual acts and measuring their physiological responses, their team created the human sexual response cycle consisting of

excitement, plateau, orgasm and resolution. The description of each stage focused mainly on the physiological mechanisms of the body's response. For example, the excitement stage was characterized by self-lubrication, heavy breathing, erect nipples, blood swelling and increased sensitivity of the erectile tissues in the pelvis, vulva, and clitoris. The work produced by Kinsey and by Masters and Johnson illustrate a gravitation towards a more scientific, laboratory based measurement of sexuality that emphasizes the biological underpinnings of pleasure.

The idea of a standardized, biological, linear sexual response reinforced strict criteria for what the medical and clinical fields considered a normal sexual response. The 1974 publication of the DSM-III relied heavily on the Masters and Johnson sexual response cycle, accompanying the APA's more general categorical shift from psychoanalytical to biological psychiatry (Angel, 2010). It featured the introduction of the category of Female Sexual Dysfunction (FSD), a new umbrella term encompassing all forms of sexual dysfunction in females. In this edition of the DSM-III, each phase of the sexual response cycle is explained in terms of gendered psychophysiologic changes and expressions of sexual behavior, and the diagnostic criteria for each specific dysfunction are only briefly laid out. It is important to note that while Masters and Johnson's study was conducted within a medical framework, it did acknowledge sexuality and sexual pleasure as complex and influenced by social, cultural, and psychological contexts. However it was the biological factors of the sexual response cycle that were largely incorporated into the revisions of the DSM. These editions acknowledge several factors outside of biology that influence dysfunction; the predisposing factors mentioned for FSD include anxiety, high standards of sexual performance, sensitivity to rejection, negative attitudes towards sexuality,

and general psychopathology. However these more social or comprehensive factors still function to inform rather than negate diagnosis.

Due to the focus on the biological aspect of sexual behavior, Masters and Johnson's response cycle did not include a desire phase. The exclusion of this phase led to many criticisms that informed future DSM revisions, as desire would become increasingly central to the study of FSD (Goldey & Anders, 2012). Helen Singer Kaplan, a prominent American sex therapist, published *Disorders of Sexual Desire* in 1979 to discuss her conception of the human sexual response as a triphasic process with desire as the initial phase. She defined desire as a drive or appetite that "moves the individual to seek out, or become receptive to, sexual experiences" (Kaplan, 1979, p. 10). She also used the term Inhibited Sexual Desire (ISD) to distinguish desire disorder from the general FSD diagnosis. The influence of Kaplan's definition, as well as the use of the term ISD, is visible in the updated 1980 and 1987 versions of the DSM-III. The four stages of the sexual response cycle that informed the classifications present in the later editions of the DSM-III's were outlined as appetite, excitement, orgasm, and resolution. "Appetite" is defined by fantasies of and desire for sexual activity. The 1987 edition also featured the very first use of the term Hypoactive Sexual Desire Disorder (HSDD), defined as the "persistent or recurrently deficient or absent sexual fantasies and desire for sexual activity." HSDD replaced Kaplan's ISD, as the term "inhibited" was not as clearly defined and had a psychoanalytic connotation (Brotto, 2010). The prevalence of HSDD was measured at 20% of the total population, affecting females at a much higher rate. In other words the DSM-III claims that 1 in 5 individuals "suffer" from the sexual dysfunction of low desire.

Kaplan's work laid the groundwork for the increasing attention given to the prevalence of low desire in women and the growing body of research and literature produced in the early 21st century that interrogated the definition and potential measurements of desire. Low sexual desire was experienced by a considerable number of women, but the focus remained on how to diagnose and treat it rather than how to investigate the myriad of social, cultural, relational, and personal reasons influencing female desire. The later DSM-III editions' enforcement of a biology-focused sexual response cycle reflect a lot of the work that came out of the 60s and 70s. This categorical shift from psychoanalytical to biological attempted to create more reliable, objective diagnostic criteria (Angel, 2010) and paralleled the shift away from frigidity in that it aimed to be more specific, not more feminist (Tyler, 2011).

The evolution of Hypoactive Sexual Desire Disorder

The 1994 DSM-IV similarly defined sexual dysfunction in terms of the sexual response cycle, but included several new criteria that work to specify HSDD classification. Desire replaced appetite as a stage in the model present in the DSM-III; the terms appetite, desire, libido, interest, hunger, drive, and motivation are often used interchangeably in the professional literature discussing HSDD and sexual disorders more generally (Brotto, 2009). The text added categories that recognized sexual disorders' relationship to substances and unrelated medical conditions, as well as acknowledged the influence of culture, ethnicity, religion, and society on sexual experiences and expectations. The description of HSDD in the DSM-IV is also long and detailed, divided into the sub groups of lifelong vs. acquired, generalized vs. situational, and due to psychological factors vs. due to combined factors.

One of the most important changes between the 1987 DSM-III and the 1994 DSM-IV is the inclusion of the criterion"marked distress" in the classification of HSDD. The prevalence of low desire accompanied by marked distress is considerably lower than the prevalence of low desire without accounting for marked distress (Oberg, et al., 2004; Dennerstein et al., 2006). In this way it worked to reduce overdiagnosis, as well as further clarify the parameters of the disorder and respect asexual identity. It wasn't completely successful in this regard, as the DSM-IV still failed to acknowledge that distress can be experienced by asexual individuals in reaction to socio-cultural pressures related to sexuality (Brotto, 2010). The second added criterion of "interpersonal difficulty" was the result of suggestions that sexual difficulties and distress are often the result of the intricacies of partner dynamics and the relationship itself (Bancroft et al., 2003; Rosen et al., 2009; King et al., 2007). The criterion also attempted to avoid over-pathologization, as well as address the potential for "marked distress" to place excessive emphasis the individual.

Both interpersonal difficulty and marked distress are intended to inform diagnosis, however as in every DSM, the DSM-IV left diagnosis up to the clinician's judgement. This is due to the lack of data, the complexity of low desire, and the inability to reach a medical consensus on what constitutes low libido and how to quantify HSDD (Wood, et al., 2006). The context of the person's life is supposed to be taken into account in clinical judgement through the addition of guiding subtypes, categories, and criteria. The argument can be made that the increased specificity of HSDD works to prevent inaccurate diagnosis or overdiagnosis. Yet the creation of subtypes doesn't disqualify certain individuals from having HSDD or foster a more

comprehensive understanding of sexual complexity; instead it allows for flexibility and variation in the meaning and experience of HSDD in a way has the potential to broaden its prevalence.

Defining desire

The drastic changes seen in the contemporary DSM-V stemmed from the increasing focus on sexual desire and the many criticisms of the continued use of the sexual response cycle. Desire is central to HSDD, and yet there wasn't a medical consensus on how to measure or define it. Kaplan had framed desire as drive for sex, similar to hunger or thirst. According to Lena Levine, a prominent American psychiatrist who studied sexual dysfunction and served on the DSM-IV subcommittee on gender identity disorders, desire is the ''sum of forces that incline us toward and away from sexual behavior" (Levine, 2002, p.39). She considers feelings of desire as central to one's own identity, equating it to a voice in that it is a constant internal dialogue and to a barometer in that it measures and reflects many aspects of our lives. These definitions are in line with the strict, biological approach that places enormous weight on a person's ability to feel desire. Others defined desire more inclusively as the subjective awareness of wanting to attain a sexual goal (Regan & Berscheid, 1999). Grappling with how to define desire accompanied efforts to create a model in the context of HSDD. Desire was thought of by some to be indicated specifically by an individual's sexual behavior, while others focused on whether sexual desire should be considered as spontaneous or responsive.

Pushback on Masters and Johnson's lasting influence was seen through an increasing preference of the model of responsive desire, in which desire is seen as a non-spontaneous action in response to sexual stimuli, over the earlier notions of spontaneous desire (Everaerd & Laan,

1995; Basson, 2000). Studies have shown that some women engage in sexual activity without feeling desire (Beck, Bozman, & Qualtrough, 1991), women may or may not engage in sexual activity for reasons unrelated to desire (Cain et al., 2003), and sexual desire may be experienced in the absence of sexual activity (Brotto, et al., 2009). Rosemary Basson published an article in the *Journal of Sex and Marital Therapy* in 2000 to address the issues with the use of a universal, linear cycle as a framework for classifying low sexual desire. In reframing the definition of HSDD to include unresponsiveness to sexual cues, Basson expanded receptivity to triggered as well as spontaneous desire (Basson, 2000). The sexual response cycle she proposed consists of neutrality, sexual stimulus, arousal, desire, emotional and physical satisfaction, and emotional intimacy. Through her rejection of the model of female sexual response used in previous editions of the DSM, HSDD is redefined as a combination of the absence of spontaneous desire and the absence of responsive desire to sexual triggers. She also notes the overlap that occurs between desire and arousal and the need for more specific subtypes of HSDD and FSAD.

While varying definitions and models of desire circulated in medical and clinical literature, it became evident that desire was hard to measure and distinguish from arousal. The DSM-IV has separate classifications of the Hypoactive Sexual Desire Disorder and Female Sexual Arousal Disorder (FSAD). Many researchers felt that this differentiation was artificial (Ishak & Tobia, 2013; Basson, 2000; Brotto, 2010) and noted that a lack of desire does not necessarily prelude pleasure or satisfaction (Cain, et al., 2003). There were studies showing the disconnect between the female brain and female genitals, for example showing that a female may experience genital arousal when exposed to sexual stimuli despite a lack of any feeling of desire (Bancroft, 2010; Meana, 2010). The existing scientific evidence was generally unable to explain

female sexual desire, let alone concretely distinguish between desire and arousal. The growing body of information regarding this blurry distinction eventually led to the DSM-V's merging of HSDD and FSAD into one disorder labeled Female Sexual Arousal and Interest Disorder (FSAID).

It has clearly been difficult to form a medical and clinical consensus on female sexual issues and the dominant model of female sexual response in the DSM fails to acknowledge the complexity and variation in women's sexuality. This lack of understanding is reflected in the discrepancy that exists between clinical perceptions of female desire and women's perceptions of their own desire. In a UK study involving 401 women, the prevalence of sexual disorders determined by a tool commonly used in clinical diagnosis differed significantly from the prevalence of sexual disorders as reported by the women themselves (King et al., 2007). This suggests that clinical diagnosis for low desire disorders in women uses criteria that may be insufficient or irrelevant to women's self-reporting of sexual problems. We will explore the efforts to address the need for a subject-centered, context-focused framework to understand female sexual issues more in depth in Chapter 4.

The contemporary Diagnostic Statistical Manual

Critics of the dominant model of sexual response called for a new classification of FSD that departed from the reductionist approach of previous editions of the DSM. The major changes in the contemporary DSM-V were the elimination of the human sexual response cycle and the merging of desire and arousal disorder into FSAID, defined as "a lack of, or significantly reduced, sexual interest/arousal." These revisions are not necessarily the result of an effort to

create a more holistic, contextualized, feminist approach to sexual issues. Female HSDD continues to be used in clinical settings, by academic, medical, and popular literature, and in the marketing of sexual medicine. This is also true of the human sexual response cycle, which still represents the dominant model of sexual response. In the DSM-V, FSAID is featured alongside Female Orgasmic Disorder, Erectile Disorder, Delayed and Premature Ejaculation, Genito-Pelvic Pain/Penetration Disorder, and Male HSDD. It must manifest in at least three of the following: absent or reduced interest in or initiation of sexual activity, erotic thoughts or fantasies, excitement or pleasure during sexual activity, responsive interest or arousal to stimuli, or genital and nongenital sensations. The removal of the term "hypoactive" hypothetically worked to deemphasize sexual deficiency as well as broaden our understanding of sexual response beyond biology (Brotto, 2009). While the DSM-V still emphasizes clinical judgement for diagnoses due to lack of data, it mentions the importance of understanding the complex interplay between culture and biology, as reflected in the inclusion of partner factors, relationship factors, vulnerability factors, stressors, cultural and religious factors, and medical factors. In principle, there appears to be a greater effort to address the complex nature of sexuality and to move away from reductionist models that fail to include life context.

Addressing the 43%

In 1999, an article featured in the *Journal of the American Medical Association* gave birth to a statistic that would have a lasting legacy in the world of sexual dysfunction. The article, written by Edward Laumann from Chicago University, deemed sexual dysfunction an important public health concern affecting 43% of women between 18 and 59 years old

(Laumann, 1999). Since its publication, this journal has been cited thousands of times in both scholarly articles and the popular press. It prompted the forming of the International Society for the Study of Women's Sexual Health (ISSWSH), a group of doctors nurses, sex therapists, and scientists, with the goal to drive further study of female sexual dysfunction (Schulte, 2015). Laumann's "43%" came in the wake of the hugely successful marketing campaign of Viagra, and proved very important in justifying a market of unmet need for treatment of female desire disorders. Looking at the success of the Viagra campaign and the high prevalence rates of dysfunction being publicized, it became clear that a 'female Viagra' could prove necessary and lucrative. I will explore this "Viagra Phenomenon" in the following chapter to illustrate how the drug's emergence affected the way the pharmaceutical industry would interact with sex and how it catalyzed considerable efforts to researching a female equivalent.

The early 2000s featured several different approaches to address low desire in women after the FDA's issue of draft guidelines for drug development to treat Female Sexual Dysfunction. These draft guidelines, intended to represent the FDA's position on the development of FSD treatment, included "recommendations for sponsors on the design of clinical trials in support of new drug applications for the treatment of female sexual dysfunction" (Tiefer, 2001). It discussed trial populations, outcome assessment tools, endpoint measurements, and safety considerations (U.S. FDA, 2016). In the 2000 guidelines, the FDA stated that the primary endpoints should be based on the number of successful and satisfying sexual events (SSE), limited to "satisfactory sexual intercourse, sexual intercourse resulting in orgasm, oral sex resulting in orgasm, and partner-initiated or self-masturbation resulting in orgasm" (Tiefer, 2001). The draft guidelines and prevailing understandings of female sexual issues perpetuate the

historically orgasmocentric approach to female sexuality that defines success through orgasm and excludes social and interpersonal context.

Female sexual dysfunction has been understood in a variety of ways, as reflected in the many revisions to the DSMs, the different disorders and dysfunctions that fall under the FSD umbrella, and the constant criticism surrounding each classification. There has been a consistent tension surrounding the addition of criteria for clarity in diagnosis of sexual disorders, while as it legitimizes the disease and encourages more careful diagnosis, it also creates a narrow model of sexual response and medicalizes behaviors that stray from the standard. Although the medical understanding of female sexuality has evolved in clarity, sensitivity, and complexity, it still rests on a simplified and symptomatic understanding of sexual response consistent with a reductionist point of view. Addyi is not a departure, but rather a continuation of the centuries-long evolution of female sexual disorders. Its development simultaneously legitimizes the medicalization of female sexuality and prompts important questions regarding societal norms and expectations of female sexuality and desire.

CHAPTER II. THE QUEST FOR THE LITTLE PINK PILL IN THE SEXUOPHARMACEUTICAL ERA

"Sexuality must not be thought of as a kind of natural given which power tries to hold in check, or as an obscure domain which knowledge tries gradually to uncover. It is the name that can be given to a historical construct: not a furtive reality that is difficult to grasp, but a great surface network in which the stimulation of bodies, the intensification of pleasures, the incitement to discourse, the formation of special knowledges, the strengthening of controls and resistances, are linked to one another, in accordance with a few major strategies of knowledge and power." (Foucault, 1990, p. 106)

In a 2015 interview with Fortune Magazine entitled "Most Powerful Women: Next Gen," Cindy Eckert wants to make it clear that Addyi is not the 'female Viagra' that it has been nicknamed by the popular press. She details the differences in the way the two drugs function and declares that the barometer of Addyi's success should never be measured against an on-demand drug for men, but rather on the fact that with access to Addyi, women with a medical disorder have the choice to make their own sexual health decisions. According to Eckert, Addyi's comparison with Viagra should only go so far as to say it will be as revolutionary for female sexual health as Viagra was for male sexual health. While the mechanisms of Addyi and Viagra are drastically different, Viagra focusing on a blood flow issue and Addyi targeting the brain, a lot can be learned from looking at the story of Viagra in relation to Addyi. Its emergence in 1998 was a huge success and directly spurred the race to find a female equivalent. Studying its impact on Addyi provides an illustration of the growing phenomenon of corporate interests to invest in the medicalization of sexuality in the sexuopharmaceutical era (Tiefer, 2006) and allows us to begin to understand the difficulties confronted in the quest for the little pink pill, despite many efforts in research and development. It also sets the stage to interrogate how the feminist community was conflicted and divided in conversations surrounding Addyi's approval.

Addyi is shrouded in ambiguity and ambivalence; the lack of medical, social, and feminist consensus on female desire complicates its position in contrast to its male counterpart.

The Viagra phenomenon

> "Viagra, an ED pill packaged as a male enhancement drug, represents medicalized and commodified masculinity, reinforcing 'normal' masculinity on both individual and social levels. At the center of this feedback loop is the embodied man, who must come to terms with the 'clinical gaze' that represents medical social control as well as the potential for empowerment and, by association, self-control that Viagra appears to symbolize in our postmodern age."(Rosenfeld & Faircloth, 2006, p. 22)

Viagra quickly became a blockbuster drug, a term designated for drugs that accumulate at least $1 billion in annual sales (Rosen, 2005). Like Addyi, it too was discovered accidentally; a developing treatment for Angina produced blood flow to the penis instead of the heart, resulting in the "happy accident" that would become Viagra. Although there were concerns voiced in the media for the pill's potential to be abused or used recreationally, this posed only a brief interruption in its development (Loe, 2004). Viagra was fast-tracked through the FDA approval process without any input from external experts or non-governmental expert committees (Tiefer, 2001) and approved in March of 1998, since then bringing in tens of billions in revenues (Mukherjee, 2018). The late 20th century alignment of pharmaceutical marketing, government policies, society's growing interest in sex and pills, and the success of Viagra is coined as the "Viagra phenomenon" by sexologist, clinical psychologist, and anti-Addyi activist Leonore Tiefer (Tiefer, 2006). Tiefer was very interested in the implications of the Viagra phenomenon for sexology, and has used the concept to illustrate how the pharmaceutical industry's enforcement of the idea that complex sexual problems are medical conditions and the reduction

of sexuality to its biological mechanisms. In the case of Viagra, erectile dysfunction positions the "penis as the patient" (ibid., p. 285).

Viagra's immediate and impressive sales have been attributed to three main things; defining erectile issues as a medical dysfunction, widening the audience of those affected, and selling the drug as a fail-proof solution (Moynihan & Mitzes, 2010). Although the interactions between female sexuality and medicine are unique, the gravitation towards a clinical, biological, medicalized approach to sex in the later 20th century applied to male sexuality as well. "Erectile dysfunction" (ED) was coined to replace the previous term "impotence" 6 years before the approval of Pfizer's Viagra (ibid.). This re-labeling was in line with the biological understanding of sex epitomized in the writings of Masters and Johnson and Kinsey; ED was now understood as a biogenic rather than psychogenic problem. The primary criteria in the DSM-V for erectile disorder is that in approximately 75% to 100% of sexual events, an individual experiences marked difficulty in obtaining or maintaining an erection, or experiences a decrease in erectile rigidity. A diagnosis can be made even if the erectile issues are of mild severity.

Similarly to the DSM's presentation of HSDD, the factors relating to partners, culture, religion, self-esteem, and psychiatric comorbidity are mentioned, but only in their influence on the presentation of ED symptoms rather than as factors that might prevent a medical diagnosis. ED diagnosis centers the biological sexual response of the penis, and therefore it leaves out the social context of relationships, emotions, well-being, upbringing, and attitude towards sex (ibid.). Ericka Johnson, a researcher and professor who studied the presentation of masculinity on Pfizer's Viagra website in Sweden, observed trends in the discussion of ED in scholarly articles in a Swedish medical journal from 8 years prior to Viagra's approval through 8 years after

(Johnson, 2008). In the years leading up to 1998, the papers stressed the evaluation of biological factors, emotional well-being and interpersonal relationships in diagnosing ED. After Viagra emerged, the discussion was disease-centric and focused on the physical factors. The understanding of the patient and of sex narrowed, and the diversity of the authors also narrowed to primarily include urologists. The shift illustrated in Johnson's study accounts for the progression in the medicalization of sexual problems as exemplified in defining erectile issues as a medical dysfunction.

Viagra was fast-track FDA approved in 6 months only 2 years after it was patented. In order to bolster sales, the audience of those affected by the dysfunction was widened to include as many potential consumers as possible. Edward Laumann's 1999 article on sexual dysfunction which gave birth to the 43% statistic for FSD also estimated the prevalence of ED at a range of 10 million to 50% of the US male population (Laumann, 1999). While initially ED was mainly associated with older men experiencing dysfunction attributed to medical problems such as prostate cancer or diabetes, Pfizer broadened the market and in turn allowed for recreational use by including any man who experienced issues getting an erection, keeping one, or who just wanted to enhance his performance (Conrad & Leiter, 2004). The expectations of erectile functioning became more demanding "so that most penises would fail or falter at some point or other and so that the incidence of 'impotence,' or at least 'erectile insecurity,' would escalate" (Tiefer, 2006, p. 279). It was a fail-proof solution and was advertised as such. Pfizer employed direct-to-consumer advertising (DTCA), which steps outside of the realm of the doctor's office to position patients as consumers in the market of pharmaceutical drugs (Conrad & Leiter, 2008). It was in 1997 that the FDA released guidelines for TV drug advertising that allowed for certain

prescription DTCA, feared by some to potentially contribute to the medicalization of the human experience (Bonaccorso & Sturchio, 2002). By 1999, Americans on average saw 9 prescription drug advertisements a day on TV (Conrad & Leiter, 2008). Broadcast DTCA grew from $55 million in 1991 to $4.2 billion in 2005 (USGAO, 2006) with 330% growth from 1996 to 2005 (Donohue et al., 2007). A competitive market was developing in the early 2000s for erectile dysfunction with similar treatments such as Levitra and Cialis. Famous male celebrities, such as race car driver Mark Martin and former NFL football player and coach Mike Ditka, addressed the "millions" of men with erectile dysfunction in hyper-masculine advertisements. By 2004 drug companies spent $382 million in advertising for ED drugs in the U.S. and had sales of $1.36 billion (Snowbeck, 2005). The public image of Viagra as depicted in its advertisements targeted the demographic of middle-aged and older, white, middle and upper-class, heterosexual men. However the population of users extended beyond Pfizer's defined target group to include men of different ages, sexual preferences, socioeconomic levels, racial groups, and even women (Loe, 2004). Viagra's position as a quick-fix drug emerged out of and reinforced heteronormative stereotypes and expectations of masculinity while simultaneously becoming a widely used everyday man's drug. Viagra is a very familiar example of "economic forces and social meanings" generating the making of a disease (Kukla, 2016, p. 185). The pharmaceutical industry framed sexual problems regarding erection as a medical condition, one that potentially half of the men in the U.S. experience.

Early attempts at addressing low female sexual desire

Addyi was FDA approved as the first drug to treat Female Sexual Dysfunction 17 years after the FDA approval of Viagra. Cindy Eckert argued that the difference between the drugs' timelines is the result of sexism within the medical field and the FDA, however the quest for the little pink pill began immediately after Viagra's success. Paralleling the path of Viagra, low desire was categorized as a dysfunction and a large potential market of unmet need was established. There were many early attempts to design a female version of Viagra -creams, patches, pills, clitoral therapy devices- and there wasn't a lack in funding or interest to conduct research. Yet despite all of this attention, the pharmaceutical industry was unable to design a successful 'female Viagra'. The early attempts have been criticized for relying on the human sexual response cycle and reinforcing sexual scripts that uphold normative assumptions of femininity and sexuality (Fishman & Mamo, 2001).

Following Viagra's launch, there was a race to develop indices and measuring tools to better understand FSD and inform drug development, such as the female sexual function index and the decreased sexual desire screener (Lodise, 2017). As early as 1999 a cream was patented that was said to induce multiple female orgasms and eliminate the need for foreplay, although with limited success (Riordan, 1999). A few other non-pharmaceutical approaches were approved by the FDA, such as a clitoral therapy device that uses suction to increase blood flow to the clitoris and in turn aids in vaginal lubrication and clitorial sensation. The EROS device, sold with a prescription at just under $400, was shown to be relatively effective in improving symptoms, however the studies were small, short, and lacking long-term follow ups (Wilson, et al., 2001). Research on the ability of Viagra to treat FSD was also investigated by Pfizer in the

early 2000s due to Viagra's huge success at addressing male sexual dysfunction, however it concluded that female sexuality was more complicated than anticipated. The large majority of women with low desire didn't respond to Viagra in the same way as men did (Kohn, 2008). The drug caused blood flow to female genitals but did not necessarily lead to increased sexual desire, a phenomenon known as "arousal nonconcordance". While for males there is a 50% overlap between blood flow and the feeling of being "turned on," this overlap is reduced to 10% for females (Nagoski, 2015). This gendered difference is rooted in the importance of context for the female sexual response, which will be explored more in Chapter 4. Pfizer decided to stop their studies of Viagra's effect on low female sexual desire after 8 years of research. HSDD *was* being heavily researched since the time of Viagra, but a simple quick-fix, fail-proof solution was proving difficult to find.

Even though it took 17 years for a drug that specifically targets FSD to be approved, prescriptions were being written for women long before. Between 2006 and 2007, 2 million testosterone prescriptions were written for women who were diagnosed with HSDD (Kwan, 2008; Snabes & Simes, 2009). Procter & Gamble applied to the FDA in 2004 for the Intrinsa testosterone patch for women, which was the first medicine ever to be brought to the FDA for female sexual dysfunction. Its target audience was women who suffer from HSDD, the "disease of low libido" as the P&G team called it at the FDA hearing, or who have had a hysterectomy (Moynihan & Mitzes, 2010). The patch "delivers small transdermal pulses of the sex hormone thought to play a crucial if poorly understood role in male and female libido alike" (Angier, 2007). A large survey conducted by Procter & Gamble found that of 30 million women who are naturally menopausal, 3 million are distressed by their lack of sexual desire (New View

Campaign, 2014). This gave rise to the statistic that 1 in 10 women have HSDD. Procter & Gamble hired a global public relations team and advertisement agency, sponsored meetings and debates on the topic, consulted sex experts, funded an education package for doctors about HSDD, and put aside $100 million for advertising prior to their FDA hearing (Moynihan & Mitzes, 2010). At the hearing, the company spokesperson Mary Johnson claimed there was a "large unmet need" for a treatment for FSD, and highlighted the fact that their proposal received priority review status from the FDA. Despite this attention, research, and funding, the FDA voted unanimously against approval due to doubts regarding the adequacy of the scientific data in terms of efficacy, the powerful placebo, the side effects, and the long term health risks. The efficacy was measured at one additional sexually satisfying event (SSE) per month when compared to placebo, with a "sexual event" defined here as any sexual behavior that does or does not involve an orgasm (EMA, 2010 & Spark, 2005). One study published in the *Drugs and Therapeutics Bulletin* warned that common side-effects of the Intrinsa patch included "acne, excessive hair growth, breast pain, weight gain, insomnia, voice deepening and migraine" including unknown long term effects such as increased risk of breast cancer (Moynihan & Mitzes, 2010, p. 165). This first attempt at an FDA approved drug proved that the search was going to be very different from the story of Viagra.

The discovery of Boehringer's little pink pill

In 2006, two years after the rejection of the Intrinsa testosterone patch, the German pharmaceutical company Boehringer Ingelheim International discovered flibanserin, also known as Addyi. The drug, originally designed as an antidepressant, was found to have the side effect of

increasing female sexual desire. Flibanserin is a psychotropic medicine and functions by targeting the part of the brain linked to sexual motivation, although the exact mechanisms by which it does so are not completely understood. According to the director of Women's Healthcare of Princeton, Maria Sophocles, it is a "once-daily, oral, mixed serotonin agonist and antagonist" (Kunzmann, 2019). In a press release, Boehringer used Procter & Gamble's "1 in 10" statistic to claim the existence of a serious unmet medical need of an HSDD treatment and began conducting clinical trials (Meyer-Kleinmann, 2008).

Boehringer and several other drug companies organized and sponsored a conference on sexual medicine at the grand lecture theatre of Palais des Congres in 2009. It coincided with the company finishing up their trials before applying to FDA, so their excitement surrounding the drug's supposed success and efficacy was evident (Moynihan & Mitzes, 2010). Anita Clayton, a spokesperson with financial ties to some of the world's leading drug companies like Pfizer and Boehringer, gave a noteworthy talk on the concept of the "powerful placebo," stating it was the major reason for Intrinsa's rejection by FDA. According to her and other researchers in sexual health, the effect of the powerful placebo explained why there was still no sexual drug that showed a meaningful benefit for women despite the research and money directed at this assumed large market. Clayton claimed that the powerful placebo plays a problematic role in the logistics of FDA approval, and advised them to de-emphasize the placebo effect to ease the approval process (ibid.). Also in attendance was Lori Brotto, a psychologist and sex researcher whose work regarding female desire and arousal influenced the DSM revisions of HSDD (Brotto, 2010). Supported by Leonore Tiefer, Brotto talked about how the discussions around FSD and HSDD ignore the role of relationships, focus too much on the individual, and inflate the

prevalence estimates (Moynihan & Mitzes, 2010). The Paris conference was the site of uncertainty and conflict surrounding sexual medicine.

After the completion of Phase III clinical trials for flibanserin, Boehringer submitted their application to the FDA. The five Phase III and two extension studies are collectively known as the BOUQUET studies, each one named after a type of flower; Dahlia, Violet, Daisy, Orchid, Rose, Sunflower, and Magnolia (Clayton et al., 2010). In order to qualify for these trials, participants had to be women in stable, communicative, monogamous, heterosexual relationships of one or more years and had to have a certain distress score on the decreased sexual desire screener to indicate they could be diagnosed with HSDD. Both the highly feminized trial names and the narrow participant requirements raise questions about the politics embedded in this drug development. Whose low desire is being prioritized? The Phase III trials had coprimary endpoints of both a change in SSE/month and in the sexual desire score recorded by participants in an electronic diary, the eDiary. Although the requirements for participation were very strict, the criteria for what constituted a sexual event were broadened to include sexual intercourse, oral sex, masturbation, and genital stimulation by a partner. These primary and secondary endpoints are informed by FDA draft guidance, as there isn't a clear standardized roadmap for approval of a medicine to treat HSDD due to "the difficulties in measuring a complex cognitive experience such as sexual desire" (ibid., p. 644). It is not surprising that in many of the trials there was no notable difference between the placebo and flibanserin, however with certain dosage and time of ingestion the results were said to have a positive risk-benefit ratio. This was not enough for approval; after reviewing the trial data the FDA rejected the drug in June of 2010 based on its lack of effect on daily sexual desire and the concern regarding potential adverse effects (Joffe et

al., 2016). Due to the extensive research required to gain approval, Boehringer pulled the plug on flibanserin (Grogan, 2010). Despite the company's efforts to promote HSDD through hiring professionals and celebrities, highly incentivizing leading sex experts to attend conferences, and conducting several drug trials, the U.S. was still without an approved treatment to target FSD.

Sprout's fight to "even the score" through FDA approval

The Sexual Medicine Society's 2010 meeting proved to be an important moment in the timeline of flibanserin. The meeting was attended by Cindy Eckert, the head of the U.S. based pharmaceutical company Sprout that sold implantable testosterone for men (Pollack & Bray, 2015). Dr. Irwin Goldstein was also in attendance, considered a "modern-day Masters and Johnson" by Eckert, and an important figure in the development of Viagra and Boehringer's efforts to get flibanserin approved. Dr. Goldstein stopped Eckert at the meeting to show her a video he recorded of the moment in which he notified Boehringer's clinical trial participants that flibanserin had been rejected by the FDA. After seeing these women shake their heads, cry, and tell him what the drug would mean for their relationships, Eckert decided to sell off her profitable business in men to take on sexual medicine for women, requiring her to "strap on her pink boxing gloves and start throwing punches" (MacKenzie, 2018).

It was 2011 when Sprout pharmaceuticals entered the quest for a 'female Viagra'. When the company applied to the FDA for the first time in 2013, the global ED market had just reached $4.3 billion (Schulte, 2015). Viagra, Cialis, Stendra/Spedra, Levitra, Staxyn, MUSE, Zydena, Mvix and Helleva all existed as FDA approved treatments for male sexual dysfunction. However Sprout's initial submission for a female equivalent was rejected off the bat due to the high risk

and modest benefit; the FDA requested additional studies to be conducted regarding interactions with other drugs, the fatigue side effect, and the alcohol interactions (ibid.). Eckert voiced her disappointment, stating that the existing data warranted approval, but since a low value was assigned to the benefit of increased sexual desire, the risk undoubtedly would outweigh it. In the case of Addyi, Eckert claimed the lack of empathy for women's experience affected the benefit value. On the other hand, Barbara Mintzes, co-author of *Sex, Lies and Pharmaceuticals* and professor at the University of British Columbia, stated "it is hard to see what is sexist about the national drug regulatory agency refusing to approve a drug that was ineffective" (Thacker, 2014). This tension between interpreting the FDA's consistent rejection as a reflection of its institutional sexism or as a careful and accurate analysis of the data presented was prevalent in discussions within the feminist community. As Sprout continued to gather research and data in preparation for a second submission, several women's health organizations became involved in the controversy surrounding Addyi's 2013 rejection. Differences in ideologies and attitudes toward sexual medicine caused a rift in the position of women's groups. While some such as the New View Campaign urged the FDA to continue to reject the drug, others such as the prominent Even the Score campaign organized to encourage approval.

In 2014 the FDA announced 20 meetings on "patient-focused drug development" to bring together clinicians and patients to discuss diseases that remain without approved treatments (U.S. FDA, 2013). Usually these patient-focused meetings are reserved for life-threatening, incurable diseases, however this time female sexual dysfunction was added to the list (Block & Canner, 2016). The FSD drug hearing was a two-day event in Maryland attended by pharmaceutical companies, company allies, and women recruited and paid to testify about their experience with

low desire (New View Campaign, 2014). It was also attended by organizers of the Working Group on A New View of Women's Sexual Problems, or simply the New View campaign, an international collaboration of clinicians and social scientists created by Leonore Tiefer. The group lobbies against drugs targeting FSD and proposes a complex, woman-centered definition and approach to sexual problems in order to avoid the reduction of sexuality to biological mechanisms (Tiefer & Beres, 2005). They were in attendance with the goal of investigating and unearthing the research and promotional techniques of pharmaceutical companies that are biased towards profit rather than individual pleasure. The New View participated in the FDA hearing of Intrinsa in 2004, the FDA hearing of flibanserin in 2010, and the FDA's hearing on drug development for FSD in 2014. Through speaking out, providing data and petitions, and centering women's experiences, the group has fought actively against flibanserin and the medicalization of female sexuality.

At the 2014 hearing, the New View commended the FDA for its continued pro-women rejection of the unsafe and ineffective drugs developed to treat FSD. They raised concerns regarding the history of the medicalization of sexuality, the ambiguous drug safety and efficacy, the rhetoric used to promote sexual medicine as the cure to a disease, and the appropriation of feminist rhetoric in the pro-Addyi argument. They also presented the FDA with petitions they had collected as well as a "juicy bibliography of 27 counter-narratives to the narrow and unenlightened (not to mention inaccurate and self-serving) view of women's sexuality and sexual problems offered by the pharmaceutical industry" (New View Campaign, 2014). This included a range of studies regarding female sexuality; a study focusing on the lack of physician knowledge of the complexity of female sexual disorders (Bachmann, 2006); national survey results

suggesting the predictors of sexual distress from women's perspectives were not in line with DSM criteria (Bancroft et al, 2003); a Swedish study indicating that 6 months post-birth parents often show mutual discontent with their sexual relationship but happiness in the overall relationship (Ahlborg et al., 2005). The New View Campaign actively voiced their concern with the pro-Addyi Even the Score campaign, described by the New View as a "flagrant marketing tactic disguised as a pro-woman initiative" (New View Campaign, 2014). Similarly, others have called the campaign "classic faux-advocacy" and claimed it "emotionally blackmailed" the FDA into approval (Cassels, 2015). Even the Score's ties to corporate interests brought about a lot of controversy and attention, especially as their campaign was credited as very influential in Addyi's FDA approval.

Even the Score was a coalition of nonprofit and for-profit organizations formed in June of 2014 to urge the FDA to accept Addyi, framed as a grassroots effort to expose gender bias in the FDA. The leaders of the group said that it evolved out of discussions among existing women's groups (Tavernise & Pollack, 2015) and was created "to serve as a voice for American women who believe that it's time to level the playing field when it comes to the treatment of women's sexual dysfunction" (Hogenmiller et al., 2017). In early 2014 a group of women's organizations including the National Organization for Women (NOW) and the National Council of Women's Organizations (NCWO) met with the director of the FDA Center for Drug Evaluation and Research who had also served as assistant commissioner for women's health at FDA (ibid.). They invited Anita Clayton, the psychiatrist with financial ties to Boehringer that gave a noteworthy talk on the concept of the powerful placebo in 2004. Clayton, at this time a paid consultant of Sprout Pharmaceuticals, suggested the women organize a campaign to lobby

against the FDA. In a *Huffington Post* column, Clayton claimed the FDA's rejection of Addyi came out of a male-centric approach to FSD and urged them "overcome the problem of institutionalized sexism- unconscious and perhaps unintended, but damaging nonetheless" (Clayton, 2014). A public relations company was approached and the campaign managed to garner support from much of the nonprofit women's health community in Washington DC and included organizations such as the American College of Nurse Midwives, the National Association of Nurse Practitioners in Women's Health, and the Black Women's Health Imperative (Tavernise & Pollack, 2015). However, board members at several of the participating organizations such as the American College of Nurse Midwives, the Jewish Women International, and the Black Women's Health Imperative said they were unaware of their involvement in the Addyi campaign and thought the campaign was a "sexual health equity" campaign rather than a campaign in support of sexual medicine. One board member commented, "to me, it really looks like we and probably some of those other organizations were tricked into being part of something that we were never intending to endorse" (Block & Canner, 2016). Many other women's groups refused to support Even the Score, such as the National Women's Health Network and Our Bodies Ourselves. While its support aided in its visibility and power, a considerable amount of that support was misled and misinformed.

A rift in the feminist community

The ideologies of the Even the Score campaign and the New View campaign are at odds with each other; although both claim to have the mission of female sexual empowerment, the method by which to achieve this empowerment is conceptualized differently between the two.

Even the Score, and more generally those in favor of sexual medicine, view Addyi as a tool for women to reclaim control over their sexual lives. The New View believes true agency involves promoting a more holistic, women-centered, inclusive approach that acknowledges social, relational, and cultural contexts. This tension is representative of a several-decade-old ambivalence within the feminist community towards female sexuality.

The conversation surrounding sexual medicine after Viagra's introduction is reminiscent of feminist discussions in early stages of the contemporary feminist movement. The sexual liberation movement of the 1960s centered on the idea that women's liberation would be achieved through a shift in sexual attitudes and behaviors. Feminist thinkers urged women to be sexual agents, enjoy sexual pleasure, experiment with new sexual encounters, and "be sexually free" (hooks, 1984, p. 148). Sexual liberation was a means by which to resist the patriarchal, conservative norms imposed on women's sexual lives, and worked to revise the framework of sex in America through encouraging sexual behavior outside of heterosexual marriage (Fahs, 2011). Though challenging the repression of female sexuality, the movement did not deconstruct the gendered power relations present within the sexual sphere; society is more responsive to feminist demands that are non threatening and work to maintain the status quo such as engaging in more or better sexual activity (hooks, 1984). The movement failed to address the stigma connected to asexuality or low libido. Being sexual was still natural, while not being sexual was unnatural. The same ideology is expressed in contemporary mass media which frames sex as an "expression of inner desires" that every girl should be doing (Ussher, 1997, p. 4). This position is criticized for reinforcing strict gendered definitions of sexual freedom, the heterosexual matrix, and patriarchal domination over female sexuality. It does not address women's expression of low

desire or difficulties achieving sexual satisfaction (Fahs, 2011). Some feminist thinkers that stood in opposition to the sexual liberation camp denounced sexual contact with men altogether as the means to achieve sexual freedom.

To have sex or not to have sex? Pleasure can be both a source of empowerment and disempowerment (ibid.). Sexual liberation provided some key realizations regarding America's relationship to sexuality, but it is important to recognize that the eradication of male domination in the sexual sphere requires an approach that goes beyond the individual. "At its worst, sexual liberation is part of the cult of individuality which only demands legitimization of the expression of the individual's need, what appears to be her raw 'impulse' life, against the demands of society without considering a political reordering of the social order itself" (Person, 1980, p. 629). A feminist approach that solely emphasizes female individuality, autonomy, freedom of choice or equality as having what men have will not successfully reform sexism in the bedroom, the medical field, or sociopolitical spheres.

Addyi's marketing and the position of Even the Score take a liberal feminist position in their construction of empowerment through Addyi. When operating in a system that supports sexopharmaceuticals, it seems *only fair* that woman would have the opportunity for a sexual enhancement pill if men do. The argument operates under the paradigm of Viagra, a concept we will dive into further towards the end of the chapter. Liberal feminism platforms are centered around the concept of equality and improving the position of women within the existing system. Recognizing male domination in the sexual sphere, pro-Addyi rhetoric positions the drug as a way for women to demand their right to desire and reclaim power through sexual pleasure. However the platform fails to go beyond or outside of the dominant, masculine standard. It

doesn't question or reject the need for a sexual drug in the first place, or explore how the drug's position is complicated when produced in a market with ties to corporate interest and profit. Within this paradigm, sexual medicine is assumed to be the best solution to treat sexual problem, and female empowerment is conceptualized as gaining what men have. But the existence of a drug intervention for male sexual issues does not necessitate a drug intervention for female sexual issues; two wrongs do not make a right.

The New View Campaign is not against addressing female sexual issues or improving low sexual desire. It doesn't denounce sexual satisfaction, but rather takes issue with current medical models, frameworks, classifications and solutions. In contrast to the more liberal feminist position in pro-Addyi rhetoric, the New View advocates for a drastic reform of society's relationship to female sexuality, fundamentally denouncing the existing system as perpetuating the profitization and medicalization of the female body. The group has three major issues with the current state of sexual medicine. First of all, it ignores the relational context of sexuality. A diagnosis of HSDD and prescription for Addyi ignore the role of relationship factors and general context in a woman's experience of sexual desire. Secondly, it assumes universality in women's relationship to pleasure, ignoring the variety of opinions, needs, attitudes, experiences, behaviors, and issues regarding sexuality. Thirdly, it equates male and female bodies as it operates within the male analog, a concept that will be discussed further when exploring an alternative model of sexual response. The New View redefines female sexual problems as "discontent or dissatisfaction with any emotional, physical, or relational aspect of sexual experience" (Tiefer, 2001, p. 86). While Addyi supporters believe the medicalization of low

desire and the availability of a medical solution can work to legitimize and address their issues, Addyi's opponents problematize the classification of sexual disorders in the first place.

There is no unified, feminist position on sexual medicine or the classification of sexual problems such as HSDD. Arriving at a consensus would be a complicated goal; a consensus often requires the oppression of a minority opinion by a majority opinion and there is great diversity in women's experience and relationship to sexuality. Women fighting for and against Addyi claim to be fighting for female empowerment, but their avenues are in direct opposition with one another. "In the name of women, some are genuinely working hard to find effective treatments for women's sexual 'dysfunctions,' whereas others are just as genuinely mobilizing to tell women that they may be victims of a system that seeks to impose sexual standards that serve patriarchal and economic hegemonies" (Meana, 2010, p. 116). The medical approach falls short in that it perpetuates feelings of inadequacy and fails to recognize the complexity of female sexuality, simultaneously producing drugs which may be unsafe for women's health. The sociopolitical approach may unintentionally shame or stigmatize the women who seek out sexual medicine to relieve distress associated with low desire. Supporting Addyi is not inherently less "feminist" than opposing it, however its necessary to acknowledge the ways in which Addyi continues to reinforce the norm, despite being framed as a "game-changer." Is it revolutionary to give women the option to take a pill to increase their sexual desire within monogamous, heterosexual, long-term relationships without addressing the social, political, relational, cultural or personal factors that may be at play?

The score becomes 26 to 1

While campaigns involving women's organizations lobbied both for and against the approval of Addyi, Sprout Pharmaceuticals raised money in preparation for the hearing. By 2015 they had raised over $15 million for the clinical trials (Schulte, 2015), had collected data on a total of 11,000 women in 68 trials with low sexual desire disorder in the U.S., Canada, and Europe (Eckert, 2017), and had raised more than $100 million from private investments to support its development, approval, and distribution (deBruyn, 2015). Many were eagerly awaiting the 2015 FDA hearing; the controversial 'female Viagra' had gotten a lot of attention. *Time* magazine listed Addyi as "the number one inanimate object that drove the news in 2015" (Block & Canner, 2016). In January of 2015, Cindy Eckert had 8 minutes to pitch her drug to a "sea of blue and gray suits" at the J.P. Morgan Healthcare Conference (Marinova, 2017). Many times she found herself presenting to a room in which she was the only woman, noting the social discomfort of most male investors that she presented to (idib.). Despite societal discomfort surrounding female sexuality, in August of 2015, a full 17 years after the approval of Viagra, Addyi finally became the first FDA-approved treatment for FSD. In Eckert's words, "science had finally won" (Eckert, 2017).

With the combination of what she considered significant evidence and an increased level of empathy, the "score" became 26 to 1. Although Even the Score stated "there is still a long way to go before we achieve true gender equity in sexual health – and Even the Score will be there every step of the way," the day after the approval of Addyi was the last day they posted on their website (Hogenmiller et al., 2017). Is FDA approval of the first drug treatment for low sexual desire all that was needed for true gender equity? Many of the groups that lobbied against

Addyi's approval thought that the approval was a direct result of the Even the Score campaign tactics. Steven Woloshin and Lisa Schwartz, physician-researchers at Dartmouth Medical School and the founders of pharmaceutical education company Informulary, believed that the approval was an override of scientific evaluation. Upon observing the data, the researchers didn't understand the approval because the drug interaction was "so alarming that [the trial] was stopped early because so many people had low blood pressure or fainted" (Block & Canner, 2016). Those involved in Even the Score obviously disagreed, publicly urging people to realize the distinction between bullying and advocacy. One activist in the campaign said "if the science didn't support approval, the F.D.A.-appointed advisory committee of doctors, clinicians and other safety experts wouldn't have approved it" (Tavernise & Pollack, 2015).

Addyi's FDA approval did not signify smooth-sailing from there on out. Its approval was made with certain conditions; a black box warning was issued as well as an accompanying REMS program due to the strong need for more evaluation and patient-specific counseling regarding the need, use, and safety risk of the drug (U.S. FDA, 2015). The FDA uses black box warnings to indicate serious or life threatening risks associated with a medication. Addyi's side effects include severe low blood pressure and loss of consciousness, heightened by alcohol use or liver problems (ibid.). In clinical trials, participants noted dizziness, nausea, fatigue, somnolence, and insomnia (Moynihan & Mintzes, 2010). The REMS program was initiated due to the risk of severe hypertension and syncope that accompanies alcohol use. It requires prescribers and pharmacies to enroll in a training and certification process, in addition to making pharmacies check prescriber's certification prior to distributing the drug. Sprout was also

required to refrain from direct-to-consumer advertising for 18 months to focus on educating doctors about HSDD and Addyi (Thomas & Morgenson, 2016).

The FDA was put in the position of assessing a drug for which there was little medical or social consensus, with experts disagreeing on either side and pressure from competing feminist campaigns. Regardless of the basis for or accompanying restrictions of Addyi's approval, it was immediately sold by Sprout pharmaceuticals for $1 billion in cash to the pharmaceutical company Valeant International. The $1 billion exchange verified the confidence that Big Pharma had in Addyi's potential; the drug was given a high value based on expectations that it would prove as revolutionary as Viagra.

The paradigm of Viagra

> "In a paradigm where men's desires reign and their power is exercised and reinforced repeatedly, beliefs about women as dysfunction, particularly in heterosexual contexts, seem far less threatening than a nonflattering assessment of men's sexual abilities. Women's *bodies* become the targeted problem, not men's *abilities*." (Fahs, 2011, p. 136)

Viagra was the little blue pill that changed sex in America forever (Loe, 2004). Its emergence ushered in the sexuopharmaceutical era, which emphasizes and rationalizes pharmaceutical intervention for sexual problems. The paradigm of Viagra denotes sexual medicine as the appropriate treatment for sexual disorders; Viagra for ED and Addyi for HSDD. Sexual medicine affects sexual expectations of both men and women, as the technology shapes and is shaped by societal norms. Operating within the paradigm of Viagra perpetuates narrowly define and demanding sexual behavior, requiring men to have unfaltering erections and women to have a consistently high sex drive. Reaching these expectations may indeed require medical

intervention for many individuals, which is why it is so necessary to challenge the expectations themselves.

Although the development of a drug to target low female sexual desire followed a similar strategy to Viagra- labeling the issue as a disorder, increasing the potential audience, and capitalizing on gender stereotypes in the marketing of the drug as a simple solution- the hunt for Addyi was met with a level of ambivalence that does not play as clear a role in male sexual medicine. This uncertainty reflects a lack of cultural consensus and a societal discomfort with female sexuality. The medical and pharmaceutical fields want female desire to be neatly and objectively quantifiable, but that is not how female desire works. One cannot measure an increase in female desire the same way erectile functioning can be measured, due to the ambiguity and variability in disorder classification and the shifting definitions of desire.

The story of Viagra and the early stages of the search for a female Viagra provides insight into the complicated process of developing and approving a treatment for FSD. Addyi operates within the paradigm of Viagra, which poses sexual medicine as the solution to sexual dysfunction. Beyond issues with safety and efficacy, the drug was politicized through competing feminist frameworks to sexual medicine and more generally female sexual behavior. By looking at the early stages of the development of a 'female Viagra,' I hope to highlight the lack of consensus on female sexual issues that currently exists in medical, academic, and social spheres. This will lead us into the following chapter in which I focus on the ways in which the pharmaceutical industry attempted to capitalize off of gendered messages embedded within Addyi, and yet failed to profitize successfully as in the case of Viagra. The controversy over

Addyi did not end at the 2015 FDA hearing, and in the following chapter we will explore how taking it to the market brought new challenges.

CHAPTER III. THE "REAL LAUNCH" OF ADDYI AND THE PINK CEO

"For me, pink is about owning it as a woman. You have two options when it comes to gender stereotypes-you can either rail against them, have them paralyze you in frustration, or you run right toward it as I do. Pink, for me, became the transition from underestimated to unapologetic. When people said I had a 'little pink pill' and patted me on the shoulder, I understood there was some dismissiveness there, and that's what needed to be addressed. So I started wearing hot pink." - Cindy Eckert (Marinova, 2017)

Addyi's position in the sexopharmaceutical era has been complicated, in stark contrast to the development, approval, distribution and marketing of Viagra. A promising billion dollar deal with an international pharmaceutical company did not produce the predicted market success, initially due to issues with cost, distribution, insurance coverage, and the HSDD educational campaign. Despite constant setbacks to the drug's availability, Cindy Eckert's determination to fight for Addyi did not falter. Eckert became a leading figure in the marketing campaign for the drug. Labeling herself the "Pink CEO," she took to social media and press coverage to educate the public about Addyi and it's potential to be a sex-saving drug. Eckert frames Addyi as providing women access to the choice to reclaim their sexual desire. She also frames it as a matter of female representation in the medical and pharmaceutical fields. This chapter recounts the challenges faced in the introduction of Addyi, the necessary relaunch, or rather "real launch" (Godnick, 2018) of Addyi in the summer of 2018, and the role of Eckert in the gendered and heteronormative marketing of the drug. This timeline forms the foundation by which I will explore the reasons behind Addyi's failure to be as revolutionary as Viagra its reinforcement of sexual normalcy consistent with conventional, heterosexual norms. As Eckert said in the opening quote, the production and distribution of Addyi required her to run towards gender stereotypes rather than let them paralyze her. But what are the social implications of operating within the

existing paradigm in which sexual medicine plays a large role in our interactions with desire, sex and sexuality?

Addyi's first flop on the market

Sprout pharmaceuticals raised a lot of money and conducted a considerable amount of research to get Addyi approved, but it was a small company that would need help in the marketing and distribution process. At the time of Addyi's approval, Valeant was doing really well; it posted revenue of 8.3 billion in 2014 with 18,000 global employees. Valeant promised to retain all of Sprout's employees and allow Sprout investors to remain entitled to future profits (Pollack & Bray, 2015). Aware that the controversy surrounding the drug would make it difficult for Sprout to find an interested buyer, Valeant's chief executive believed their company was Addyi's best bet to do really well on the market (ibid.). Cindy Eckert noted that the partnership with Valeant "brings access to more women, more affordable access, and takes it across the globe" (Eckert, 2015).

It became very clear a few months after the billion-dollar exchange that Addyi was not making the splash Sprout had hoped it would; in fact almost everything that could go wrong did. Within a few weeks of Valeant's purchase, the international company faced allegations of improper accounting and hiked drug price (Gandel & Reuters, 2016). Prominent politicians such as Bernie Sanders requested information on why they hiked the price of two heart drugs, which was discovered to be common practice for the company; they increased the price of medications by an average of 66 % (ibid.). Off the bat, Valeant doubled the price of Addyi and severed ties with the planned distributor (Thomas & Morgenson, 2016). Within the first three to four weeks

of Addyi's launch, the demand was incredibly low; in the first month only 277 women were prescribed Addyi compared to Viagra's half a million prescriptions (Armstrong, 2015; Edney & Colby, 2015). Despite the attention in the press and online, women were making the decision not to take Addyi, potentially due to the questionable efficacy, potentially harmful side effects, and lack of general knowledge regarding both the disorder and the drug. Due to the FDA's REMS program, doctors were required to watch a ten-minute informational video and fill out paperwork in order to prescribe Addyi. Without basic promotional materials or a comprehensive educational campaign, Addyi's team of 150 sales representatives was ill-equipped to address the 35,000 OBGYNS and 450,000 primary care doctors in the U.S. (Thomas & Morgenson, 2016); only 4,000 prescriptions written between February and September 2016 at a monthly cost of $800 (Block & Canner, 2016). This meant a monthly average of 600 prescriptions were written compared to almost 800,000 for Viagra and Cialis (Koons, 2018).

Another hurdle Addyi faced was insurance coverage, despite the fact that Viagra is covered by most insurance companies. Dr. Goldstein from the Sexual Medicine Society meeting in 2010 and now a paid Sprout consultant called the difference in coverage was startlingly sexist (Cohen, 2016), although Valeant had doubled the $400 per month price that Anthem Insurance agreed it would cover (Thomas & Morgenson, 2016), but under Valeant the cost had doubled. One woman with Blue Shield Insurance was refused coverage for Addyi because the company required a psychiatrist's diagnosis of HSDD and because she was on a medication that had a potential side effect of low libido (Paiella, 2016). The spokesperson for Blue Shield California responded to CNN's coverage on the woman's experience by saying that a committee of pharmacists, physicians, and psychiatrists reviewed the medical evidence and determined that

HSDD should be diagnosed by a psychiatrist, as the black box warning necessitates a careful diagnosis before taking the drug (ibid). This reflects a general lack of understanding of how to diagnose and classify HSDD. The woman would have to pay $800 a month for Addyi while her boyfriend's Viagra was covered even though he does not have erectile dysfunction and takes the drug as an enhancer. A spokesperson for America's Health Insurance Plans also chimed in to say that the FDA's eventual approval of Addyi was a result of the Even the Score campaign rather than convincing data, because "if there's a question mark around a coverage decision, that usually means there's a question mark around the efficacy" (Cohen, 2016). The National Women's Health Network's one-year report card for the anniversary of Addyi's FDA approval assigned Addyi a D for doctor training and an F for natural demand, calling the safety training program "laughably bad" (NWHN, 2016). Valeant tried to blame the small sales on female patients' reluctance to take the drug rather then on the failure of the training program, as 82% of prescriptions written were going unfilled in 2015 (Wieczner, 2017). Cindy Eckert has claimed that the modest sales are a result of the FDA restrictions on a direct-to-consumer marketing campaign and the need to educate the public, medical professionals, and medical providers about Addyi and HSDD (Eckert, 2017a).

Whether Valeant was not interested or not able to sell Addyi effectively, the drug that was supposedly entering a large market of unmet need was set to generate less than $10 million in sales in 2016 (Wieczner, 2017). Addyi had not lived up to its expectations and Valeant was facing a lawsuit for its failure to meet the obligations named in the billion-dollar-exchange. Sprout shareholders sued the pharmaceutical company and Valeant decided that returning Addyi to its original owner was better than fighting Sprout in court or launching a revamped marketing

campaign. Sprout reclaimed Addyi along with an additional $25 million, which would be used to cover startup expenses as they prepared to relaunch the drug in 2018.

The "Real Launch" of Addyi and the ethics of accessibility

By the summer of 2018, Addyi had faced three rejections from the FDA, a failed launch after FDA approval, and a lawsuit. Finally it was back in the hands of Cindy Eckert at Sprout Pharmaceuticals and ready to re-launch to the public. Because of the sensationalism spurred by the media and the controversy among feminists, medical experts, and women's organizations, Addyi's re-emergence was long-awaited. If Sprout wanted the drug to make a bigger splash this time around, it would need to step up its distribution strategy and bypass the restrictions imposed by the FDA's REMS program. This was largely accomplished by the use of telemedicine.

Accessibility was one area that proved very difficult for Addyi under Valeant's ownership. As Eckert said, "it was theoretically in the supply chain, but for a woman to have gotten this drug in the last two years was like winning the Powerball" (Marinova, 2018). Sprout slashed the price back to $400 a month, meaning those with insurance coverage would pay $25 a month while those without coverage would pay $99 a month (Koons, 2018). Although cheaper, the avenues of education still needed to be defined. In order to address the lack of doctors and pharmacies who were knowledgeable of HSDD and certified to prescribe Addyi, the drug became accessible via telemedicine. Before 2018, only 10% of the pharmacies in the country stocked the drug (MacKenzie, 2018). With telemedicine, women could consult a doctor from anywhere in the country and have the drug delivered by mail to their doorstep. However through Sprout the required consultations cost an out-of-pocket fee of $75, considerably complicating

their financial accessibility. Accessibility as represented by Sprout's consultation fee as well as their partnership with the telemedicine brand Hers, gives insight into the audience they are trying to reach.

Sprout partnered with the telemedicine brand Hers, a direct-to-consumer sister company to the several year-old site Hims. Hims launched to sell hair loss and erectile dysfunction drugs and in the first week already had $1 million in sales (Tindera, 2018). It had $97 million in venture capital funding from investors to launch Hers, a female equivalent which would sell skin creams, birth control, and of course Addyi (ibid.). The website uses rhetoric similar to Eckert's, claiming "women have been pat on the shoulder and ignored when it comes to giving us a solution to this very real, very common concern." The drug is framed as a game changer that will address female low libido and allow women to reclaim their sex drives. Although attempting to make Addyi more accessible, Hers doesn't accept insurance. That means the women who use it have to pay $99 a month. When asked why anyone would want to pay $99 when an insurance plan can potentially cover the drug, Hers said that its goal is to put power back in the hands of women, addressing gaps in accessibility by allowing an alternative, more convenient and discreet way to get Addyi. This could benefit women with demanding work schedules or who don't want the drug to show up on family insurance records, but it does so at the expense of economic accessibility. While direct-to-consumer telemedicine can allow for easier, more discreet access to Addyi, it can potentially compromise affordability.

Widespread accessibility is vital for a drug to be able to reach a large audience across geographic and socio-economic lines, yet there is a lot of controversy regarding the ethics of telemedicine as a route to access. Telemedicine is becoming more common as technology has

evolved to create new and alternative communication and distribution pathways in medical care and pharmaceuticals. One main concern for the rise of these alternative patient-provider interactions is the implications of the loss of face-to-face consultations. The American Medical Association (AMA) has emphasized the need for telemedicine to be used only as a complement or supplement to live visits, and be reserved for patients who have a relationship or history with the provider (Mehta, 2014). The Texas Medical Board (TMB) stated that prescribing medicine without this pre-existing relationship has the potential to compromise safety and efficacy (Worth, 2015). One has to be especially careful with telemedicine in the case of Addyi, a highly controversial drug with a black-box warning. The DSM-V has supposedly evolved through the inclusion of partner factors, relationship factors, vulnerability factors, stressors, cultural and religious factors, and medical factors., but when these consultations are occurring online and over the phone, will a doctor take the time to ask questions that will deepen their understanding of the complexity of their patient's relationship to desire? And with the price of these consultations, whose accessibility is being prioritized?

All pink, all the time

After Sprout reclaimed ownership of Addyi from Valeant, Eckert became a leading figure in the marketing campaign for the drug. Labeling herself the "Pink CEO," she took to social media and press coverage to educate the public about Addyi and its potential to be a sex-saving drug. Through the employment of gendered advertising, Cindy Eckert and her drug became all pink, all the time. In addition to increasing accessibility and recognition of the drug, Eckert became somewhat of a celebrity- she was the woman behind 'female Viagra,' supposedly

changing stereotypes and championing women's rights. Addyi was one step in her mission to unapologetically empower women, in both private and public spaces. But the connection between sexual medicine and female empowerment is the result of the successful marketing of Viagra; the new "Viagra wives" must keep up with their husbands.

"Your brain may be working against you when it comes to sex," reads the text on Addyi's website above an image of a heterosexual couple in bed, peeking out from under the covers (See Photo 1 in Appendix). A little farther down the page there are two images of a brain, one labeled "healthy" and the other "HSDD" (See Photo 2). The healthy brain is lit up in pink, while the HSDD brain has only small blotches of pink here and there. Below is a bold text blurb stating "millions of premenopausal women suffer from distressing low sexual desire." This statistic is informed by a Boehringer Ingelheim funded study of sexual problems experienced by U.S. women in 2008 (Shifren et al., 2008). Investigating further into the study shows several key observations not included on Addyi's website. Sexually related personal distress was observed in only 22.8% of respondents, and the prevalence of sexually related personal distress associated with the presence of any of the three sexual problems of low desire, low arousal, and orgasm difficulties was only 12%. Though the study acknowledges the significant association between distressing desire problems and socioeconomic and demographic variables such as race, partner status, employment, and level of education, over 80% of the respondents were white women, and the majority of respondents were college-educated, employed, and in steady relationships. From this information, Sprout simply concludes that millions of women are suffering from distressing low desire.

Similarly to the all-blue Viagra website, Addyi's website is entirely pink. As Eckert explained, "pink is about owning it as a woman" (Marinova, 2017). Not only is Addyi pink, but so is Cindy Eckert. At almost every promotional event, Cindy sports hot pink; pink pant suits, pink dresses, pink heels, pink glasses, pink frilly sleeves, sporting little pink pill (See Photo 3). Through her eyes, the employment of gendered marketing is a way for her to reclaim a stereotype. Making Addyi the little pink pill is in line with sexopharmaceuticals' production of gendered meanings for drug users. Cindy Eckert spearheaded the marketing of Addyi and was the driving force behind it's approval, distribution, and media presence. She took to social media and the press to garner attention, accumulating just shy of 12,000 followers on Instagram and 27,000 followers on Twitter. In her Instagram bio, Cindy describes herself as an "entrepreneur by skill, unapologetically pink by nature, helping others shatter The Pink Ceiling by choice..oh btw $1.5B in exits, (but who's counting?)." Underneath her bio is a link to the Voters' Choice Awards by WRAL, a radio station in Raleigh, North Carolina in which Cindy was voted runner up for Woman of the Year. The instagram also serves to update followers on the work Eckert is doing, such as her position as the annual Raleigh Christmas Parade Grand Marshal and the speaker at Birmingham Venture's annual meeting. She's been featured in many magazines, named one of *Entrepreneur*'s "Women to Watch," *Triangle Business Journal'*s "People to Watch" and *Inc Magazine*'s "Female Founders 100." Eckert has conducted interviews with *CNBC, Fortune magazine, Entrepreneur, Forbes*, among others. She has even given her own Ted Talk on the intentions behind Addyi, illustrating how it stems from empathy and a willingness to change the game for the sake of women's control over their own sex lives (Eckert,

2017b). Through positioning herself as a feminist figure, she uses gender stereotypes to her advantage in order to gain traction in a field traditionally dominated by male voices.

Eckert is featured in these magazines, interviews, and news stories as a result of her role in the production of Addyi, but also because of the Pink Ceiling, the venture capital firm and consulting enterprise she opened in 2016 with part of the funds from the billion-dollar Addyi deal. The name is a reference to the glass ceiling that bars women and other minorities from corporate spaces such as the pharmaceutical industry; as Eckert said "the thesis is: let's stack the billion-dollar club by smashing the pink ceiling together" (Smith, 2018). Out of the Pink Ceiling came the the Pinkubator, a startup incubator in Raleigh focused on helping female entrepreneurs launch new products and companies. The Pinkubator, rumoured to have rosé on tap, has the mission of making other women "really f**cking rich" (Robinson, 2017). It is worth noting that Eckert's work with the Pink Ceiling and the Pinkubator does provide important funding and mentoring resources for women-led or women-focused businesses through Addyi's accumulated profits. Although its mission is to support female-led business and increase female representation in fields that are traditionally exclusively male, it does not make Addyi less controversial. Eckert links Addyi and the Pinkubator in that the latter works to put money in the hands of women as Addyi did for her. In discussing the goal of the Pinkubator, she said "we talk all the time about how women need a voice. We don't need a voice- we need power. Money is power. I say that confidently because the data shows that when women have that power, they pay it forward" (ibid.). She believes women have found their voice, and the missing piece is money. This gives insight into her priorities for female empowerment; her position in the Pinkubator shows that she

is prioritizing money as a form of female empowerment. But have all women found their voice? Which women's voices do we value and uplift?

Corporate Feminism: Your body, your choice

> "The history of drawing on feminist language and theory to sell products has been driven by the idea that female consumers are empowered by their personal consumer choices- indeed, that choice, rather than being a means to an end, is the end itself. The idea that it matters less *what* you choose than what you have the right to choose is the crux of 'choice feminism'..." (Zeisler, 2016, p. 18)

Addyi is situated at the intersection of medicine, gender, sexuality, and capitalism. It is a medical technology, but it is also a product within a market. Potential patients become potential consumers, and their understanding of and relationship to the drug is shaped by its advertising. The corporate interests in selling drugs embedded with gendered messages is a concern for many women (Fahs, 2011). Addyi's marketing strategy capitalizes on feminist rhetoric; the drug represents the key to female sexual empowerment, the choice to reclaim power over female sexual lives, the fight against sexism in sexual medicine, and the means to make women really f**cking rich. Andi Zeisler's *We Were Feminists Once* provides an insightful analysis into the ways in which feminism has been rebranded and co-opted by mass media to drive marketing and advertising campaigns. Though the author doesn't focus on sexual medicine, her account of how feminism is bought and sold can be useful in framing Addyi.

The selling of Addyi relies on the medicalization of female bodies to meet societal expectations. Products geared towards female audiences, especially of a white, middle-class background, are often marketed to address a problem that "the consumer might not ever know she had until she was alerted and/or shamed for it" (Zeisler, 2016, p. 25). They depend on the

creation of insecurity, often in line with cultural expectations of gender. Advertisements use rhetoric to appear in the spirit of feminism, yet capitalize off of addressing the insecurities that they create or perpetuate. While the framing of Addyi by Sprout Pharmaceuticals and Cindy Eckert may seem less obvious than Zielser's example of the "freedom spray" aerosol douche or the "Liberated Wool Sweater" (ibid., p. 7-8), the company capitalizes off of cultural insecurities related to expectations of femininity.

Addyi's marketing campaign adopts choice feminism by employing feminist messages to advertise and profitize through building on the idea that any choice made by a woman is a feminist choice. In this "empowertising," having the option to take the drug becomes an expression of liberation in itself (ibid.). Choice plays a big role in Eckert's discussions regarding Addyi; in a 2018 tweet she wrote "this is about choice- women can take Addyi or not take it, but for women who need it, they deserve the option" (MacKenzie, 2018). The power of choice coincides with the power of the purse, an important tenet of marketplace feminism. Who holds the power to purchase Addyi, and which women does Addyi make "really f••cking rich"? According to Zeisler, the easy target demographic of feminist advertising is and has historically been white, middle and upper class, cisgendered women. One relevant critique of choice feminism that is especially relevant to Addyi is that it disregards limits posed by socioeconomic, political, or racial barriers, assuming the choice is accessible to everyone. "We know logically that choices aren't made in a vacuum: we assign financial, aesthetic, and moral value to any number of choices in the course of each day, and most of us get that these choices mean something in our larger world" (Zeisler, 2016, p. 187). It's necessary to challenge the idea that choice is a tool for empowerment in itself, regardless of the choice made or the implications of

the availability or promotion of that choice. The prominent rhetoric of Addyi's marketing frames empowerment as centering on technological equality and individualized choice.

'Female Viagra:' A very different story

Although given the name 'female Viagra' before it was even discovered, Addyi was not the game-changer for women's sexual lives that Viagra became in the turn of the 21st century. It wasn't that there was no interest for a female sex-saving drug; it was clear that the funding, research, interest, and supposed unmet market existed since the early 2000s. Yet Addyi's story was not as straightforward as Viagra's, which was fast-tracked through the FDA approval process and introduced to the market with staggering sales. Cindy Eckert has said herself that Addyi is no Viagra, highlighting the different mechanisms of the drugs' function. But the difference goes beyond what area of the body the two drugs target; Addyi has been the topic of feminist debate and media controversy, and has faced three FDA rejections, advertising restrictions, black box warnings, and unimpressive sales. So, why is Addyi failing to be for women what Viagra is for men?

Beyond the fact that Addyi and Viagra work differently, the mechanisms of Addyi create a high barrier for usage. For one, the drug is a long-term commitment, as it must be taken every day over the course of several months in order to judge efficacy. The safety is a point of concern for potential users and was a large part of the FDA's rejections. Individual women have expressed apprehension about its safety (Fahs, 2011), in addition to various organizations and researchers (Block & Canner, 2016). The National Women's Health Network went so far as to launch a campaign in the wake of Addyi's approval called "Pass on the Pink Pill- or Pass Out!"

to warn women of the risks of low blood pressure, dizziness, and sudden loss of consciousness. Addyi's black box warning strongly discourages alcohol use, as it increases severe hypotension and syncope risk. Under the drug interaction section of Addyi's drug monograph, as found on the U.S. health network Athenahealth website, over 40 substances are listed as contraindicated, over 70 are advised to avoid, and over 200 are listed as important to monitor while using Addyi (Epocrates, n.d.). These safety concerns, in combination with the low efficacy rates, play a role in the low number of users.

The lack of knowledge about the drug and the original challenges faced in distribution presented high barriers for access. As Eckert said, getting the drug would have been like winning the Powerball in Addyi's first two years in the supply chain. The ban on direct-to-consumer advertising and the REMS program made it difficult for medical professionals and women to even be aware of the drug in the first place. In addition, Valeant severed ties with the distributor, failed to launch an effective educational program, hiked the prices, and couldn't get insurance coverage of the drug. These variables created an initial setback for Addyi's emergence, and though some were addressed in the relaunch of the drug in the summer of 2018, the safety concerns, low efficacy rates, high price, long term commitment, and lack of knowledge continue to play a role in Addyi's inability to revolutionize the female sexual experience.

Beyond the mechanisms of the drug and its high barrier for usage and access, some have pointed to the role of potential cultural understandings of female sexuality in the difficulty of finding a successful 'female Viagra'. Researcher and professor Rebecca Kukla considers the attempt to medicalize female sexuality a failure, highlighting several cultural reasons that worked to resist medicalization. These reasons include the conceptualization of female sexuality

as useful for other reasons outside of the pursuit of pleasure, unlocatable to one specific part of the body, mysterious and unpredictable, and fragile and context-dependent (Kukla, 2017). Whether there is truth in these cultural understandings is besides the point, because their importance is in the role they play in Addyi's failure.

Kukla points to the notion of female sexuality as serving a purpose beyond the pursuit of pleasure, woven into social narratives specifically as a way to negotiate, control, or manipulate male behavior. This functions to link sexuality to social needs and narratives, and challenges the idea of an effective physiological intervention. Women have sex for a variety of reasons both within and outside of the quest for physical pleasure. Studies have shown that some of women's primary reasons for engaging in sexual activity are to satisfy a partner, avoid interpersonal conflict, promote relationship intimacy, avoid rejecting a partner, express love, escalate depth of connection, explore curiosities, and celebrate (Meana, 2010). Desire can be present even if sex is not the goal, but rather the means. Should the motivating goals of closeness, intimacy and relationship maintenance be considered a part of female sexual desire, or considered a collection of non-desire-based motives? Should there be a distinction between sexual activity pursued because of these motives and sexual activity pursued because of a physical, pleasure-focused motive? If female sexual desire is thought to be connected to all of these different identities and goals, in contrast to the cultural perception of male sexuality's link to erectile functioning and pleasure, a successful solution to female sexual issues is not going to be an easy find.

The notion that female sexual behavior operates to serve social purposes also works in other ways that complicate the search for a 'female Viagra'. It is interesting to think about the relationship between sexuality, masculinity, and femininity. Meika Loe, author of *The Rise of*

Viagra, recounted a conversation she had with a U.S. doctor and his patient in order to illustrate how masculinity is often perceived as inherently linked to sexual pleasure. According to this doctor, a functioning penis is integral to the male identity. "For many men the idea of not being able to 'get it up' is a fate worse than death" (Doyle, 1983, pg. 205). As we saw in Chapter 2, this link between sexual function and manhood was capitalized on by the marketing of Viagra. Pfizer was selling a drug to address "a symptom of 'failed' masculinity" (Johnson & Asberg, 2017, p. 88). Most of Loe's male interview subjects were in agreement with this attitude, which makes sexuality a requirement for masculinity and constructs femininity in opposition to both masculinity and sexuality (Loe, 2004). Female sexuality is tied to social mechanisms beyond sexual pleasure, as sexual endeavours can be a tool for social negotiation, a fulfillment of the role of mother and wife, and an instrument of intimacy.

The trope that female behavior, thoughts, moods, and sexuality are unpredictable and mysterious can be traced back many centuries and is still present today. Beyond the mystery of what female sexuality is and how desire functions, is the question of where it is located. Female sexuality can't be isolated to one part, as it's conceived as ever-shifting, everywhere, and nowhere. Low female sexual desire can't be solved with a pill that enhances blood flow to the genitals nor one that targets the brain. Desire is not a concrete, easily-definable concept, and it has no consistent referents. Without consistent referents, it is incredibly difficult to identify criteria for HSDD diagnosis. While the cultural understanding of female sexuality as mysterious and unpredictable works to resist medicalization, it has also been noted as an excuse as to why female sexual issues are too difficult to address; "women are just too complicated to measure. Everyone was saying this, from transport planners, to medical researchers, to tech developers:

they were all knocking their heads up against Freud's riddle of femininity and coming away baffled and defeated. Female bodies are too inharmonious, too menstrual and too hormonal" (Perez, 2019, p. 314). In order for positive resistance to medicalization, it must be accompanied by efforts to create a deeper understanding of female sexual health rather than used as an excuse to remain ignorant.

What do women want? As Kukla points out, this question has been the subject of much debate in popular culture, medical literature, and interpersonal conversations. Addyi relies on this question, because the diagnosis of HSDD rests on the discrepancy between what women feel and what they *want* to feel. It is supposed to be revolutionary, and yet it capitalizes on conventional standards of normalcy.

> "I've pretty much given up hope. My marriage is OK because my husband is a good man. We have sex whenever he can't take it anymore. I think we have both settled on that, but I still wait for the day he asks for a divorce...I hope it gets approved to that other women won't have to go through what I am...I just wanted to write this and say thank you. Thank you for not telling me it's my fault. Thank you for not telling me it's all in my head. Thank you for not telling me that I am broken and I am not fulfilling my wifely duties only because I don't want to. Mostly, thank you for letting me know I am not alone." -Addyi user (Eckert, 2017b.)

The quote above is from a woman in Texas who reached out to Cindy Eckert to express her yearning for the approval of Addyi. She brings up important points regarding how the medical diagnosis of HSDD and availability of Addyi relieve her of personal stress and guilt associated with low sexual desire. There is a theme present in this quote as well as in the testimonials of other female users and resistors of Addyi: distress related to an inability to keep up with a standard of normal sexual libido, whether that standard is based on cultural sexual scripts, a previous level of libido, or a measurement based on a partner's desire.

In *Performing Sex: the making and unmaking of women's erotic lives*, author Breanne Fahs draws a key observation regarding women's varied reactions to 'female Viagra'. In the interviews she conducted with women who were supportive of a pharmaceutical treatment for low desire, the disconnect between a woman's experience and her expectations regarding desire was especially clear. There was concern, fear, and frustration surrounding low libido and the inability to alleviate sexual pressure from partners (Fahs, 2011). The requirements of Addyi's clinical trials participants to be cisgendered women in long-term heterosexual relationships, the language used in the medical literature, Sprout's advertising campaign and relationship to accessibility, and the rhetoric employed by Cindy Eckert work to privilege specific bodies and sexualities. The classification of disorders and medical interventions work to denote what is normal and natural from what is not. In the case of sexual disorders, "to act sexually is deemed natural, normal, to not act, unnatural, abnormal" (hooks, 1984, p. 151). Sexual abnormality becomes behaviors that stray from "genital-centered, intercourse-oriented, heterosexuality based on love and monogamy" (Seidman, 2010, p. 7). This renders certain identities and expressions atypical and deviant.

Feminist critiques on the role of sexual medicine in keeping women in the conventional roles of partner, wife, or mother reveal a parallel to early notions of frigidity discussed in the first chapter. The diagnosis of frigidity was centered around traditional notions of femininity and heterosexuality, accompanied by an emphasis on the importance of sexual pleasure in maintaining marriage. Addyi as a treatment for HSDD holds a similar power, still reinforcing narrow rules as to what constitutes "normal" sexual behavior that are consistent with conventional, heterosexual norms. In the design and development of drugs to target FSD, the

expectation is that a normal woman should be sexually serious, easily aroused, fully lubricated, and orgasmic (Loe, 2004).

While challenging the conceptions of female sexual normalcy is vital, I do not wish to undermine the experience of distress associated with low libido. As Fah's interviews illustrated, distress is often rooted in the discrepancy between a woman's libido and that of her partner, as well as between what a woman actually feels and what she thinks she *should* feel. Low sexual desire is the most common presenting sexual complaint in women, reported at much higher rates in women (Meana, 2010). This raises questions about societal conceptions of female sexuality and desire, and the social implications of sexual medicine's role in our interactions with desire and sex. What do we consider "normal," and what would be the ramifications of challenging, resisting, or redefining normalcy?

Female sexual desire is not a simple concept. There is a lack of consensus in the feminist community and the medical field towards desire and sexuality, evident in the varied and changing clinical definitions and models of desire. Kukla's fourth cultural understanding of female sexuality that works to resist medicalization within current medical frameworks is the notion that female desire is fragile and context-dependent. Personal, sociocultural, or relational contexts do not play a role in the contemporary hegemony of female sexology, which in turn creates difficulties in effective design and development of treatments. Models of sexual desire and sexual response continue to emerge; I will present one in particular in the following chapter that centers the importance of context, challenges the dominant framework as represented in the FSD literature and the DSM, and illustrates how contemporary standards misconceive of sexual functioning in the medicalization of female sexual issues.

CHAPTER IV. DISPUTING ESSENTIALIST CONCEPTIONS OF FEMALE SEXUALITY

"Whatever your experiencing in your sexuality- whether its challenges with arousal, desire, orgasm, pain, no sexual sensations- is the result of your sexual response mechanism functioning appropriately...in an inappropriate world. You are normal; it is the world around you that's broken." (Nagoski, 2015, p. 9)

The dominant models of sexual response that inform contemporary classifications of disorders are rooted in conceptions of sexual normalcy. I will argue that we define existing sexual disorders through a flawed model, which results in problematic and ineffective drug interventions. In the previous chapters, I looked at the evolving nature of the classifications of female sexual dysfunction, examined the problems faced in the introduction of the only FDA approved pharmaceutical for low female sexual desire, and argued that Addyi falls short as a 'cure' for HSDD. I contend here that there is a need for a more nuanced model of sexual response, and propose the Dual Control Model (DCM) as a more appropriate, comprehensive approach to sexual response. Emphasizing the importance of context, variability, and the female experience, the DCM challenges and potentially rejects the foundation by which Hypoactive Sexual Desire Disorder is defined. In presenting the DCM as one alternative model of sexual response, I will explore the potential ramifications of its acceptance on the current definition of female dysfunction.

As we have seen, the female experience is not always centered in the production of medical knowledge regarding female bodies. Research notes the phenomenon of medical professionals ignoring significant health concerns reported by female patients; the sexopharmaceutical era is characterized by a focus on female sexual issues of pleasure over those of pain. Endometriosis, polycystic ovarian syndrome, and pain disorders relating to sexual

activity have not been the subject of as much attention as low female sexual desire (Moynihan & Mintzes, 2010). Cindy Eckert applies this phenomenon to sexual medicine, stating "I saw this portrait of a woman, a woman who had raised her hand many times along the way and said, 'something's wrong, something's changed, something's different,' and had been patted on the shoulder and dismissed...What ignited me is that we have a medical condition that we have known about since the 70s and yet we're still patting women on the shoulders and telling them to relax" (Mackenzie, 2018). Eckert's connection is short sighted in that it ignores the long history of a hyperfocus on female sexuality, with female sexual desire becoming increasingly emphasized in medical and academic literature following the gravitation towards a biological, essentialist approach to sexual behavior in the later 20th century (Meana, 2010). There have been efforts to quantify, study, address, and cure low female sexual desire for decades, heightened in the quest for a 'female Viagra,' because there is social utility in female sexual functioning within its promotion of successful long-term partnerships and reproduction. Although there has been effort and attention directed towards developing a drug treatment for HSDD for many years, the process of finding an effective one is difficult and complicated due to the misinformed scientific and technological approaches taken to understand and address female sexual issues.

Low female sexual desire is framed as abnormal through the production of medical research, literature, disorder manuals, and pharmaceutical interventions. It implies that there is a normal level of sexual desire that the majority of women experience, and therefore those who fall outside of that majority are disordered. According to Laumann in his 1999 article, 43% of women aged 18 to 59 have female sexual dysfunction. If just under half of women are classified as "disordered" under the current assumptions of sexual response, the narrow bounds of

normalcy must be reconceptualized. In reality, there is great variability in female sexuality that cannot be encompassed in the current models and definitions of sexual normalcy in the DSM.

Female sexual normalcy is defined within male-dominated paradigms. The male analog functions to equate the male norm for natural and normal sexual behavior to all bodies. Caroline Criado Perez, author of *Invisible Women,* coined the term the "gender data gap" to describe the process of structuring the world according to the male body, in all walks of life including the medical field (Perez, 2019). As an example of the gender data gap at play in pharmaceutical development, Perez explicitly references the use of 23 male and 2 female participants in Sprout's clinical trial on Addyi's alcohol interaction, despite well-documented data that shows male and female bodies process alcohol differently (Schumaker, 2015; Harrison, 2015; Thomasson, 2002). These practices have serious consequences for female drug users in terms of safety and efficacy.

The male analog plays a large role in the definition of desire that characterizes the human sexual response cycle. I discussed the competing theories of spontaneous and responsive desire in the first chapter. The DSM assumes spontaneous desire, but studies have shown that only 15% of women tend to experience spontaneous desire in contrast to 75% of men. Furthermore, about 30% of women tend to experience responsive desire, while the remaining 50% or so experience a combination of the two (Nagoski, 2015). If drug development is conducted within the paradigm of Viagra and with an understanding of female sexual response filtered through the male analog, is Addyi's low efficacy rate a surprise? Through applying knowledge and models based off of male bodies, omissions and assumptions are often made regarding the complexity and nuance of female desire and sexual response. This in turn hinders appropriate and accurate design of treatment. I do not intend to suggest a caricaturization of sexual response with male sexuality

understood as simple and female sexuality as complex; that is not supported by biological or social studies of sexuality. Rather, I seek to explore the implications of medicalizing female sexuality within heteronormative, male-dominated sexual norms and highlight an alternative model that challenges contemporary classifications of female sexual dysfunction.

The Dual Control Model: how it works

The human sexual response cycle used in the DSM classification of sexual dysfunction is problematic in the way it reinforces misunderstandings about female sexual desire and response. It is too linear, too simple, too universal, and too male. In her book Come as you are, Dr. Emily Nagoski raises attention to an alternate model of sexual response that accounts for individual variability called the Dual Control Model (DCM), created by Erick Janssen and John Bancroft at the Kinsey Institute (Janssen & Bancroft, 2007). Under this model, the mechanisms in the brain that coordinate sexual response behave in the same way as those that coordinate other aspects of the nervous system, which function through the dynamic partnerships of accelerator and brake.

The sexual accelerator, or Sexual Excitation System (SES), functions by constantly scanning an individual's internal and external environment for sexualy relevant stimuli- "things you see, hear, smell, touch, taste, or imagine" (Nagoksi, 2015, p. 48). The information triggers the SES to send signals from the brain to the genitals. The sexual brake, or Sexual Inhibition System (SIS), is composed of two levels of brakes which send neurological "off" signals. The first brake functions similarly to the accelerator in its reliance on context, scanning the internal and external environment for potential or immediate threats. In Dr. Nagoski's words, this brake would be responsible for sending "off" signals that would prevent someone from getting aroused

in an inappropriate setting, for example. The second brake is a more chronic and subtle "no thank you" signal, associated with the threat or fear of performance failure (Janssen & Bancroft, 2007). Arousability is redefined as this two-part process comprised of activating the accelerator and deactivating the break, involving a complex coordination between internal and external contexts and stimuli.

Rethinking sexual normalcy and dysfunction through the DCM

The DCM resists sexual essentialism through its recognition of context and variability. The model allows for sexual variation between different people and across life stages, as there is no one "correct" partnership between accelerator and brakes. SES and SIS are considered traits because all bodies possess them, but they vary in sensitivity from person to person. The sensitivity of one's accelerator and brakes is both biological and reliant on life context, which incorporates sociocultural, gendered, relational, circumstantial and personal factors. Beyond rejecting essentialist models created within a male-dominated paradigm, the DCM also encourages the deconstruction of "dysfunction" as it's currently defined.

One of the difficulties in accurately quantifying and classifying female sexual desire is the inability to arrive at a consensus on how to define and locate it. Desire as discussed in the context of the human sexual response cycle is spontaneous and universal. Recall Kaplan's notion of desire as a hunger or a thirst, perpetuating sex as a natural, innate drive rather than a learned response. If sexual desire was a drive, like hunger or thirst, then a lack of sexual desire would indicate unhealthy or disordered behavior. Therefore unlearning the concept of the sex drive negates the interpretation of libido fluctuations as indicators of normal sexual functioning.

According to the Dual Control Model, desire is the presence of arousal, which involves activating the SES and deactivating the SIS, combined with the right context (Nagoski, 2015). Emphasizing the contextual aspect of desire accounts for variability among and within gendered groups and views desire not as linear, but rather circular, overlapping, complex and nuanced. Desire is an unlocatable process of interactions, rather than a fixed, determined state.

Context consists of person's external circumstances and internal brain state in the present moment. Nagoski provides the important example of stress as a predictor of sexual interest. Stress reduces sexual interest in 80-90% of people and reduces sexual pleasure in basically everyone (Nagoski, 2015). Self-criticism and frustration are two forms of stress that can significantly affect sexual pleasure (ibid.). Considering that the classification of HSDD and the target audience for Addyi revolve around heterosexual, long-term partnerships, relational context is of particular importance. Relationship factors are critical in experiencing sexual desire, fantasy and arousal (Meana, 2010). An individual's relationship well-being, along with their own general well-being, is the best predictor of distress accompanying low desire, one of the HSDD diagnostic criteria and the primary reason people seek treatment (Bancroft, Loftus & Long, 2003). The Dual Control Model's emphasis on accounting for context in the assessment of sexual difficulty interrogates the role of interpersonal interactions.

The DCM emphasizes individual uniqueness in sexual response, yet it also notes gendered trends in the coordination between SES and SIS. As I previously mentioned, I do not intend to promote a strict binary between male and female sexual response. However it is important to recognize differences between cisgendered groups in order to deconstruct dominant assumptions and omissions regarding female sexuality and encourage a more comprehensive and

careful approach to female sexual issues. Women, on average, tend to have more sensitive brakes and less sensitive accelerators than their male counterparts. A sensitive brake is the strongest predictor of sexual issues, as it correlates with low sexual desire and difficulty with arousal and orgasm. Women also tend to have more complications in the overlap between the brain's response and the genital response to sexually relevant stimuli (Nagoski, 2015). This phenomenon of "arousal nonconcordance" was the reason why Viagra and testosterone interventions proved unable to successfully address low female sexual desire. The differentiation between genital response and subjective arousal goes against the standard narrative that often dictates sexual expectations.

The current models of sexual response and classifications of sexual disorders demand universal and constant readiness for sexual partnered activity, disregarding the common tendency of cisgender women in long-term heterosexual relationships to lose sexual desire with partners (Meana, 2010). Key reasons for reduced sexual libido for women in long-term relationships include the institution of the relationship, over familiarity between partners, and the de-sexualization of roles. This trend, occurring within the specific target audience for potential Addyi users, necessitates an incorporation of the relationality of desire to address female sexual issues. I am not suggesting that monogamy is inherently detrimental for female sexual desire. There is of course variation in this trend, with some relationships working better than others to sustain sexual desire. However recognizing and exploring the myriad of factors that contribute to low female sexual desire such as relationship dynamics and sexual preferences can direct focus to addressing a willingness to feel desire, rather than expectation.

A "new view" of sexual issues needs to recognize the influence of context to prompt exploration into the sexual scripts which inform and organize our sexual experiences. Sexual desire is tied to a gendered social learning process, as we organize our experiences according to the sexual scripts we are exposed to. The cultural template by which we learn sexual goals and expectations moves us towards or away from certain types of sexual behavior (Nagoski, 2015). As a general example, boys tend to learn to associate things that make them aroused with erections, while girls link sexually relevant cues to social context and environmental awareness due to the less obvious physiological response (ibid.). Interrogating sexual scripts provides insight into the societal ambivalence towards female sexuality. We grow up with contradictory messages about sex and sexuality that are internalized in our own relationship to sex. It is with these sexual scripts that a discrepancy between what women feel and what they think they should feel is created.

Addressing female sexual issues within the DCM

The widespread acceptance of the Dual Control Model would necessitate a reevaluation of the dominant classifications of and treatments for female sexual disorders. The DCM challenges sexual normalcy, which forms the foundation of sexology. If we acknowledge that variation in desire between individuals and life stages is natural and common, it becomes difficult to classify low desire as a disorder. Desire as it is viewed under the Dual Control Model is subjective, complex, experiential, and interactive, resisting measurement by existing clinical indices and tools. The model undermines the biological and essentialist framing of dysfunction through highlighting its failure to accommodate for context, such as social or relationship

factors. It becomes clear why a drug solution to low female desire is implausible and unpromising when pleasure, desire, and arousal are viewed as complex and unique processes, rather than fixed states based in one area of the brain or body.

While the DCM works to shift contemporary perceptions and expectations of sexuality, it still acknowledges the importance of finding ways to address female sexual issues without resorting to a purely normative framework. Drug interventions such as Addyi focus on the biological, without interrogating sociocultural, relational, or individual context. In order to understand a woman's sexual difficulties, questions should be asked regarding the sensitivity and triggers of her accelerator and brakes. Nagoski has written worksheets to calculate SES and SIS sensitivity, identify stressors and stress management strategies, and assess sexual cues and threats, as examples of potential avenues to understand the root of sexual issues. This approach necessitates a mindful and self-reflective learning process to ground one's sexual behavior in the situations or cultural expectations that may be a source of distress and low desire. The key to leading a satisfying sexual life according to the DCM is to accept your sexual functioning as normal, identify the contexts that affect your accelerator and brakes, and develop skills to maximize the contexts that increase sexual feelings. You don't need Addyi to do that.

Final thoughts

The development of Addyi is contextualized within a long history of medicalizing female sexuality, characterized by an increasing emphasis on biologically essentialist frameworks. The attempts to design a 'female Viagra' proved slow and complicated despite pharmaceutical interest and funding, as well as a large estimation of market interest. Addyi was met with

institutional and social opposition due to the contentious interactions between corporate interest and female sexuality. The drug was sensationalized through Cindy Eckert's media presence and the coverage of competing feminist organizations' discussions of the role of Big Pharma in treating female sexual issues. The response towards Addyi illustrates the cultural ambivalence towards female sexuality and the consistent struggle to define, locate, measure, and treat sexual behavior that falls outside the lines of "normalcy" as defined by sexology.

The relationship we have with ourselves and with each other is mediated through the production of knowledge and technology. The definitions, classifications, and treatments promoted to address sexual issues are rooted in male-dominated norms that uphold sexual essentialist approaches to medicalization. The hegemonic model of female sexual response demands constant, universal sexual readiness within long-term, heterosexual partnerships. Failing to account for sexual diversity has led to a fruitless search for an effective drug to target low female sexual desire. Addyi represents the most successful pharmaceutical treatment for HSDD introduced thus far, and yet it is fraught with controversy and uninspiring results. Framed as a game-changer for female sexual issues, the 'female Viagra' was accompanied by high barriers to usage, questionable safety, low efficacy, and a feminist countermovement. In order to revolutionize female sexuality, we must interrogate the misconceptions that informed interventions like Addyi.

Current medical approaches to address female sexual issues are simply not working. The rise of alternative models such as the Dual Control Model undermines the current male-dominated paradigm to promote a comprehensive understanding of female sexual response. The DCM asserts that diversity in desire is normal and urges individuals to value their sexuality

despite the inability to fit into the the standard cultural narrative. Through challenging the internalized messages that guide sexual expectations and frustrations, attention is directed at the real-life contexts that shape our sexual experiences. We can uphold women's agency and autonomy in sexual research by asking questions beyond the *what* to look at the *why* and the *how*. These questions provide a starting point for progressive, women-centered research into the science of female sexual well-being.

ADDENDUM. THE HUNT CONTINUES

This past year, the FDA accepted AMAG's New Drug Application for Vyleesi, or bremelanotide, a new pharmaceutical treatment for HSDD. In contrast to Addyi, Vyleesi is taken as desired rather than daily, impacting neural pathways in the brain with only mild to moderate side effects (AMAG, 2018). It represents a more efficient Addyi, but does its avoidance of Addyi's high barriers to usage indicate that its a better tool for female empowerment? Will Vyleesi be the blockbuster 'female Viagra' that developers have been searching for? Does an on-demand solution represent a more developed medicalization of female sexuality? Vyleesi continues to promote the investment of energy and funding into drug development without interrogating the sociocultural values embedded within the technology we produce. This new drug may have less safety precautions and higher efficacy rates than Addyi, but it is predicated on the same misconceptions and expectations of female sexual desire. It operates, even more successfully than Addyi, within the paradigm of Viagra to reinforce conventional standards of female sexual normalcy and disempower sexual diversity. I suspect that the drug will not live up to its claims, given its reliance on flawed and incomplete understandings of female sexuality. Its failure to address low female sexual desire successfully would add a layer to the claims argued in this thesis and reinforce the need to direct energy away from pharmaceutical treatment for female sexual issues. The drug's FDA hearing is set to occur within the next several months, and then it will be introduced to the market. Vyleesi is estimated by AMAG to have $1 billion in revenue potential. Time will tell.

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Appendix

Photo 1: Sprout's marketing on Addyi's website. Retrieved from https://addyi.com/addyi/, accessed 3 January 2019.

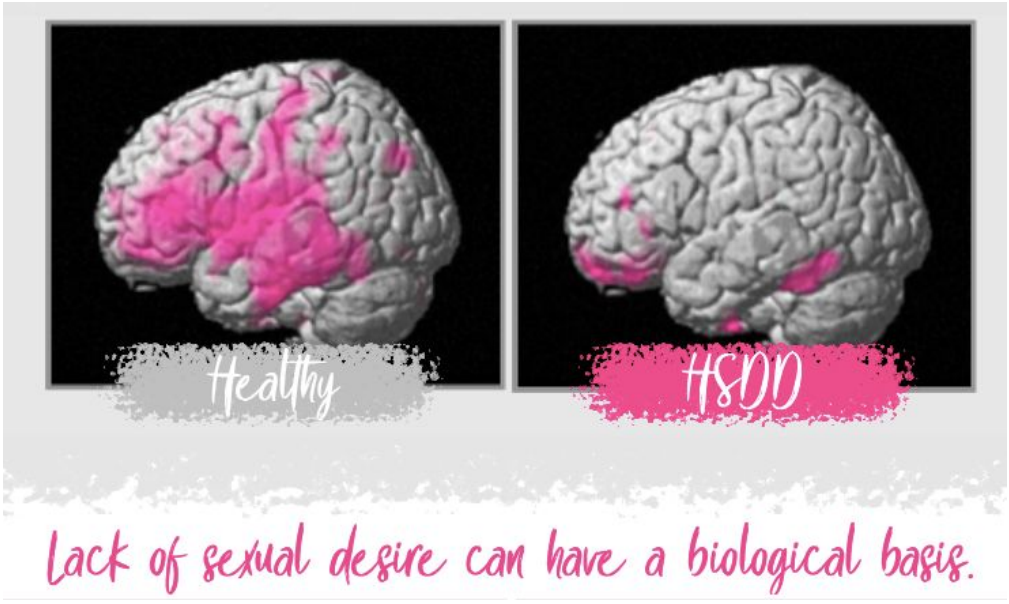

Photo 2: Sprout's marketing on Addyi's website. Retrieved from https://addyi.com/addyi/, accessed 3 January 2019.

Photo 3: Sprout Pharmaceuticals CEO Cindy Eckert, by Jillian Clark Photography. Mackenzie, M. (2018, June 27). Why the woman behind the so-called "female Viagra" won't stop fighting for women. *Forbes*.

Photo 4: Sprout Pharmaceuticals CEO Cindy Eckert as featured on the title page, by Jillian Clark Photography. Mackenzie, M. (2018, June 27). Why the woman behind the so-called "female Viagra" won't stop fighting for women. *Forbes*.