Health Communication, 25: 119–130, 2010

ISSN: 1041-0236 print / 1532-7027 online
DOI: 10.1080/10410230903544910

Routledge
Taylor & Francis Group

Who's Guarding What? A Poststructural Feminist Analysis of Gardasil Discourses

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In May 2006 the Gardasil vaccine was approved for implementation in the United States to prohibit the spread of four strains of the human papillomavirus (HPV) that can lead to cervical cancer. Through a poststructural feminist reading, I critique ideologies at play throughout the Food and Drug Administration (FDA) approval hearing for this vaccine. I explore the conditions that gave rise to the adoption of the Gardasil vaccine as evidenced in the hearing transcript, and probe contradictions between choices the FDA enacted for the feminine body with those recommendations from lead scientists of Merck that urged the inclusion of males in the vaccination process. Along the way, I respond to appeals from scholars to address matters of health policy formation and implementation as critical and underexplored dimensions of health communication. I offer a vision that makes way for proactive engagement of males in reproductive and sexual health, particularly as the FDA delayed vaccine approval for males until 2009.

After breast and colorectal cancers, cervical cancer is the third most prevalent cancer worldwide, the second most prevalent cancer among women, and one of the most preventable and treatable forms of cancer when detected in its early stages (WHO, 2006). In the United States, 50 years of preventative screening has significantly reduced cervical cancer. Even so, more than 11,000 women are diagnosed every year (Wewers, Katz, Fickle, & Paskett, 2006). The National Cancer Institute estimated that in 2008, approximately 4,000 American women would die from cervical cancer. Unlike other cancers, cervical cancer has been directly linked to its source, as "all cervical cancers arise from HPV infected tissue" (Food and Drug Administration [FDA], 2006, p. 17). Human papillomavirus (HPV) is a sexually transmitted virus consisting of more than 100 strains. Though most often the body's immune system is capable of fighting off an HPV infection, the virus can remain undetected and/or dormant for more than 20 years (ACS, 2006a). Significant risk factors contributing to the spread of the virus include sex at an early age, multiple sex partners, having sex with partners who have had multiple partners, and smoking (Wewers et al., 2006).

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Given its cancerous repercussions, HPV has drawn the purview of some of the largest political and institutional structures across the globe, including the World Health Organization (WHO), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and many others. In 2000, the U.S. Congress passed public law number 106–554 that included provisional logistics for more research and increased efforts in prevention and public education (CDC, 2006a). New screening measures continue to be developed and HPV tests have been refined, expanded, and made more accessible for women. In May 2006, Gardasil was brought before the Food and Drug Administration (FDA) in a priority hearing. This priority hearing was dedicated to the approval of the vaccine Gardasil, produced by Merck Pharmaceuticals, due to its impressive test results, safety, and "potential for meeting an unmet medical need" (FDA, 2006, p. 11). Clearly, the scope and ramifications of HPV and cervical cancer have drawn the attention of numerous stakeholders.

Advocates for women's health have certainly praised the vast resources and attention dedicated to this disease. As women and men, citizens, and health advocates, we can applaud the medical breakthrough in discovering the link between this virus and this cancer. Indeed as a collective humanity, we can celebrate the reduction and potential elimination of cervical cancer, further championing the

implications and potential for future cancer research. Yet, in the very midst of this hope, many questions persist. For poststructural feminists committed to issues of health and healing, there rests a potent imperative to attend to these discourses with closer scrutiny. A case in point: "About 10,000 American men will develop an HPV-related cancer every year in the U.S., mostly in the head and neck, anal canal and the penis" (FDA, 2006, p. 21).[1] At the FDA approval hearing for Gardasil, Merck pharmaceuticals recommended that males be included in the vaccination process. Specifically, Dr. Eliav Barr explained to the committee, "We know that men transmit HPV to women . . . if you delay a vaccination in boys you will reduce the overall population efficacy of the vaccine, you will delay the time until the maximum reduction in cervical cancer that you could expect" (p. 72).

In this article, I explore the discourses surrounding the FDA approval of Gardasil. I position this process as an opportunity to critique ideologies underpinning the formation and implementation of policies that directly affect the health of both women and men, yet steadfastly focus on the female body. In doing so, I seek to respond to calls by communication scholars to focus on the discursive nature of policy debates, dialogues, and decisions (e.g., Conrad & Millay, 2001; Conrad & McIntush, 2003). Few communication scholars have investigated health care policy and policy-related debates and dialogues—even though policymaking is central to nearly every dimension of health communication. Conrad and McIntush (2003) urged scholars to explore the discursive processes through which policies are developed and enacted: "Policy windows open when powerful publics are mobilized to act. . . . Crises becomes crises only when they are perceived as such. Social conditions may exist for long periods of time without being defined in the public mind as problems that require action" (p. 412). In this case, the ways in which the problem of HPV is both constructed and defined for the public during the hearing and in the aftermath calls into question acts of policymaking. Adopting a poststructural feminist lens, I explore the conditions that gave rise to the adoption of the Gardasil vaccine as articulated in the transcripts of the FDA hearing. I then probe contradictions between choices the FDA (as a national regulatory structure) enacted for the feminine body and those recommendations from lead scientists of Merck that urged the inclusion of males in the vaccination process. These discourses offer a useful entry point for interrogating and deconstructing those discursive barriers that inhibit a full and engaged involvement of males as reproductive beings in matters of health communication, research, public debate, and the implementation of public health policies.

A POSTSTRUCTURAL FEMINIST STANDPOINT

A poststructuralist feminist standpoint provides a robust lens to analyze how discourses reflect, reinscribe, and sometimes resist hegemonic patterns. Consider Weedon's (1987) argument: "For poststructuralism biological differences do not have inherent 'natural' or social meanings . . . but are produced within a range of conflicting discourses from medicine to sociobiology to radical feminism" (p. 123). At intersections of race, class, gender, and numerous other lived differences, poststructural feminists call for explicit attention to cultural issues of power, articulation, and authority (e.g., Dow & Wood, 2006; Harter, Kirby, Edwards, & McClanahan, 2005). Additionally, poststructural feminism, informed in part by the work of Foucault, directs our attention to subjugated knowledges and subject positions in health contexts, voices that have long been "disqualified in the hierarchy of knowledge and sciences" (Foucault, 1972/1980, p. 82).

To begin, poststructural feminist theory assumes that subjectivities for women and men alike arise and are reinscribed through discourse. Additionally, poststructural feminists acknowledge that organizing patterns emerge from and are contested in signifying practices (Buzzanell, 1994, 1995; Buzzanell & Liu, 2005). Social meanings make possible or deter particular forms of organizing. Regulatory agencies like the FDA are no exception. Discourses are at once the medium and outcome of institutions and individual subjectivities. Fraser (1989) argued, "Struggles over cultural meanings and social identities are struggles for cultural hegemony, that is, for the power to construct authoritative definitions of social situations and legitimate interpretations of social needs" (p. 6). Discourses offer interpretations of needs that guide the development of policies, services, and individuals' identities (Trethewey, 1997).

Numerous rhetorical critics have relied on poststructural feminist theory to deconstruct and reconstruct gendered discourses. Stormer (2006), for example, emphasized the discursive foundation of post-structural thought:

> [The] making of gendered experience is a thing that generates or results from rhetoric, a poststructural logic of both/and allows us to appreciate that gender is always antecedent to, always a consequence of theorizing rhetoric. . . . Being gendered is a part of being rhetorical and vice versa . . . one does not beget the other. (p. 256)

In essence, a feminist uptake of poststructualism can be used to denaturalize the discursive formations surrounding the Gardasil approval hearing by questioning those deeply embedded ideologies and fossilized conceptions of gender, sexuality, and reproductive health. For instance, linguistically

[1]"There are 35,000 cancers in the United States that are caused by HPV every year. Twenty-five thousand are caused by 16 and 18." A million cases of genital warts, 900,000 caused by vaccine types. Six-thousand cases of RRP (Recurrent Respiratory Papillomatosis), 5,400 are caused by vaccine types in both men and women and boys and girls" (FDA, 2006, p. 70).

attending to matters of gender, a continued emphasis on women needing protection prevails. With regards to sexuality, men remain undereducated, while women continued to be stigmatized. Men's sexuality is rarely linked to their role as potential fathers, while women continue to be held and seen as largely responsible for their and their partners' education in matters of reproductive health. In this case, with a persistent focus on the female body, authorities continue to dismiss the interactive role men partake in matters of sexual health and reproduction.

A poststructural feminist imperative is to deconstruct discourse not only at the confluence where competing and colliding agendas manifest turbulent waters but where the waters appear deceivingly serene and well beyond the site of contestation. As poststructural feminist theorists, we are not only bound to question whose needs are being addressed in discourse but to acknowledge the historically contingent and contextual nature of exactly who is defining those needs (Naples, 2003; Weedon, 1987). Exactly whose door is being guarded, and whose needs are truly being met? And, who is left out of the frame of sexual and reproductive health and accountability? It is here that discourses direct the lives of the personal from the arm of potent political institutions. The public hearing between Merck and the FDA leads us to ask: Were we being lured into believing that it is in women's best interest to have women only vaccinated? Did we think our "nation" was not ready for this sort of male reproductive address? As it has been concluded that men are indeed carriers of HPV, have studies been conducted that would lead us to understand how/why males are less prone to cancers of similar sensitive organs and tissues than females (i.e., more comprehensive studies on male sexual health)?

These questions inevitably lead us to address the material consequences of our collective meaning-making, and the ways in which these are further textualized in the bodies of women and men, and the policies that direct our ways of living and being in the world. With an emphasis on the critical junctures of discourse, meaning-making, and sociopolitical/institutional structures, poststructural feminism draws attention to the materiality of communicative practices (Ashcraft & Mumby, 2004; Turner, 1987; Weedon, 1987). Flushed from the confluence of competing discourses, then, lie those material outcomes that profoundly impact our collective understanding and expressions of gender. In examining the trajectory of cervical cancer awareness and the effort to reduce this disease as situated in a complex web of constructs, we are reminded that "bodies are regarded as not simply shaped by social relationships, but as entering into the construction of these relationships, both facilitated and limited by historical, cultural, and political factors" (Lupton, 1994, p. 22).

In the next section, I provide background information about the FDA priority hearing for the approval of the Gardasil vaccine and outline how I collected discourses. I then describe how poststructural feminism shaped the way I analyzed the discourses.

BACKGROUND: THE PRIORITY HEARING

On May 18, 2006, the FDA's Center for Biologics Evaluation and Research Vaccines and Related Biological Products Advisory Committee[2] met with Eliav Barr, M.D., the Senior Director Vaccines/Biological Clinical Research for Merck, and Patrick Brill-Edwards, M.D., Director of Worldwide Vaccines Regulatory Affairs with Merck (and other Merck affiliates). They met to address "the safety and efficacy of the human papilloma recombinant vaccine" (FDA, 2006, p. 7). Dr. Barr, head of the clinical program for the vaccine, discussed the trials Merck had been conducting with Gardasil. Barr stated, "For over nine years . . . the program has enrolled over 27,000 women and children in 12 separate clinical studies" (p. 16). However, well before this day's hearing, Dr. Barr recounted:

> At the inception of the program, Merck and the FDA met and agreed that the primary basis for licensure was to—was based on the demonstration of the prophylactic efficacy of Gardasil, to show that Gardasil is efficacious in preventing HPV 16 and 18 and related cervical cancer. (p. 26)

At the onset of the hearing the chair directed committee members that, although they would hope to have ample discussion, the primary purpose for this meeting was "to come to a final vote on the questions that were provided in [their] packets [that morning]" (p. 10) (related to cervical cancer). Merck representatives spent 70 minutes presenting information regarding four clinical studies of varying populations including women, girls, and boys (9–16 years of age).[3] In describing the efficacy trials, Dr. Eliav Barr, director of the project, clarified the course of actions: "We had key immunogenicity and safety objectives. The most important was to bridge the efficacy findings in 16–26 year

[2]The composition of the committee included six FDA staff members, four of whom were MDs, one of whom is an RN, and two whom have their MPH. Fifteen participants were acting as temporary voting members. Of these members, 13 were MDs, one RN, and one MSN. These members represented agencies including Wyeth Research Industry, National Institutes of Health, Center for Bioethics and Culture, National Vaccine Office, Department of Health and Human Service, Baylor College of Medicine, Texas Children's Hospital, Centers for Disease Control and Prevention, and Columbia University, College of Physicians and Surgeons.

[3]Explaining how the research was conducted for prophylactic efficacy, Dr. Bar described to the committee the four protocols—5, 7, 13 and 15. Protocol 5 was specifically an HPV 16 study with the "longest term follow up in the data base" (FDA, 2006, p. 35). Protocol 7 was a dose ranging study, and 13 was "designed to look at the impact of the vaccine of CIN of any grade [and] external genital lesions" (p. 35). Protocol 15 "was designed to be a real world study to look at the impact of the vaccine on cancer" (p. 36). "And for the most important end point the study, which is HPV 16 and 18, all four types together, we combined all the studies of Gardasil" (FDA, 2006, p. 36).

olds, to nine to 15 year old pre-adolescents" (p. 29). The clinical programs

> enrolled over 27,000 subjects around the world in 33 countries and five continents. . . . The ages that we chose were those ages *that would benefit most* from administration of a prophylactic HPV vaccine, *girls and boys age nine to 15* and 16–26 year old adolescent young adult women. (p. 33, emphasis added)

With efficacy rates of 97–99%, Dr. Brill-Edwards explained, that Gardasil, an immunogenic, "induces an immune response that's many-fold higher than natural infection and it has an excellent safety profile" (p. 15).

The public hearing component of the day began at 1:30 p.m. with speakers taking the floor and five statement papers presubmitted to the committee.[4] These were not read aloud or shared for their content but rather put into the public record. Approximately 10 representatives from various national health networks, agencies, and organizations made compelling statements.[5] Each advocate urged the committee not only to approve the vaccine but to progress in an expedient manner. They further pressed the committee to commit to making the vaccination available and affordable to those who are most vulnerable. Martha Nolan, Vice-President of Public Policy for the Society for Women's Health Research, "strongly urges an expedient review and decision and depending on positive efficacy safety concerns, approval to allow this break-through advance to be available to women as soon as possible" (p. 147).

The core of my analysis focused on the transcript texts for the priority hearing. I accessed these texts through the FDA web site. The main transcript is 216 pages in length with another 25 pages of public address and two PowerPoint presentations—one created by the FDA and one by Merck. Beyond the texts included in this analysis, I also have attended numerous informational public health meetings concerning HPV, and have spoken with doctors, nurses, clinicians, and students. I have collected materials on HPV, Gardasil, cervical, anal and penile cancers, sexually transmitted diseases and related education for women and men through national and global health institutions and initiatives. As I began reading and cross-referencing texts, institutions, personal lives, and publics, a poststructural feminist lens emerged as key and further sensitized me to the discursive construction of subject positions and organizing patterns. Links across multiple texts and encounters deepened my comprehension of the transcript, HPV, cervical cancer, and the trajectory of this vaccine. My textual analysis of the FDA approval hearings explored key assumptions forwarded in the acceptance and implementation of Gardasil as well as the subsequent outcomes of the hearing for Merck.

This reading highlights and problematizes heterosexist norms and signifying practices that position women and men in matters of sexual and reproductive health. I begin by articulating how the discourses discipline females as responsible for sexual and reproductive health while abdicating accountability for males. I then query paternalistic practices masked in ideals of "protection" and through judiciary norms of policymakers/policymaking. I do not present a universal or fixed reading of these discourses, nor is it possible to address the multitude of issues in this rendering. I offer a plausible and viable poststructural feminist reading, and in doing so invite other readers to enter the discourses from their standpoints.

INSTITUTIONAL DISCIPLINE: SUBJECT POSITIONING OF FE/MALE BODIES

From the onset of the hearing to the aftermath of educational campaigns and implementation, the issue of HPV and Gardasil has been largely framed by the endpoint of preventing cervical cancer. The dominant framing of Gardasil serves not only as a directive in focusing our attention on women but also diverts queries away from implications of, for, and by men. Moreover, vestiges of historical and culturally bound ideals protract a contemporary hold on female bodies as sites of contestation and conquest. Though the committee is limited to making a decision for the approval of Gardasil for women, they are told that this vaccine works to protect women's bodies not only against a virus, but against, "a virus that . . . impacts men . . . [where] men are the primary vector for transmission of HPV to women and . . . infection in men is the cause of the acquisition of the disease in women" (FDA, 2006, p. 25). The vaccine was designed to protect those who are not or have not been previously infected with HPV—females and males alike. Merck's "proposed indication also includes the population of children and adolescents, nine through 17 years of age and women 18–26 years of age" (p. 90). Dr. Barr's information to the committee is telling. He notes that of HPV types in the United States, Gardasil "covers 70 percent of anal canal, 70 percent of other HPV related cancers, 65 percent of pre-cancer transmission in men, 90 percent genital warts, 90 percent RRP [recurrent respiratory papillomatosis] lesions and transmission to women" (Food and Drug Administration, Merck Research Laboratories, 2006, slide 25). Nevertheless, the FDA primarily focused its directives toward girls and women. Here, "*the FDA considers* the data submitted by the BLA [Biological Licensure Agency] to be

[4]Though not immediately available with the transcript, I have since been able to acquire and identify them as equally supportive in their requests for vaccinating women and girls.

[5]The National Women's Health Network, American Society Health Association, Society of Gynecologic Oncologists, Women in Government, Coalition of Labor Union Women, Medical Director, Association of Reproductive Health Professionals, Reproductive Health Technologies Project, Society for Women's Health Research, National Coalition for Cancer survivorship, and American Society for Reproductive Medicine.

supportive of the use of Gardasil in *preadolescent and adolescent females* nine to 17 years of age and females 18–26 years of age" (FDA, 2006, p. 90, emphasis added).

Much of the hearing focused on links between specific strains of HPV and cervical cancer. Links between HPV, penile, and anal cancers in men were far less frequently discussed. Yet, in tugging this medical curtain-hold aside, the vulnerabilities of our male counterparts are revealed. In the United States, penile cancer accounts for approximately 2% of all cancers in men. In 2006, 1,530 men were diagnosed with penile cancer (CDC, 2006b). However, "anal cancer is almost as common in men and women who have had anal sex as cervical cancer was in women before the Pap test" (ACS, 2006c, ¶ 21). Before the Pap test, "approximately one in thirty women were at risk for cervical cancer" (FDA, 2006, pp. 18–19). The same two strains that cause 70% of cervical cancer in women, HPV-16 and HPV-18, "also cause at least 70% of precancerous lesions on the penis" (Geipert, 2005, p. 631). Lead researcher for a 4-year study on HPV in men, Dr. Anna Giuliano, of the H. Lee Moffitt Cancer Center & Research Institute, reported that although "the incidence of penile and anal cancers are rare, anal cancer has more than doubled among gay men in the last 30 years" (p. 631). The HPV strains that cause 90% of genital warts, HPV-6 and HPV-11, are an important component of the vaccine for very good reasons: "500,000 new cases of anogenital warts are diagnosed yearly in the U.S." (ACS, 2006c, ¶ 20). However, Giuliano noted that although the warts are "benign [they are] extremely bothersome lesions that affect mostly young men" (Geipert, 2005, p. 631).

Given the scope of the HPV problem, it is of significant concern that extensive screening protocols for the detection of HPV in men have yet to be developed. While countless women learn about the importance of regular gynecological exams, men have no established protocol, no annual exams, or comprehensive health education directing their lives. In matters of sexual and reproductive health, it continues to be far more common for men to attend to matters of sexual health only if or when visible symptoms of infection are evident. Though genital warts are one indication of HPV (types 6 and 11), the virus is likely to remain undetected in men, as is true for their female counterparts (ACS, 2006a). In this campaign, unquestioned norms, vestiges related to the trail of women's health, are embedded within Gardasil clinical trials. Here the disciplined female body continues to undergo "*intensive evaluation and genital inspection*, as well as an evaluation of *frequent Pap testing*" (FDA, 2006, p. 36). While we focus on the female body, consider the trajectory of this virus: "HPV six and 11 together cause about 90 percent of genital warts in women and men" (p. 25). Dr Barr also explained that the HPV virus types 16 and 18 "were carried along with six and 11 in most cases" (p. 81). Genital warts, which significantly impact both women and men, appear to provide the means of transportation for the viral strains that cause cervical cancer. Yet still, "there are no tests approved to detect early HPV- related cancers in men, as there are with women and the Pap test" (ACS, 2006c, ¶ 23).

Men do indeed receive information about protection and responsibility; however, it is most often related to the emphasis on condom use, and the prevention of sexually transmitted infections (STIs). With regard to HPV, those who rely on condoms for protection have been largely unaware that this virus, while transmitted through sexual activity, is spread via skin-to-skin contact. Although doctors believe the use of condoms significantly reduces HPV transmission, those areas not protected by a condom are potential sites of transmission. The discrepancy in vaccinating only women for a virus that is transmitted via sexual contact from men to women, men to men, and women to men has significant implications for women's health, healing, and safety. It is important to note that during the trial, there was no discussion about the spread of the virus between women or between men.

The paternalistic intertwining between gender and sexual health and accountability has evolved and been rearticulated throughout social, discursive, and historical constructs. These ideals are firmly rooted in the formation of laws that govern, in politics that convey, in the historical construction of a biomedical model and the practice of medicine as we know it today (Foucault, 1972/1990; Lupton, 1994; Rosser, 2000; Leavitt, 1984). Moreover, the material outcomes are further contextualized in technologies, policies, and practices that connect the site of sexual and reproductive responsibility with women. Paradigmatic approaches to understanding and problem solving with regards to reproduction continue to preface women's bodies as the source and focus of problems and of disease, and ultimately as sites of conquest. These assumptions are so taken for granted that we rarely question the empirical nature of science or its presumed wisdom (Montgomery, 2006). We have normalized annual exams for women, yet we don't insist that men attend to their reproductive/sexual health with the same earnest fortitude. Indeed, most men don't dread their first "annual exam" until the age of 50. This is extraordinary, given the evidence presented revealing men have greater rates of HPV genital warts over their lifetime (Food and Drug Administration, Merck Research Laboratories, 2006, slide 25).

This paradox clearly indicates the potency by which micro- and macrostructural forces are intricately bound. These multiple sites and contradictory policies resurrect Foucault's (1972/1990) testament to the discipline and regulation of bodies. Modern medical imperatives continue to perpetuate substantial emphasis, expectations, and material outcomes for sexual and/or reproductive health primarily with women, regardless of the shared nature of sexual experience, or the impact male behavior has on the spread of infection for both women and men. Since the approval of

Gardasil, popular magazines, local and national newspapers, and insurance companies have promoted the vaccination for women, with scarce attention to males. Institutional directives place responsibility directly on the shoulders of women, mothers, and daughters for ensuring participation in the vaccination process, including judiciary attempts to mandate that all girls be vaccinated before entering middle school (Associated Press, 2007). Institutional discourses continue to reinscribe stagnant ideologies concerning women, sexuality, and accountability. However subtle, or not, subject positioning is evident in the unquestioned norms of who gets tested and how, in heterosexist mandates, and an intense focus on the "problematic" female body in need of rescue.

In the next section, I focus on the ways in which paternalism and protection function throughout these discourses. I link these patterns with the subject positioning of fe/male bodies in signifying practices and material outcomes and finally to consider the implications therein.

PATERNALISM AND PROTECTION: WHO IS GUARDING WHAT?

Despite temporal shifts, the heralding of a new millennium, and advances in technology and information dissemination, the interplay of paternalism and protection continues to bind women to specific sexual and reproductive roles while concurrently minimizing men's education and accountability. Moreover, acknowledging that the traditions of patriarchy have been bound to the state, home, and family, many feminists recognize the increasingly paternalistic role the state continues to assume, ever blurring boundaries between political, public, and private life spheres (Ertürk, 2004; Fraser, 1989; Naples, 2003; Weedon, 1987). In its material role perched as the "ultimate authority" for health, the FDA serves as the proverbial "father figure" from whence all decisions are derived, all mandates handed down, and whose ultimate authority is presumably unquestionable. Situated as such a potent force, the macro sociopolitical structure/figure appears to provide "protection" for all women and girls who might come into contact with "the virus." Yet where is public concern for men?

Consider the subtextual meanings endowed in the drug's name—"Gardasil." Such an overt implication of "guarding" is deeply laden with historic renderings of paternalistic ideology that protects the vulnerable from the villain, but fails to fully address the "villain." In the case of this priority hearing, both women and men reify the need for "protection" for women from this virus. For instance, advocate, Martha Nolan, Vice-President of Public Policy for the Society of Women's Health Research, asserted that Gardasil "has the ability to spare thousands of women the fear of cervical cancer and the suffering associated with it" (FDA, 2006, p. 147). On the other hand, in discussions related to males, penile or anal cancers, fear, and losses related to fatherhood were never equated or even associated with their potential infection.

Indeed, at the hearing participants were frequently reminded that vaccinating men will *help* women: "HPV has been implicated in anal cancer and cancer of the penis. In addition, male vaccination would reduce the incidence of infection . . . in the portion of the female population that might remain unvaccinated" (p. 146). Here, men are framed in a protective/paternalistic stance. Heroically encased, his subject position is active, not passive—*men reduce the incidence of infection.* Moreover, in explanations of the clinical trials, committee members learn further that "we didn't test the partners [of clinical study participants] to see whether, let's say the partners were introducing HPV to them" (p. 80). The spread of infection via men is disproportionately discordant; the female body maintains scrutinized centrality throughout the discourse. Paternalism and protection work in tandem to perpetuate subject positions for women (i.e., in need of protection) and men (i.e., protector), and do so in such a way that they go largely unchallenged, almost unrecognizable.

Consider one of the lead opening statements of FDA committee member Dr. Monica Farley. She clearly stated that although many people were registered to present statements for the public hearing, the "primary purpose for today's meetings was to come to a final vote on the questions that were provided in [their] packets [this morning]" (p. 10). Notably, those questions were specifically narrowed down so that members were making decisions solely related to material outcomes, determined by the FDA: whether or not to support the implementation of Gardasil for women only. Opportunities to make an informed decision based on the presentations of both Merck and FDA appear to have been predetermined by the FDA even as Merck representatives implored:

> From our perspective we would like to be able to propose labeling that would allow flexibility and decision making for groups that are really going to make vaccination policy, today in this country, to evaluate whether gender-neutral vaccination should be used or female only vaccination based on *their read of the data.* (p. 72, emphasis added)

Addressing the committee, Dr. Barr further explained that Gardasil "induces an immune response that's many-fold higher than natural infection and it has an excellent safety profile" (p. 15). Over 12 trials, test results indicated 95–100% range of efficacy rates for the product (pp. 43–50). Summing up these impressive results, Barr confirmed, "When you compare boys to women and girls to women, you see that anti-HPV levels at month seven are *substantially higher in all of the children* compared to adults, and *particularly high in boys.* . . . We met the criterion for

immuno-bridging[6] in this study . . . using month seven data" (p. 56, emphasis added). Yet Dr. Miller (FDA) responded to the observation and question posed by a committee member, "It looks pretty convincing that this vaccine is—also prevents the infection. Do you have any biological plausibility that the vaccine will not be efficacious or safe in males?," with her statement, "We have no efficacy data right now in males—that's a point. I know there's been—just an article with HSV vaccine that there was efficacy in women and none in males. *It's just one study*" (p. 116, emphasis added). Though she went on to say that efficacy tests are ongoing for males, she surmised, "We don't have really have any safety data in males right now over the age of 16" (p. 116). Given that tests were performed in age ranges of 9–15 and 16–26 years old boys, girls, men, and women, this is a curious response.

Dr. Barr provided insight on previous attempts to eradicate a universal disease with a non-gender-neutral vaccine, using two vaccination programs. Barr explained that in the case of rubella, "a female only vaccination failed to eradicate congenital rubella syndrome. It required a gender-neutral vaccination" (p. 72). Using this example he determined, "When you try to target vaccines to a particular population, you can't eradicate the disease very well, compared to universal vaccination" (p. 72). If, as we understand, HPV is the virus that causes cervical cancer, and we know that men transmit HPV to women, and we know further that double vaccination programs have failed in the past, the determination for a gender-specific vaccine remains troubling.

Contradictions permeate the text. In reference to male efficacy, Dr. Markowitz (FDA) clarified, "We haven't seen the modeling data at this meeting and it's hard to evoke some of the modeling data to comment on the number of cases of CIN [cervical intraepithelial neoplasia] that would be presented" (FDA, 2006, p. 194). He further suggested, "There's a lot of assumptions that have gone into a lot of the different models. But I don't think we should use, right now, unless we have the modeling data to make that decision" (p. 194). On the other hand Dr. Barr attested, "We know that genital warts in men and women have a comparable histology, a comparable natural history. The disease is impacting hair-bearing characterized cells in both instances . . . while the shape of the organ is different, the skin is the same" (p. 166). He concluded, "When you look specifically at external genital lesions . . . external vulvar lesions . . . efficacy is 99 percent. So the point that we're making is that efficacy of Gardasil in men is highly likely to be significant" (pp. 166–167). Regardless of gender, one constant remains steadfast: "Sexual activity and differences in numbers of sexual partners represents the most powerful predictor of risk for infection with HPV" (p. 161). Given the statistical impact HPV has on the entire population, in tandem with the scope of human sexuality and the direct link of HPV to cervical cancer, it becomes increasingly difficult to imagine why the entire process was not positioned as a gender-neutral vaccine from the onset.

In the next section, I further scrutinize the ways in which language shapes, rearticulates, and in some cases resists, the hegemonic discourses of sexual and reproductive health—and the ensuing stigma.

THE (RE)PRODUCTION OF STIGMA IN REPRODUCTIVE HEALTH CARE

Across time and space, the female body has been intricately linked to those structures that define our fundamental norms of knowing, living, and being. With regard to sexuality and reproductive health, the biomedical model too often privileged a male body as norm, with she as other. Goffman (1963) argued that stigma emerges from within a *language of relationships* where the demands for the norm impose a *virtual* (and) *actual social identity.* Nielsen, Walden, and Kunkel (2000) suggested that "institutionalized heterosexuality . . . requires active maintenance. It appears to be enforced (both internally and externally) through a combination of stigmatizing and rendering invisible any alternatives to it" (p. 292). Stigma continues to be resurrected and reified through dominant ideologies that, as Condit (1990) described, are an "identifiable set of discourses that have identifiable effects because they are shared by an identifiable public" (p. 7). As in *The Scarlet Letter*, women continue to be isolated to stand facing a stigma-born scrutiny either alone, behind medical curtains, or under the determination of regulatory proscriptions that continue to span the sociohistorical/sociopolitical realm.

Consider the testimony of Ellen Stovall, a two-time survivor of Hodgkin's lymphoma. As president and chief executive office of the National Coalition for Cancer Survivorship, she spoke to the lack of cervical cancer survivors on the floor today, explaining that their absence should not be interpreted as a lack of interest or support. Instead, Stovall argued that the stigma surrounding sexually transmitted diseases prevents individuals from speaking in public about their experiences. Stovall explained, "Because these cancers are caused by sexual contact . . . they may create more of a sense of isolation and stigma for those who are diagnosed with them . . . That may be why this committee has not received more requests for appearances by cervical cancer survivors" (FDA, 2006, p. 154). The persistent dilemma of women being placed in positions of fearing to speak up for their own critical health issues, those clearly born out of

[6]"The concept of 'immuno-bridging' is used to 'bridge' or to extend efficacy data from the age groups studied in clinical trials of the quadravalent HPV vaccine to either age categories. The rationale is that participants in the HPV vaccine clinical trials demonstrated measurable increases in type-specific HPV antibody levels, as well as reductions in HPV clinical-related disease. Thus, if the 'extended' age groups show a comparable immunologic response, the similar clinical efficacy would be expected" (Mahoney, 2006, p. 14).

partnered experiences, remains a legitimate issue to address. In this case, it appears that stigma discursively functions to subjugate certain experiences and knowledges.

Another public advocate, Dr. Gotstout of the Society of Gynecological Oncologists, pleaded from a heterosexist norm, tightly binding a woman's sexuality to motherhood and childbirth. She further resurrected paternalistic constructions fixed on the vulnerability of women. She emphasized the ways in which cervical cancer "disproportionately affects women during their child-bearing years and child-drearing years, resulting in childless couples and for women who have late diagnosis, leaving behind motherless children" (p. 137). She went on to "put a face on this cancer" with a story about a young woman whose cancer continued to return and due to subsequent treatments, "she was away from her children . . . more than she was with them. . . . Over the next five years, her eyes met mine in fear many times . . . I saw a plea in her eyes. I understood what she was telling me, 'I can't die now, my young family needs me'" (p. 138). Couched in these terms, Foucault (1978/1990) explained that "the hysterization of women . . . involved a thorough medicalization of their bodies and their sex . . . carried out in the name of the responsibility they owed to the health of their children, the solidity of the family institution, and the safe guarding of society" (p.146–147). Reifying Foucault's premise, Condit (1990) further argued, "'Protective' legislation for women was passed by employing and simultaneously strengthening a definition of all women as weak, vulnerable, and worthy of protection because of their inherent reproductive role—'motherhood'" (p. 6). Unfortunately, Gotstout's testimony fails to acknowledge that female sexuality may have resonance beyond the bounds of reproduction. By coupling women and motherhood, issues of male and female sexuality both emerge from and are re-embedded in and through heterosexist norms.

It is interesting to note that Gostout never addressed the connection of HPV with males who transmit the virus, never charged nor attended to the male portion of this equation. In fact, never once did she mention the importance of specifically vaccinating men but instead implored the committee to "[approve] the broadest possible application of the vaccine in order to afford the maximum protection to as many women as possible, as early as possible" (FDA, 2006, p. 139). Without calling the committee to specifically address males, Gostout's appeal is a partial one. Her silence and the silence of the women present at this hearing with regard to their male counterparts were remarkable. What does her call to "broadest possible application" suggest? With little attention to or discussion of men, her language is not nearly specific enough to address the prevalent barriers firmly rooted in these discourses. Men remain fixed on the sideline in matters of sexual/reproductive health and accountability. In this case, women are requesting, indeed pleading, for support. The FDA is not held to task for failing to introduce or even consider a gender-neutral vaccine. Why, I am compelled to ask, are we treating and isolating one body?

Finally, and consistent with a heterosexist episteme, the focus on women's bodies and cervical cancer specifically diverts attention from anal and penile cancers more closely associated with homosexuality concepts well beyond the hetero-norm of sexual practices. Importantly, lesbian sex is not mentioned throughout the discourse either; we don't know if women can/do pass HPV to women. Nielson, Walden, and Kunkel (2000) concluded, "The routinely unquestioned heteronormative expectations and proscriptions that exist as background context in contemporary U.S. culture emerge when traditional normative gender boundaries are crossed" (p. 292). Stormer (2002) continued in a similar vein: "The heterosexual matrix has been discussed as a self-sustaining complex of prohibitions, compulsions, taboos, and/or *normative scripts*" (p. 268, emphasis added). Fe/male subject positions are intricately layered amidst a heterosexist episteme, deeply entrenched in patriarchal structures that are profoundly rooted across multiple and complex social systems.

DISCUSSION: QUESTIONS, IMPLICATIONS, AND MATERIAL CONSEQUENCES

The discourses emanating from the FDA's priority hearing are enlightening as to the development of a vaccine that does not introduce a live virus and hopeful in the scope of application for a cure for cancer. Yet at its very roots, these discourses emanate from patriarchal, paternalistic, and heterosexist ideologies, thus limiting their scope and application. As Sen and Snow (1994) explained, "Deeply rooted political and cultural legacies . . . leave much of what we call *reproductive rights and choice* shackled by profound gender inequality throughout society" (p. i, emphasis in original). A long and arduous history tangled in and through multiple institutional structures continues to situate particularly women's bodies as profound sites of material conquest, contestation, and constraint. In the confluence of institutional discourses and material outcomes, we must ask, who is guarding what? The FDA as a "regulatory" commission, Merck Pharmaceutical Company, the vaccination priority hearing, and the subsequent policies and implementation process are material and embodied constructs—acts that evoke and perpetuate reproductive and sexual health as dependent on the scrutiny and deliberations of social institutions. A primary value of poststructural feminist theory for health communication scholars interested in policymaking is the imperative to address how subject positions, institutional patterns, and worldviews are reinscribed and disrupted through discursive formations.

I began this project with a desire to problematize the communicative nature of health care policymaking. A post-structural feminist analysis of these texts exposes fossilized

ideologies that continue to limit our understanding of fe/male bodies and sexual/reproductive health. The focus on cervical cancer as an endpoint serves to further illuminate the vast chasm that exists with regard to a comprehensive understanding of men's sexual and reproductive health needs and education. More clearly the interplay of the (personal) individual needs as symbiotically engaged in policy, education, power, and knowledge (the political) calls us, as communication scholars, to disentangle language constructs and to further probe the din of silence in matters of sexual and reproductive health. The imperative to disrupt enduring discursive renderings specifically within policymaking structures becomes increasingly clear as Conrad and McIntush (2003) reminded us that "monopolies are sustained by ideologies . . . [and] monopoly control is strongest when it is based on a supporting ideology tightly linked to the dominant values of the society" (p. 18). A persistent episteme on the problematic of one (female) body shadows the role of the other (male).

In this hearing, a select committee is brought together to construct a social policy regarding cervical cancer. Undeniably the worldwide scope of cervical cancer demands significant address and in-depth resources. Yet a number of factors give rise to questioning the choice to set cervical cancer as an endpoint. First, the greatest risks to this cancer are directly linked to sexual behavior. It is indeed problematic that we are focusing on one body given the scope of HPV: "Over 50% of Americans will become infected with HPV at some point in their life times [and] 10 percent of all adults will develop genital warts due to HPV" (FDA, 2006 p. 18). Since virus types for cancers that span genders have been isolated, might locating HPV as the central research endeavor realign a focus across fe/male bodies as opposed to dichotomizing them? An emphasis on cervical cancer may draw the attention and support of multiple publics, stakeholders, and resources in the quest to eliminate cancer but, ultimately, our attention is diverted by this "endpoint," symptomatic of a larger (more systemic) problem—the sexual transmission of an HPV virus.

Finally, in probing the language used to attribute justification for the vaccine, I am struck with the imposition of ambiguity in the terms used to describe and ascribe finality. A discordance resonates through texts as to when comparisons are/not "highly likely/ highly unlikely" to be efficacious, or when "strong associations" and a "comparable histology" are/not potent indicators. Significantly, the premise for extending this vaccination lies in the practices of immunobridging, where "if immune response/safety profiles are similar, then *efficacy can be inferred*" (Gruber, 2006, emphasis added). The language of likely and unlikely reveals a need for deeper inquiry into design, motivation, and justification—the core of agenda setting processes/structures of health initiatives and campaigns specifically in matters of sexual/reproductive health. Continuing to scrutinize and question the intricacies of medical terminology illuminates those "matrices of power" (Foucault, 1976/1990). More clearly, poststructural feminism aids in articulating "power and discourses that operate within institutions to produce subjectivities . . . and how subjectivities become concerns [for multiple parties/stakeholders]" (Jackson, 2001, p. 396).

Language provides not only for the construction of meaning but for the possibility of change (Fraser, 1989; Grosz, 1997; Harraway, 1997; Weedon 1987). Deconstructing the rhetorical and discursive formations that activate a vaccination campaign for young women and girls provides potential for resistance to paternalistic ideals concerning sexuality, gender, and accountability in the future enactment of health policies. Language of deconstruction is not merely one of dissemblance, but requires action in the aftermath, a rebuilding—and as St. Pierre (2000) elaborated, "It is not about pointing out error, but about looking at how the structure has been constructed, what holds it together, and what it produces" (p. 82).

Ultimately the discursive manifestations of HPV and Gardasil fail to fully include men or hold males to a standard of scrutiny their female counterparts endure. With regard to sexuality, men remain undereducated, while women continued to be stigmatized. Men's sexuality is rarely linked to their role as potential fathers, while women continue to be held and seen as largely responsible for theirs and their partner's education in matters of reproductive health. Directives and appeals of both the FDA and women's health advocates fail to fully address the issues of men's health, and fail further to fully implicate men within the sexual/reproductive context of the HPV virus and cervical cancer.

Most profoundly, this hearing fails to associate men with accountability and/or responsibility for their own partnered sexuality or implications in the transmission and spread of HPV virus. While the "priority hearing" given Merck on this day represents hope in the potential elimination of cancer and treatment for women, conversely, the discourse remains largely uncontested. Men's reproductive and sexual health remains, at best, minimally attended too. The material outcomes of this discourse reify the symbolic and practical placement of women as solely responsible for sexual and reproductive health on multiple fronts and texts. As persistent fissures they are indeed potent barriers to the elimination of sexually transmitted diseases.

The discursive model and subsequent outcomes of this project expose how policymaking institutions, unchallenged, limit our capacity for a broader sexual/reproductive health understanding for women and particularly for men. Shifting the lens we most often attend to in paradigmatic notions and ideologies of women, men, sexuality, and reproduction exposes a vulnerable underbelly of arguments, ideologies, and attitudes that have long since failed to serve a constructive purpose with regard to women's and/or men's health. Here a material outcome is an intangible in the silent chasm that resides between what is and what could be. The tangibles, alarmingly present in their absence,

require a new episteme. Missing are contemporary health and policy initiatives that envision not only the symbiotic relationships in heterosexual relationships, but those that will account for the needs of homosexual partners as well. In the realm of a poststructural feminist standpoint, we can challenge the lens of institutional patriarchy, challenging not only what institutions say and do, but perhaps more importantly what resides in the silence.

There can be little debate that women bear significant physical, emotional, financial, and pubic burden when reproductive/sexual health goes awry. While it is indeed potent and imperative that women actively participate and advocate for health particularly in relation to reproductive and sexual health matters, we only serve to enable men when we neglect to expect a proactive, partnered engagement. In further doing so we also perpetuate notions of health that place premier emphasis and responsibility solely on the individual, as opposed to the reality of our interdependent nature and experience (Lupton, 1994, 2003; Montgomery, 2006; Turner, 1987). Following a feminist poststructural imperative to offer up alternatives, we are called to address those issues that continue to be neglected, not only in this public discourse, but impending discourse as the scope and implications of HPV/cervical cancer continue to broaden throughout the world. The key for us, then, is to leave no institutional curtain closed when scrutinizing systematic forces, recognizing both our participation in and resistance to deeply embedded hegemonic practices.

That the discourse and/or hearing proceeding fail to provide information regarding transmission between same sex couples is further evidence of a limited vision regarding the scope of our collective sexual/reproductive health needs. Again, a tangible material outcome is manifested in a silent chasm that resides between those heterosexist beliefs and the realties of countless sexual couples needing comprehensive sexual/reproductive health information.

Further reifying the heterosexist norm, male virility as opposed to stigma is more often associated with male sexuality. Both HPV-related penile and anal cancers would undoubtedly invoke a significant measure of unwelcome stigma, yet no such association is invoked in the discourse. The issue is of course not to share the stigma, but to engage in alternative discursive and dialogic gestures that clearly invoke multiple-party accountabilities. As Harraway (1977) suggested, I, too, "want to argue for a doctrine and practice of objectivity that privileges contestation, deconstruction, passionate construction, webbed connections and hope for transformation of systems of knowledge and ways of seeing" (p. 287).

CONCLUSION

Our craft then lies in both deconstructing and reconstructing sexual and gendered ideologies. A participatory approach for the HPV vaccination process that includes a simultaneous vaccination of men and women might be the provisional experience that shifts not only medical approaches to health care, but the way we talk about women and men's sexuality and the way we practice care for each other. We know that issues of health related to cervical cancer are not solely situated with sexuality, but more often are further contextualized in frames of systemic regulation of women's bodies, in stigmatized, fossilized ideologies concerning women and sexuality. "Relations of power-knowledge are not static forms of distribution; they are 'matrices of transformations'" (Foucault, 1978/1990, p. 99). The summons remains: We can rearticulate and re-envision an integrative posture in matters of sexual and reproductive health concerns. As health and communication scholars we are not only integral to the process, but must be equally poised to think and act.

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APPENDIX A: EXTENDING AND ADDITIONAL QUOTES FROM THE FDA (2006) TRANSCRIPT (*EMPHASES ADDED*)[1]

The scope of HPV	There are 35,000 cancers in the U.S. that are caused by HPV every year. Twenty five thousand are caused by [HPV] 16 and 18. A million cases of genital warts, 900,000 caused by vaccine types. Six thousand cases of RRP [recurrent respiratory papillomatosis], 5,400 are caused by vaccine types in both men and women and boys and girls (p. 70).
	So, a vaccine that targets these four HPV types [6, 11, 16, 18] would target a large burden of HPV infection and a successful vaccine would really reduce the burden of HPV disease in the U.S. (p. 25)
	"Non-invasive cervical cancer [carcinoma in situ] *is approximately four times more common than invasive cervical cancer"* (ACSd, 2008, ¶ 1).
	Although HPV infection is necessary for the development of cervical cancer, *there is a long time delay between infection and the development of cancer"* (FDA, 2006, p. 27).
History	This first IND, or investigational new drug application, for the monovalent 11 vaccine was submitted in 1997 and the other INDs for the monovalent product 16 and 18 soon followed.
	In 2000, the IND for the quadrivalent vaccine was submitted and in November 2001 was the important VRBPAC discussion of endpoints that would be appropriate for phase III development of a preventive HPV vaccine.
	An advisory committee was established in 2001 to look at cervical cancer. Given the scope of cervical cancer throughout the world the "advisory committee met . . . to consider the endpoints that would serve as a basis for licensure . . . needed to consider an endpoint with a direct link to cancer." (p. 13)
	In 2002, product development program was granted fast-track status and phase III trials were started.
	In May 2005, we had our pre-BLA meeting, with an agreement to allow rolling of the BLA and a priority review.
	In August 2005, the BLA began rolling. The first part was submitted, and in December 2005, the last section of the rolling BLA was received, including phase III study data and that was the start of a six month priority review. (pp. 90–91)
Language	*The rationale* for the vulvar and vaginal cancer endpoint really *followed the same approach that we used for cervical cancer endpoints*, and this is because HPV related vulvar and vaginal canal *have a very similar natural history studies*. They all arise from HPV infected highly dysplastic tissue." (p. 29)
	While we don't have efficacy in men and we're going to do that study and that study will not be impacted by decisions made today, we know that *genital warts in men and women have a comparable histology*, a comparable natural history. The disease is impacting hair-bearing characterized cells in both instances. While the shape of the organ is different, the skin is the same. And when you look specifically at external genital lesions, and I'm talking now about external vulvar lesions—I'm not even talking about vaginal lesions, just vulvar, efficacy is 99 percent. *So the point that we're making is that efficacy of Gardasil in men is highly likely to be significant."* (pp. 166–167)
	We believe the vaccine should also be made available to men, because even though the effects of HPV in men *are less well quantified*, oncogenic HPV has *been implicated* in anal cancer and cancer of the penis. (p. 146)
	Dr. BARR: . . . We have—we also know that HPV 16 is *possibly the strongest predictor* for cervical cancer. And so, in terms of associating this virus with this lesion we came to the closest we could and developed the techniques that would make it a highly sensitive approach co comparing the two. *That's the best that we were able to do.*
	There isn't any marker that says, you know okay, here's an HPV 16. It is glomming right onto the cell and *causing it to be malignant*, if you know what I mean. *Just the strong associations between these things* and *the fact* that *persistent HPV 16 is highly likely to cause disease* and *the association with 16 is* particularly relevant to cervical cancer, 18 for Adenocarcinoma and so on. (pp. 85–86)
	We have shown in our clinical studies in nine to 15 year old boys that anti-HPV GMT's were the highest in the program, two to three fold in younger women, higher than in girls even. *The safety profile was favorable.* (p. 166)
Deciders	Given the limited exposure to discussions of sexuality in children younger than 16 years old, "*FDA and Merck agreed* that we could bridge the efficacy findings in 16 to 26 year old to the younger age range using *immuno-bridging approaches* (p. 29).
	Women remain at risk for HPV infection throughout their life time and so, *we decided to evaluate the duration of efficacy of the vaccine over a period of women in a man's lifetime*. This is important because obviously, for a vaccine to be efficacious, it should have a long term duration. (p. 56)
	that's what is the primary objective of the program, to demonstrate that the vaccine prevents the development of HPV 16 and 18 related CIN [cervical intraepithelial neoplasia] 2/3 and AIS [cervical adenocarcinoma in situ] caused by new infections." (p. 28)
	Not only that, we will protect those men against extra-genital lesions. We will prevent the cancers that we know are due to HPV in men and we will prevent some of the recurring laryngeopapillomatosis that men suffer from these infections. (p. 167)

[1]All appendix text constitutes direct quotes from the FDA hearing transcript.