One Less Risk, Or One Less Girl?
Situating Gardasil and Cervical Cancer Risk
in the Context of Risk-Reduction Medicine

by

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As members of the Dissertation Committee, we certify that we have read the dissertation prepared by Sarah Ilene Melancon, titled **One Less Risk, Or One Less Girl? Situating Gardasil and Cervical Cancer Risk in the Context of Risk-Reduction Medicine** and recommend that it be accepted as fulfilling the dissertation requirement for the Degree of Doctor of Philosophy.

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SIGNED: Sarah Ilene Melancon

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For my family

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Abstract

How does a drug with a limited safety and efficacy record become an international blockbuster? In June 2006 the FDA approved and recommended a new vaccine directed against 4 types of sexually transmitted human papillomavirus, associated with 70% of cervical cancer cases and 90% of genital wart cases. Branded as a "cervical cancer vaccine" Gardasil has been met with as much fanfare as controversy, and retains blockbuster status in Merck's portfolio. Sold as a cancer risk-reduction method, Gardasil carries its own risks, with startlingly low efficacy and elevated likelihood of serious adverse events (side effects). Through the lens of risk, this dissertation examines Gardasil's popularity in the face of evidence that it is neither as safe nor as effective as advertised. Through three distinct research projects, I identify (a) five sociological factors responsible for Gardasil's success on the heels of Vioxx, one of the biggest drug scandals in history; (b) how amongst healthy vaccinated girls, cervical cancer is experienced as a "risk object," yet when a young woman experiences a serious adverse event that "object of risk" and her "experience of risk" shift toward Gardasil; and (c) that Gardasil is so trusted among young women, that warnings about potential side effects from others made some girls more likely to get vaccinated and have a positive opinion on the vaccine, suggesting that Gardasil benefits from a broader cultural assumption that vaccines are inherently safe and effective. Physicians and pharmaceutical marketing also play an important role. Gardasil is a risk-reduction drug and vaccine purported to treat risk while it simultaneously creates new risk for further health problems in some consumers. This dissertation contributes to sociological literatures on pharmaceuticalization, pharmaceutical pseudoscience, the social construction of risk, research on regulatory agencies, and the sociology of medicine more broadly.

Introduction: Risk as an Analytic Strategy

This dissertation utilizes the concept of risk as an analytic strategy in seeking to understand the blockbuster success of the human papillomavirus (HPV) vaccine, Gardasil. Beginning in 2006, advertisements implored young women to "be one less" case of cervical cancer by using the Gardasil vaccine to prevent its precursor: sexually transmitted HPV. Gardasil has been both widely celebrated and increasingly critiqued. In the 8 years since Gardasil's FDA approval, the public and researchers alike have raised concerns about Gardasil's safety and efficacy or, as will be elucidated in this project, lack thereof. What is sold as a cancer risk-reduction tool carries its own set of health risks, which calls into question a pharmaceuticalized approach to health. Rather than construct elaborate risk-benefit ratios and statistical calculations, this dissertation makes an epistemological shift from "Who is at risk?" or "What are a person's risk factors?" to instead ask "How do people understand something as a risk?" (Hilgartner 1992). While epidemiological calculations of population-level risk statistics have their place, a sociological approach explores the meaning, experience and construction of the social phenomenon we call risk. Nowhere is risk more apparent than in our modern day healthcare system, largely based on the notion that human beings are risk-averse and should take every step possible to reduce their risks. The pharmaceutical industry increasingly sells drugs to treat risk factors rather than disease. Yet rather than trying to understand or help the research *subject* recognize his or her *proper risks*, we can shift our framework toward understanding *behaviors, experiences,* and *relationships of risk* (Aronowitz 2010; Boholm and Crevellec 2011;

Westhaver 2005).

This dissertation explores the broad question, *How do pharmaceutical companies shape our understandings and experiences of drug and disease risk?* Professor of Psychiatry David Healy explains, "drug companies obviously make drugs, but less obviously they make views of illness" (1997: 181). More than just perspectives on disease, pharmaceutical companies dominate the experience of risk and health in today's medical market. Through processes termed pharmaceuticalization, solving our health problems with a pill has become standard practice. While some scholars argue pharmaceuticalization is neither an inherently positive nor negative force, social structural changes to the US medical system and regulatory agencies in the last 20 years has allowed unsafe and unproven drugs to proliferate (Light 2010). Contrary to popular belief, Gardasil is one such drug. More specifically, this dissertation addresses the question, *How does a drug with a limited safety and efficacy record become an international blockbuster?* This chapter reviews relevant literature that informed the process of this dissertation. Next I briefly contextualize myself as a Gardasil researcher considering my personal history with human papillomavirus. I conclude with a summary of findings.

Gardasil: The Tool to Become "One Less"?

In June of 2006, the FDA approved and recommended Gardasil, a new vaccine manufactured by Merck to protect against HPV strains 6, 11, 16, and 18 for girls and young women aged 9-26. Strains 6 and 11 are considered "low-risk" and cause approximately 90% of genital wart cases, while strains 16 and 18 are deemed "high-risk" and cause about 70% of cervical cancer cases. The vaccine has been found to be almost 100% effective in preventing

infection and subsequent conditions by the four strains covered by the vaccine. The vaccine will not treat previous infection with one of these types, though it may protect against the other types (CDC 2006a). Gardasil is administered in three doses, at 0, 2, and 6 months and costs $120 per dose, for a total of $360. As of 2007, Gardasil has also been approved for use in Mexico, Australia, Canada, New Zealand, and the European Union, and more than 50 countries around the world are reviewing the vaccine (Wheeler 2007). Another HPV vaccine – Cervarix, manufactured by GlaxoSmithKline – is also available in over 90 countries. Unlike Gardasil, this vaccine only protects against strains 16 and 18 (GlaxoSmithKline 2009).

Though Gardasil protects against certain strains of *HPV*, it has been branded as a cervical cancer vaccine. Gardasil is perhaps best known for its marketing campaign declaring vaccinated women could become "one less" case of cervical cancer (Lippman 2008). The vaccine is presented as a rational choice in the context of individual risk and protection (Hobson-West 2003), aligning with the goals of public health promotion and echoing feminist rhetorics of empowerment (Chananie 2005).

Gardasil has been critiqued on the grounds of profiteering, biocitizenship and governance, surveillance, feminism, globalism, moralism, individual and parental autonomy (Casper and Carpenter 2008; Charles 2012; Connell and Hunt 2010; Javitt, Berkowitz and Gostin 2008; Mara 2010; Mishra and Graham 2012). Yet with a few important exceptions, Gardasil's safety and efficacy have been taken for granted by both biomedical researchers and social scientists.

Sexually-Transmitted Human Papillomavirus

There are over 100 different types of HPV, about 40 of which are sexually transmitted (Wiley and Masongsong 2006). Approximately half of sexually transmitted HPV strains are considered "high risk." These HPVs can cause abnormalities that left untreated, may lead to cancers of the cervix, vagina, vulva, anus, and penis. High-risk HPVs, particularly strains 16 and 18, are associated with all cases of cervical cancer, 60-65% of vaginal cancers, 20-50% of vulvar cancers, 90% of anal cancers, and 30-40% of penile cancers (Carter et al. 2001; Parkin and Bray 2006). "Low-risk" HPVs can cause genital warts or low-grade genital abnormalities that do not progress to cancer (Wiley and Masongsong 2006)

HPV is extremely common, and has been analogized to a "genital flu" for sexually active individuals (Tristram 2006: 272). At least 50% of sexually active persons will have a genital HPV infection at one or more points over the life course (CDC 2007b). Approximately 20 million Americans currently have an HPV infection, and infection is especially common among those in their late teens and early 20s (CDC 2008).

The vast majority of infections are asymptomatic and go undetected, though infected persons may still transmit the virus to their sexual partners. The virus typically resolves on its own within 1-2 years without causing any notable health problems (CDC 2007e). HPV transmission occurs via skin-to-skin contact primarily during penile-vaginal and penile-anal intercourse. Transmission is also possible between same- or other-sex partners through oral sex, non-penetrative genital-genital contact, sex toys, and genital (including anal) touching (Carroll et al. 1997; Edwards and Carne 1998). For penetrative intercourse, male condoms provide some

protection (Winer et al. 2006), but less than for other STIs. They do not cover all areas that may be infected and partners often do not apply condoms until some genital touching has occurred (Wiley and Masongsong 2006).

There is no standard test for human papillomavirus to check one's "HPV status" (CDC 2007b). Most women are tested for and diagnosed with HPV upon receiving an abnormal Papinicalou (Pap) test. This test detects cervical abnormalities that, depending on the severity and HPV strain, may progress into cancer if untreated (CDC 2007e). The Pap test may also detect pre-cancerous vaginal abnormalities (ACS 2008b), but there is no standard screening process for vulvar abnormalities (ACS 2006). For both women and men, genital warts are diagnosed visually. There is no clinical HPV test available for men (CDC 2007b). Penile abnormalities often present visually, though sometimes there are no symptoms until cancer has reached an advanced stage (ACS 2008a). Anal abnormalities may be detected via digital rectal exam, visual inspection, or report of other symptoms (ACS 2007a). Though anal Pap tests exist, and some have recommended their use in anal screening (Palefsky 2008), the CDC does not currently recommend their use (CDC 2007c).

When HPV-related abnormalities are detected there are a variety of treatment options available (Lacey 2005), though treatments for the vagina, vulva, penis, and anus are less standardized than for cervical abnormalities. Treatments do not eliminate the virus, but rather its manifestations, so recurrences are possible. For high-risk HPVs, treatments focus on eliminating lesions, combined with continued monitoring in order to halt the development into cancer (Keller, Egan, Mims 1995). Genital warts may regress on their own but patients typically

undergo treatment to eliminate warts for cosmetic purposes (Lacey 2005).

Though HPV is extremely common, HPV-related cancer is rare in the US. The incidence of cervical cancer in industrialized nations has dramatically decreased over the past 3 decades with the introduction and standardization of Pap testing (ACS 2007c). However, cervical cancer remains a major health issue worldwide, with over 500,000 new cases and almost 260,000 deaths in 2005. 95% of these cases occurred in developing countries due to a lack of screening and preventative treatment (WHO 2006). The American Cancer Society (ACS 2007c) estimates that there were 11,150 new cases of cervical cancer in the US in 2007, or 1.6% of cancers diagnosed in women. The incidence of cervical cancer is estimated at 8.9 per 100,000 (Watson et al. 2008). Other HPV-related cancers are less common. Anal cancers represent 0.02% of men's and 0.04% of women's newly diagnosed cancers. Vulvar cancer represents .5% of new cancer cases for women, vaginal 0.3%, and penile 0.16% for men. In total, HPV-related cancers are estimated to account for 0.18% of men's and 2.44% of women's cancers diagnosed in 2007. In contrast, breast cancer accounted for 26.3% of cancers in women, and lung cancer 14.8% of cancers in both men and women (ACS 2007b). While HPV-related cancers do occur in the US, they are rare.

The Study of Risk

Scholars such as Mary Douglas, Ulrich Beck and Deborah Lupton have explored the social meanings and use of the concept of risk. Lupton (1999) outlines two broad approaches scholars have taken to the study of risk. The cognitive science approach is most common, which assumes risks exist in an objective reality. Found in engineering, statistics, psychology,

epidemiology, and economics, risks are thought to be pre-existing, identifiable through scientific measurement, and controllable, so that risk may be avoided. It is this concept of risk that informs public health and the practice of modern medicine, including the use of pharmaceuticals.

Conversely, sociocultural approaches take a social constructionist approach to risk, ranging from weak (objective risks are mediated by sociocultural processes) to strong (nothing is inherently risky; risk is the result of different modes of thought). Found in cultural anthropology, philosophy, sociology, social history, cultural geography, and science and technology studies, sociocultural approaches understand that risk cannot be understood outside of the belief system in which it is constituted, and is not static. Nor is risk a neutral concept, as Douglas (1992) states, "The public debates about risk are debates about politics" (79). Sociologists Ulrich Beck (1992) and Anthony Giddens (1999) believe we live in a "risk society," surrounded by hazards generated by modernization, in which response to and interaction with risk becomes systemized.

Medicalization: Expanding Medical Territory

Medicalization is the process through which problems come to be viewed as medical illness or disorder, with medical interventions deemed the appropriate solution (Conrad 2007). For example, Conrad and Schneider (1980) trace cultural shifts in approaches to madness, alcoholism and opiate addiction from deviance, crime or sin to that of sickness. Medicalization works to legitimize social problems by providing medical solutions, and often results in a proliferation and expansion of medical and diagnostic categories (Conrad 2007). Other examples include attention deficit hyperactivity disorder (ADHD), erectile dysfunction (Conrad 2007), childbirth (Rothman 2000), premenstrual syndrome (PMS) (Markens 1996), premenstrual

dysphroic disorder (PMDD) (Offman and Kleinplatz 2004), menopause (Bell 1990) and depression (Thomas-MacLean and Stoppard 2004).

Medicalization became a sociological concern in the 1970s, and is often the subject of critique (Conrad 1992). Critics of medicaliztion view this process as negative, repressive and coercive, arguing for the de-medicalization of various "medical" problems (Lupton 1997). Feminists have been particularly concerned with medicalization, as female bodies tend to be medicalized more often than male. Historically, women's bodies have been viewed as naturally inferior compared to men's (Morgan 1998), and various female physiological processes - menstruation, reproduction, childbirth, and menopause - are medicalized in ways the male body is not. However, medicalization cannot be entirely oppressive. Riessman (2003) demonstrates how women have collaborated in medicalization; medicalization is not necessarily enacted on the passive female body. Middle- and upper-class women have historically fought for the alleviation of childbirth pain and the legalization of abortion and contraception - forms of medicalization that have benefited many women's lives.

Biomedicalization: Making the Invisible, Visible

Beginning around 1985, Clarke et al. (2003) argue that the nature of medicalization shifted as advances in technoscience - including "molecular biology, biotechnologies, genomization, transplant medicine, and new medical technologies" (162) - came to complicate and dominate the practice of medicine. Termed biomedicalization, this shift represents an increasingly expansive and complex medicalization through the use of technoscientific innovations in clinical medicine. The shift from medicalization to biomedicalization can be

understood as a move from medical *control* to the *transformation* of bodies through technology. One of the major processes of this shift includes the rise of surveillance and preventive medicine and the treatment of *risk* rather than disease.

Less concerned with controlling and curing disease, medicine focuses on "transforming bodies and managing risk through technoscientific means" (Sulik 2011: 463). Coronary heart disease provides an apt example. Seen as a "sneaky, silent disease," its risk factors are largely invisible - hypertension, diabetes, smoking, a BMI greater than 27, a diet with over 30% calories from fat, and sedentary lifestyle. While it may be known that these practices are "unhealthy," individuals often do not realize they have heart problems until they experience heart attack. After all, does a BMI of 28 *feel* different from having a BMI of 26? As Angus et al. (2005) finds, "The invisible, visceral facts of the body were known in ways that differed markedly from the sensuous, everyday understandings of the body" (2121). Yet physicians' opinions based on medical tests demystified the invisible and gave patients something specific to grasp. Thus medical technology came to define an experience that without technoscience would been largely invisible and inexplicable.

Risk can shape the understanding and experience of one's body, creating an ambiguous state between illness and health. For instance, genetic testing has led to the creation of "pre-symptomatic" persons who are "ill" but not yet "diseased. Konrad (2003) describes emerging "pre-patients" of a rare but fatal CNS disorder known as Huntington's Disease, who worry about their impending disease. Among women, awareness of breast cancer risk can generate a sense that their breasts are "time bombs" (Robertson 2000: 225). As Baines (1990) explains, "for a

woman with breast cancer, it is a chronic disease; for women generally, it can be a chronic problem" (20). Thus identifying an individual "at risk" for disease affords them options to treat their "pre-disease," yet can also cause an immense level of anxiety. Can this pre-disease be cured in time? Will it progress to "full" disease, and when? How much can an individual mitigate these risks? Biomedicalization provides a window into the body, which may generate more uncomfortable questions than answers.

Pharmaceuticalization: A Drug for Every Problem

In the last 15 years, scholars have expressed growing interest in how the process of medicalization has become increasingly pharmaceutical in character. Conrad (2007) suggests that as emerging "engines of medicalization" (10), the pharmaceutical industry and market interests are driving the conceptualization of disease by marketing illnesses to promote pharmacological solutions. Not only are social problems framed as medical in nature, but now pharmaceutical (Williams, Gabe and Davis 2008). Abraham defines pharmaceuticalization as "the process by which social, behavioral or bodily conditions are treated or deemed to be in need of treatment, with medical drugs by doctors or patients" (Abraham 2010: 604). Andrew Lakoff (2005) suggests disease is increasingly defined in relation to the drugs to which it responds, driven in part by the FDA requirement that drugs be approved for specific diagnoses.

Pharmaceuticals are used not only to treat, but aim to prevent disease (Greene 2007). "Protodisease" is a major source of profit for the pharmaceutical industry (Rose 2006) as risk factors are increasingly framed as diseases themselves (Moynihan, Heath and Henry 2002). This is not a shift away from biomedicalization, but rather a logical development from it. From

visible disease to risk management, biotechnology and epidemiology have changed the practice of medicine such that "statistical tabulations of risk" and "guidelines and rating scales" become the way in which doctors assess patient health more than examining his or her physical body. For the pharmaceutical industry, identifying risks via biotechnology is a goldmine, allowing the development of new markets with unmet medical needs (Applbaum 2009). As Epstein and Mamo (2014) have noted, pharmaceuticals "produce risk as well as risk markets" (156).

While some scholars are careful to describe pharmaceuticalization as a neutral process, neither inherently harmful nor beneficial (Simon, Gabe and Martin 2012), others characterize this broadening of the pharmaceutical scope pejoratively, as "disease mongering." Moynihan (2006) has been among the most outspoken against this practice, believing it serves the pharmaceutical industry's bottom line far more than patient health. Most explicitly, he argues, are industry-based "disease-awareness campaigns," aimed more at selling drugs than educating about health. For example, Eli Lilly heavily promoted premenstrual dysphoric disorder (PMDD) once they received FDA approval to expand the use of fluoxetine (Prozac) for the treatment of PMDD under a rebranded name, Sarafem. As a business industry - and the world's most profitable sector at that (Henry and Lexchin 2002) - "Big Pharma" is undoubtedly concerned with stock prices and keeping investors pockets growing. Whether bigger profits equal healthier patients is questionable. What can be said is that where there once were the sick and the healthy, most everyone is ill or "at risk" for illness today, which keeps Big Pharma's business booming.

Spinning Our Wheels: The Logic of Risk Reduction in Modern Medicine

This brief overview of the state of current medical practice is meant to highlight the

sociological nature of risk as an object of analysis and the sociomedical context in which Gardasil was created. In todays biomedicalized world, humans are only ever apparently healthy until diagnostics and screenings show the "numbers are not quite right." At that point the suffering begins whether it is fear of a diagnosis, fear following a diagnosis, or side effects from a new medication "marketed for those whose numbers aren't right" (Healy 2012: 6). "Risk reduction as efficacy" is the new paradigm which may or may not target a disease (Aronowitz 2010). Increasingly, risk factors such as high cholesterol are framed, treated and experienced as disease. Suddenly risk becomes an experience, and not a good one.

The irony remains that these diagnostic categories are human-made creations, often marketing gimmicks for the pharmaceutical industry, and are more "appearances of science" than meaningful scales. Healy (2012) laments, the "artful use of rating scales or blood tests conceals the fact that we don't know what were doing. When we do know what is wrong the absurdity of simply practicing according to the figures becomes clear" (81). Healy refers to 2000-2010 as the era of "measurement mongering" to promote drugs. Contrast this environment with the 19th century, when illness was inferred through visible symptoms and signs of pathological lesions located in the patient's body through the medical gaze, a practice which requires constant surveillance (Armstrong 2002; Foucault 1973). At present, patients are heavily surveiled, though indirectly; the medical gaze is more directed at a patient's lab results and the prescription pad than his or her physical body.

This cultural obsession with "the numbers" becomes even more ironic in examining which numbers the pharmaceutical industry wants seen. Industry-sponsored clinical trials are

designed more with efficacy than safety in mind, and even then pharmaceutical companies selectively present data to depict positive statistically significant results for their drugs. Far from utilizing a calculated "risk-benefit ratio," there is no standard method for quantifying the benefits of a drug during the FDA review process. Drugs are approved through a qualitative judgment of selectively reported company-generated data. It is no wonder that over the last 40 years new drugs have rarely provided benefit over existing medicines, that adverse drug reactions rise 15% each year after tripling between 1995 and 2005 from 156,000 to 460,000, or that 20% of new drugs are dangerous enough to receive a serious warning or are removed from the market (Lexchin 2012; Light 2010; Light, Lexchin and Darrow 2013; Sack 2010). Vioxx, Merck's last blockbuster before Gardasil, was responsible for 88-139,000 heart attacks and strokes, and 30-40% of patients died (McGoey 2009). This is just a small selection of "the numbers" that are not advertised on drug commercials or in the doctor's office.

To add insult to injury is a lack of efficacy against many "patient centered" outcomes, even for drugs commonly prescribed. Reducing laboratory numbers to fit the "normal" range is not the purpose of medical care. The real goal is avoid heart attack, stroke, or cancer, and too often manipulating the numbers has no impact on anything more than the numbers themselves. It is commonly assumed - and promoted by the pharmaceutical industry - that statin drugs lower total and LDL cholesterol, and this in turn will reduce heart attack or stroke (Brody 2010). However "the strength of the causal association does not necessarily predict what will happen when the causal factor is removed" and this approach oversimplifies complex biological processes (Aronowitz 2010: 24). Avoiding heart attack and stroke takes more than lowering two

laboratory figures, no matter how attractive this simple solution may appear. A study of 25,000 men revealed cardiovascular deaths were caused by poor physical fitness 3 times more often than high cholesterol. In fact unfit males had a 60% higher chance of death, while men with elevated cholesterol but no additional risk factors had no increased risk of death (Abraham 2004). Risk of death is 4 times less for individuals who walk just 2 or more hours per week than those taking statins (Light 2010). It may be easy to swallow a pill, yet ironically statin drugs are associated with muscle weakness and pain that may make exercise more difficult (Fernando et al. 2011). Nonetheless, these drugs are routinely prescribed and American cardiovascular health continues to suffer.

To summarize, Americans spend a majority of their present-day medical efforts running around in circles. Measuring invisible risks, taking medications to reduce risk, submitting to even more diagnostics to reassure they're getting the numbers right, all attempting to "tame uncertainty" (Lupton 1994) only to die just the same, if not sooner from drug side effects. Debates about rising healthcare costs and insurance premiums often fail to recognize just how much treatment is wholly unnecessary or even harmful. It is out of this context that Gardasil proliferated, a risk reduction vaccine promoted to women ages 9-26 that was only 17-44% effective against all HPVs in clinical trials (Paavonon & Lehitnen 2008), had clinical trials designed to mask serious side effects by comparing the vaccine to an aluminum-based "placebo" (Tomljenovic and Shaw 2011) and has a sharp decline in HPV 18 antibodies, which cannot be detected in 35% of women after 5 years. Diane Harper, lead researcher on Gardasil and Cervarix, has stated HPV vaccines will only yield a public health benefit if over 90% of sexually

active females are vaccinated and it is effective for at least 15 years. The vaccine would also have to not cause additional health problems that would take the place of the missing HPVs and cancers. Unfortunately for the millions of women who have used Gardasil, the evidence points to the opposite direction. Even more unfortunate are the thousands of adverse drug reactions to a vaccine that treats a risk already mitigated by Pap smears.

Autobiography: Behind the Research

As I have learned over the last 5 years working on this project, "research is a process" (England 1994: 82). Knowledge is not just reported by researchers but actively constructed (Finlay 2002). In presenting the final product, the process of creation is typically obscured. Yet scholars ranging from Merton to Mills to feminist methodologists believe revealing the "back stage" of the research project serves to contextualize the author's work. Highlighting the "researcher's position" reflects the notion that one's social location shapes their experience in the world, which shapes one's research questions, interests and analytic strategies (Cotter, Ill and Letherby 1993; Mills 1959 [2000]).

C. Wright Mills refers to sociology as a "craft," observing that "the most admirable thinkers… do not split their work from their lives. They seem to take both too seriously to allow such dissociation, and they want to use each for the enrichment of the other" (1959 [2000]: 195). Whether I am an "admirable thinker" remains to be determined, but what is obvious is that the sociologist not only scientifically explores social life, he or she is a part of it. Finlay (2002) asserts that reflexivity - self-awareness - is beneficial and necessary at every stage of research. Yet she warns, reflexivity can "prove a painful business" (541) as personal insights can be

uncomfortable. Yet awareness can better illuminate the social processes under study, help the researcher explore her biases, and lead to new areas of exploration.

Such was the process of this dissertation.

A Sociological Autobiography

"What's a colposcopy?" I called down the hall to my roommate. "Its when the doctor looks inside your colon with a camera," he yelled back. "Well my gynecologist just called and said I have an abnormal pap smear and need to come in for one and a biopsy… So I don't think its that…" In my second year of graduate school, I realized in this moment I had no idea what a pap smear was even for. I parked myself in front of Google for hours that evening, and the next, and the next. A colposcopy, I learned, was a microscope for looking at the cervix. As it would turn out, I had a severe high risk CIN3 HPV infection. Within days I was a walking encyclopedia on human papillomavirus.

Sadly my ability to recite volumes of HPV statistics was useless in preparing myself for what would be my "experience of [cervical cancer] risk" (Aronowitz 2010). Feet cold in stirrups, legs were splayed open to not only a doctor but 5 interns without my permission or consent. In some healthcare facilities this might be normal, but it was unexpected and upsetting for a 23 year-old terrified of undergoing a medical procedure on the most private part of my body. At the time, I did not realize I could have said, "No." The doctor and interns spoke over me as if I did not exist but for the infected cervix on display. The biopsy was taken with minimal communication - "this might pinch a little" - before a sharp pain shot through my cervix, cramping my uterus and lower back instantaneously. I never felt less human in my life. Finally

making eye contact, the doctor explained I might feel some minor cramping and bleeding. She did not tell me that not only would bleed heavily, but the dark iodine solution applied to my internal organs to highlight the infected parts of my cervix would exit my vaginal canal in dark gooey clumps. Within minutes of leaving the doctor's office, the thin pad I was given was completely soaked through. Still in pain, I had to stop at the overpriced university convenience store to purchase additional protection, hoping I would make it to the bathroom before embarrassing myself.

After battling my first doctor for a referral, who saw nothing wrong with our previous appointment, I switched to a doctor I would describe as more 'patient-centered' for a procedure to remove the infected areas. She looked like Tina Fey and looked me right in the eye as she happily answered all my questions. She introduced me to every nurse in the room during the exam and subsequent procedure. While the loop electrosurgical excision procedure (LEEP) was even more painful than the biopsy, I felt comfortable and cared for. A section of my cervix was removed and the wound cauterized.

I remember the first time I saw a Gardasil ad - cancer from a virus? I was shocked. But I quickly went on with my life, as graduate school had more pressing concerns. So when my doctor recommended the vaccine and explained how it worked, I jumped at the chance. Cervical cancer was not my concern; I only hoped to never have to go through this experience again. I was thankful my insurance covered the vaccine, but I was so invested in avoiding future infections I would have paid out of pocket if I needed. I sat anxiously waiting the jab from the thin sliver of a needle. As most of the University Student sample experienced in Chapter 3, the

shot was very painful; the tiny needle deceiving in its strength. I went home feeling as though something good had come out of a terrible experience.

Unlike many women who feel ashamed or dirty after an HPV diagnosis (Nack 2008), I was comforted by statistics about how common HPV was, yet also upset I had not heard of this STD before. And thus I made it my mini crusade to, as Gardasil commercials implored, "tell someone." In the years that followed, I would convince both my sisters and several friends to get vaccinated. As a graduate student lecturer, I would spend an entire day on HPV and Gardasil each semester, answering questions and attempting to normalize the disease. Several students told me I was instrumental in their choice to be "one less." I was a "brand evangelist" - thankful to Merck for the chance of avoiding HPV infection again.

I began studying HPV and Gardasil in sexual health promotion, completing a pilot project that informed my original dissertation proposal. My scientific inquiry into the social context of HPV and Gardasil began as a feminist critique of female-only vaccination. I was an ardent supporter of universal HPV vaccination – after all, women get HPV from *someone*, usually a male – though I never agreed with mandates.

Yet over the next several years I would slowly discover that the story I so proudly told about Gardasil was only partially true. Three specific incidents complicated my once rosy view of the vaccine. First was my discovery that extended use of hormonal birth control increases the risk of HPV infection (CDC 2014). At the time of my diagnosis, I had taken birth control pills for 7 years, beginning in high school to treat acne. Yet not a single doctor or nurse ever informed me of this risk, and the doctor who treated my HPV subsequently wrote me a prescription for the

pill. Why was I never told? If I had stopped the pill, would I have avoided infection? The LEEP procedure is 90% effective (Planned Parenthood 2014), and my doctor assured me my infection would likely be gone by my next appointment. My next two pap smears came back abnormal, which caused a great deal of anxiety, but fortunately the third and ever test after was clear. Did the pill cause my infection to last several months longer than my doctor expected? Or was it due to Gardasil? Second, I did not know at the time - and presumably neither did my doctor - that when Gardasil is administered to an HPV-positive female, it can worsen existing infections. Had I known the HPV vaccine demonstrated an efficacy of -44% in HPV-positive women clinical trials (VRBPAC 2006), I would have at least waited to get vaccinated until after my infection cleared. Finally was the realization that I experienced an adverse event after my first vaccine. My 8th university student participant said she experienced amenorrhea (missed period) for two months after she was vaccinated, yet was not sexually active or pregnant at the time. As I reviewed my interview notes, I remembered that I had also experienced amenorrhea in the two months following my first Gardasil shot. It was a striking experience as I was on hormonal birth control at the time, and never before and never since did I miss a cycle while on the pill. Yet until this interview, I had no reason to connect it to Gardasil. While certainly not serious or life-threatening, many young women will agree a it is not a desirable experience. At the time, I attributed my missed cycle to stress from the entire HPV experience. Perhaps I was right, perhaps I was wrong; I will never know.

And thus my focus shifted from feminist critique and vaccines for all to in-depth exploration of the pharmaceutical industry and questioning whether these vaccines are of use to

anyone. This story constitutes my personal "experience of risk," the fears, worries and physical pain of navigating cervical cancer risk. In a position located part-way between healthy university students and girls with serious adverse events, part-way between 'expert' (with enough academic knowledge to read medical journals, yet not enough to have complete comprehension) and layperson with a personal experience, my location allowed me to examine the HPV vaccine from multiple perspectives and question my own assumptions about risk, vaccines and pharmaceuticals.

Writing a dissertation challenging the safety and efficacy of a vaccine is scientifically risky in itself. While vaccines are viewed as increasingly suspect in popular culture, academia largely accepts vaccination; in fact, in a variety of fields questioning vaccines is akin to medical heresy. As Dew (1999) observes, "social science has traditionally supported increasing vaccine intake, implicitly accept[ing] the medical model's claim to scientific truth" (380). At an academic conference I attended during the course of this research, I once observed a graduate student present her research on parents who question or refuse vaccination for their children, particularly their opinions on Gardasil. As she methodically outlined their concerns over safety and efficacy, with a single statement she dismissed every one of their worries: arrogantly asserting that "vaccines are safe and effective," therefore "Gardasil is safe and effective" so these parents had no true cause for concern. I was put off by her attitude, yet was only beginning to investigate these issues and continually questioned whether it was possible the reality of Gardasil could be so far from the popular image. At various times I agonized over my own sanity, reading article after article celebrating Gardasil – how could so many intelligent, educated physicians,

nurses, researchers, and public health workers be wrong? Aren't these the individuals we trust to look after our health?

Ultimately I realized to cling to a belief that any FDA-approved drug is safe and effective simply because it is so widely utilized is unscientific. As detailed in Chapter 1, Vioxx – which caused 88-139,000 heart attacks and strokes (Tomljenovic and Shaw 2012) – provides an apt example, yet just is one of many. Anti-depressants, statin drugs, and glucose monitoring are routinely prescribed yet have low clinical efficacy and may cause more dangerous side effects than expected, given their common use (Havas 2009; Healy 2012; McCormack and Greenhalgh 2000). Thus it became apparent that to practice science and further knowledge, sometimes one must take the risk of challenging the very frameworks science holds dear. Thomas Kuhn (1962) observes that scientific revolutions follow a crisis when "normal science" is unable to resolve puzzles within the existing paradigm. As the literature critiquing the pharmaceutical industry and risk-reduction medicine continues to grow, drugs are the the fourth leading cause of death (FDA 2009). While the massive literature on "big pharma" and risk gave me a wealth of documents to cite, it was disheartening to see scientists dedicating their careers to uncovering pharmaceutical harm while millions of Americans continue consuming unsafe drugs. Will we face a scientific revolution in medicine? I am hopeful, though only the future will tell.

In the process of this dissertation both my personal beliefs and sociological perspective on the institution of medicine underwent a profound evolution. Yet even more important than my scientific perspective on Gardasil, pharmaceuticals, or medicine more broadly, I am leaving graduate school with the knowledge that some risks are necessary, that the loudest voices in the

conversation are not always the most accurate, and even when I think I know – *especially* when I think I know – to remain open and always ask questions. As a Jew(ish) social scientist, it seems odd to end my "sociological autobiography" with a quote from the Christian Bible. Yet a religion I do not practice can remind me that mainstream science does not hold a monopoly on truth, that our knowledge is only ever partial, and that sometimes it is wise to risk being the fool:

> Do not deceive yourselves. If any of you think you are wise by the standards of this age, you should become "fools" so that you may become wise.
> – 1 Corinthians 3:18

Overview of the Project and Key Findings

The 3 papers in this dissertation each represent a unique approach to understanding the construction of risk in relation to HPV, cervical cancer and Gardasil. I will briefly review findings from each chapter.

Paper 1 addresses the research question *How has Gardasil become so successful on the heels of the Vioxx scandal, with safety and efficacy data that is questionable at best?* Drawing on Foucault's concept of "regimes of truth" (1980 [1977]), I identify five sociological factors responsible for Gardasil's success: (1) the environment of pharmaceuticalization, (2) medical expertise, public health and the social construction of vaccines, (3) the practice of pharmaceutical science and the construction of Gardasil certainty, (4) the delegitimization of opposition and the "anti-vaccine movement," and (5) federal level institutional support through

the practice and policies of legal and regulatory agencies.

Paper 2 addresses the research questions *What happens to our notions of risk when the tool to reduce risk causes new health problems? How does a patient-consumer's understanding and experience of risk change following an adverse drug reaction?* I draw on the concept of "risk object" and Boholm and Crevellec's (2011) notion that risk is a relationship between "objects of risk" and "objects at risk" (see also Hilgartner 1992; Kendra 2007). I compare the experience of HPV, cervical cancer, and Gardasil risk for healthy female university students and young women who have experienced serious adverse events following Gardasil vaccination. For healthy females, cervical cancer is the object of risk, their young active bodies the potential future object at risk. Among those who experience serious adverse events, the object of risk shifts from cervical cancer to the Gardasil vaccine, as the experience of risk shifts from a vague possibility of cancer down the road to present-tense side effects with intense physical discomfort, pain and disability. The object at risk, however, remains the patient-consumer's female body. This paper examines risk not as a perception that can be right or wrong, or a calculation of probability. Rather risk is an experience that is emotional, psychological, and embodied.

Paper 3 explores four research questions centering on how young healthy women decide to get vaccinated and what shapes their opinion on the Gardasil vaccine. The questions include (1) *How does where a young woman learned about HPV, cervical cancer and Gardasil impact their opinion on Gardasil and whether or not they get vaccinated?*, (2) *How do social relations influence a young woman's opinion on Gardasil and whether or not they get vaccinated?*, (3) *How does a sense of risk (for HPV, cervical cancer, or Gardasil) impact a young woman's*

opinion on Gardasil and whether or not they get vaccinated?, and (4) *For each of the above questions, how does each causal condition relate to one another in producing the outcome?* Using the method Qualitative Comparative Analysis (QCA) I explore how education, social relationships, and a sense of risk combine to shape a woman's decision to get vaccinated and her opinion on the vaccine. Key findings include the importance of physicians and Gardasil marketing, which was expected. The most surprising finding demonstrated that when a young woman was warned about the possiblity of Gardasil side effects, she was more likely to get vaccinated. This suggests that even in the face of information to the contrary, vaccines are culturally accepted as safe with few real risks of their own.

Conclusion

This dissertation reflects both a personal and professional evolution of thought and development as a social scientist. Far beyond the particulars of Gardasil, this dissertation has served to open my eyes to the broader societal "issues" contextualizing my own personal "troubles" (Mills 1959 [2000]: 8). Developing my sociological imagination through an exploration of risk and pharmaceuticals highlights how risks, drugs and health may feel like personal choices while our options are structured by norms and institutions we did not choose. Examining the broader context in which biomedical tools like a vaccine against human papillomavirus is created allows one to place Gardasil within a history of pharmaceutical industry corruption, shifting regulatory agency laws, and a culture of medicalization, biomedicalization and pharmaceuticalization. The healthy active girl depicted in the Gardasil commercials is not simply "one less." She is emblematic of an entire generation of girls who

were faced with a choice their mothers did not have to consider. Risks shape the contours of our life decisions, and thus Gardasil is both an object of study and a conduit for understanding the larger role and experience of risk in contemporary social life.

Chapter 2

Fool Me Twice? Post-Vioxx Merck, Strategic Risk, and Gardasil Safety and Efficacy

It was a pharmaceutical fairy tale… In September 2004 pharmaceutical giant Merck & Co. voluntarily withdrew its blockbuster drug Vioxx (rofecoxib) from the market. FDA approved in 1999, Vioxx was a non-steroidal anti-inflammatory drug (NSAID) COX-2 enzyme inhibitor prescribed for osteoarthritis, acute pain and dysmenorrhea (FDA 2004b). Citing increased risk of cardiovascular events with regular use, the corporation claims to have acted responsibly and in the interest of patient health. The FDA applauded this move, as Acting FDA Commissioner Dr. Lester M. Crawford said, "Merck did the right thing by promptly reporting these findings to FDA and voluntarily withdrawing the product from the market" (FDA 2004a).

Within two years it became abundantly clear this was not the case. In fact, Merck was well aware of the cardiovascular risks associated with Vioxx since its earliest trials in 1996. Widespread efforts to downplay these risks continued even after Vioxx was withdrawn from the market. Nonetheless, by 2006 over 27,000 lawsuits were filed against the company by individuals and their families who suffered heart attack and stroke while taking the drug. It has been estimated that in the 5 years Vioxx was on the market, between 88,000 and 139,000 patients experienced heart attack, 30-40% of whom died. By 2005 the media questioned whether the company would be permanently crippled or even survive (McGoey 2009).

But Merck not only lived to tell, but came to thrive once more. Between 2005 and 2007, Merck's stock more than doubled (McGoey 2009). Why? In large part, because of Gardasil.

Gardasil, a vaccine against 4 strains of human papillomavirus, was branded the "cervical cancer vaccine" and advertised as 98% effective. Its marketing campaign and FDA approval coincided with the Vioxx trials. In 2005 Merck launched its first "educational" campaign, entitled "Make the Connection" to address public knowledge deficits and raise consumer awareness of the causal link between HPV and cervical cancer. 2006 saw the "Tell Someone" campaign, urging women to tell their female friends and family about the HPV-cervical cancer relationship. The aim of these marketing programs was to generate public interest in Merck's next blockbuster-to-be, Gardasil, by pre-selling young women on a risk many didn't know they had. Gardasil was approved by the FDA in June 2006, and shortly after Merck sponsored famous the "One Less" campaign where women were urged to "Become one less life affected by cervical cancer" (Gerend and Magloire 2008; Weeks 2008). That year, Merck was awarded Brand of the Year by *Pharmaceutical Executive* magazine for creating a "market out of thin air" (Herskovits 2007: 60). 2006 brought in $235 million in Gardasil sales (Business Wire 2007), which jumped to $1.5 billion in 2007 (Pettypiece 2008). In November 2007 Merck announced it would pay a settlement of $4.85 billion for the approximately 45,000 Vioxx plaintiffs represented in the 27,000 lawsuits against the company. Merck's stock rose 2.1% when announced, surpassing its share in the months preceding Vioxx's withdrawal (McGoey 2009).

Did Gardasil save the day? The vaccine has been widely celebrated by the medical and popular community, while also wrought with controversy. Highly publicized critiques have emerged on multiple dimensions. Religious conservatives were concerned that vaccinating against human papillomavirus, a sexually transmitted disease, would give young girls a "free

pass" to have sex (Casper & Carpenter 2008). Many expressed concern over the high cost of the vaccine ($360 USD for all 3 shots), worrying whether the vaccine was in the interest of lining pharmaceutical pockets more than patient health, particularly considering the low cost (and continuing necessity, even if vaccinated) of pap smears. State mandates were widely controversial, as 24 states attempted to require vaccination for 6th grade girls. Backlash caused Merck to cease lobbying for mandates in 2007 (Mello 2012).

Yet most important for patient health, and most alarming following the Vioxx scandal, is the question of Gardasil's safety and efficacy. Gardasil has been said to be "well tolerated" (Haupt and Sings 2011), having an "impressive safety profile" (Gostin 2011). Yet it is no secret that the vaccine was fast tracked through the FDA and clinical trial participants were only followed for 5 years at the time of its approval, so long-term data were not available. As early as 2007, mainstream media reports of severe adverse events surfaced such as miscarriage, paralysis, seizures, autoimmune disorders and death (FoxNews.com 2007; Huffington Post 2009; Kotz 2008; Krueger 2009; Mullen 2008). Public figures including Michelle Bachmann and Katie Couric have questioned the vaccine (Herper 2013; Tomljenovic 2012). Now almost seven years after its approval, have researchers begun to probe deeper into the question of Gardasil safety and efficacy, finding the vaccine to be far less safe and efficacious than Merck, the FDA and public health agencies claim (Tomljenovic, Shaw and Spinoza 2013). Nonetheless, Gardasil has continued to be a success for Merck, receiving FDA approval for boys and men ages 9-26 in 2009 (FDA 2009). Gardasil is Merck's 7th most popular selling drug and is the fastest growing (Silverman 2013). In 2012, Gardasil yielded over $1.6 billion in sales (Merck 2013).

On the heels of one of the largest pharmaceutical scandals in history, amidst controversy from a variety of angles, why then, has Gardasil been so widely accepted? The aim of this paper is to identify the sociological factors responsible for the popularity of Gardasil, centering on the social construction of risk. Various scholars have argued that risk is a sociocultural concept - that what is considered risk, how we arrive at these conclusions, and how we interact with risk cannot be understood outside of the sociological belief system in which it is constituted (Douglas 1992; Lupton 1999). The pharmaceutical industry relies heavily on the risk of disease in promoting their products. Gardasil is a prime example, initially marketed to reduce the risk of cervical cancer, a disease far from the minds of most young women. Yet as evidenced by Vioxx, drugs may carry a risk to health as great - or even greater - than the risks or conditions the drug is purported to address. Nonetheless, it is generally assumed that drugs on the market are safe and effective. Risk is not a simple, factual calculation but rather a social concept applied far more readily to diseases than drugs.

It is easy to point the finger at greed and the pharmaceutical profit motive to explain why disease risk socially trumps drug risk. Pharmaceutical companies are surprisingly economically vulnerable. Profits come primarily from a few blockbuster drugs (those with annual sales of $1 billion or more), so any rumor of harm can send investors running (Gale 2009). Clearly it is in the interest of Big Pharma to downplay any evidence against their drug's safety or efficacy, but pharmaceutical companies do not operate in isolation. The success of Gardasil and other drugs would not be possible without sociocultural and sociopolitical institutional support.

I argue that it is a constellation of five sociological factors responsible for Gardasil's

success: (1) the environment of pharmaceuticalization, (2) medical expertise, public health and the social construction of vaccines, (3) the practice of pharmaceutical science and the construction of Gardasil certainty, (4) the delegitimization of opposition and the "anti-vaccine movement," and (5) federal level institutional support through the practice and policies of legal and regulatory agencies. These five factors characterize the production of disease risk as social truth, as it pertains to Gardasil. According to Foucault, every society has its own "regime of truth." This includes (a) which discourses are accepted and socially function as truth, (b) methods by which we determine truth from falsehood, (c) accepted techniques and procedures by which we may acquire truth, and (d) the status of those understood to speak truth. Foucault describes the regime of truth in the West today having five elements: (1) scientific discourse and the apparatuses said to produce scientific discourse are the focus of truth, (2) there exists a continual political and economic demand for truth, (3) truth is the primary object of dissemination and consumption through educational and informational institutions, (4) truth is created and communicated under almost exclusive control of particular economic and political institutions (including but not limited to academia, the military, and the media), and (5) truth is at the center of "ideological" debates (Foucault 1980 [1977]).

In *The History of Sexuality, Vol. 1*, Foucault argues that discourse simultaneously constitutes and is constituted by power. Through various centers of power-knowledge, such as medicine, psychiatry, criminal justice and education, discourses produce truths, such as the 'truth' of sexuality. Sexuality is not a drive that is repressed by the powers that be. Rather, sexuality is a "historical construct," a network linking physical bodies, pleasures, the incitement

to speak of sex within accepted discourses, the creation of knowledge about sex and the exercise of both control and resistance are at once joined. This, according to Foucault, is the production of sexuality. We are not, as many have argued, sexually repressed. Rather, a multiplicity of discourses centers on the production of sexuality (Foucault 1978).

For example, where the confession was once a Christian ritualistic technique for creating truth, the practice has spread to other relationships such as parent/child, teacher/student, or psychiatrist/patient. The confession, no longer religious in nature, scientifically creates truth in two stages. First, the individual speaking, second, the 'expert' listening, recording, and interpreting. For instance, whereas same-sex sexual behaviors were once considered an act of sodomy, in the 19th century the homosexual emerged as a type of person: "The sodomite had been a temporary aberration; the homosexual was now a species" (43). The patient admits his or her acts, and the psychiatrist interprets the truth of his or her sexual personhood. Thus, the truth of the homosexual is created through the power dynamic between patient and psychiatrist, within a cultural context of discourse that categorizes sexual acts as a means of normalization and social control (Foucault 1978).

Truths, therefore, cannot be universalized. Rather they are part and parcel of a broader social system. Examining the development of the State following the middle ages, Foucault observed that war had an increasingly prominent place in society. War slowly became less about individual or group conflict, and more a permanent privilege of the State. As war became professionalized with State sanctioned militaries, a discourse arose regarding its nature. War was no longer an issue of sovereignty but rather the basis of social institutions. War was responsible

for the birth of states, as the "cipher of peace" (268). This discourse necessitated taking one side or the other, invoking a "strategic truth that will allow him to be victorious" (268). The State was both created by and required these truths to be sustained (Foucault 1980 [1977]).

A similar process occurs in the social production of risk. Centers of power-knowledge, including public health organizations, regulatory agencies, universities, federal offices, the physician's office and even the pharmaceutical companies themselves both create and are created by an understanding that human beings are at risk for disease. Central is the "rational" position that those risks are best mitigated, and that privileged individuals and institutions have authority to speak on risk and prescribe (literally or figuratively) risk-reduction methods. The truth created within this discourse is highly strategic, emphasizing the risk of disease while downplaying the risk of drug (or other risk-reduction methods). For medical institutions to admit that drugs can be just as dangerous as - if not more than - the disease, would challenge the entire system and raise the question of why we need these centers to begin with. Do we need to reduce our risk? Or are our risk-reduction efforts *increasing* the likelihood of illness?

To explore these issues, I will first detail the Vioxx scandal and describe how the actions of Merck and the FDA shepherded an unsafe drug to market and allowed it to stay. Next I will review the mainstream story celebrating Gardasil. I will review each of five sociological factors central in the production of disease risk, which has allowed for Gardasil's widespread success. Finally I will conclude with a look forward to the future of Gardasil and similar risk-reduction drugs, and the possibility of resistance within our present regime of scientific truth.

Fool Me Once, Shame on You: Vioxx

The mid-to-late 90s were an anxious time for Merck & Co. Between 1999-2001, Merck's patents on its 5 best-selling drugs would expire, with two more set for 2007 (Culp & Berry). Aiming for a blockbuster - a drug yielding over $1 billion in sales per year - Merck put a majority of their eggs in the Vioxx basket. Vioxx was approved in 1999, and in its 5 years on the market, over 107 million prescriptions were dispensed (Krumholz et al. 2007) to over 20 million Americans (Smith 2006), yielding annual sales of up to $2.5 billion (Topol 2004).

But to patients, Vioxx was anything but a lifesaver. Merck claims to have acted responsibly by *voluntarily* withdrawing the drug in 2004 as soon as conclusive evidence of cardiovascular harm was in (Culp & Berry 2007). Yet the earliest trials in 1996 showed signs of concern over cardiovascular risk. When Merck submitted its application to the FDA in 1998, not a single study evaluated cardiovascular events. The submitted trials were small, for short treatment periods of less than 12 months, in patients with low risk of cardiovascular issues and researchers did not collect relevant outcomes to measure cardiovascular problems (Krumholz et al 2007).

In January 1999 Merck was seeking to expand FDA licensure for Vioxx and ran a randomized controlled trial known as the VIGOR (Vioxx Gastrointestinal Outcomes Research) study to show that Vioxx had fewer gastrointestinal side effects than its competitor, naproxen (McGoey 2009). This was found to be true, however, early analysis of the data presented to Merck's safety board in November 1999 found 79% higher risk for serious cardiovascular problems or death. The board conducting the study was supposed to be independent but it was

later found that the head of the board's family owned $70,000 in Merck stock, and was awarded a two-year consulting contract before the study's conclusion (Krumholz et al 2007). Merck did not present the analysis because as Merck's attorneys later said, it was "only preliminary and thus potentially flawed." Raw data was given to the FDA and Merck was not legally obligated to do anything more (Culp & Berry 2007)

By the time the study was published in 2001, the data was manipulated to obscure the cardiovascular risk. The paper included data where gastrointestinal issues were recorded for one month longer than cardiovascular events. During that month, additional cardiovascular events occurred that would have demonstrated increased risk. Further, the report presented the data in an unorthodox fashion, as though naproxen were the intervention group, only noting the relative risk, while failing to show the absolute numbers of cardiovascular events. Importantly, all other results were appropriately reported. Nonetheless, the paper demonstrated a significant increased risk of myocardial infarction. But instead of admitting fault, Merck instead claimed that this was due to a protective effect of naproxen against cardiovascular issues, though no scientific evidence existed to support this claim (Krumholz et al 2007).

It was a 2004 study that put the nail in Vioxx's coffin. The APPROVe (Adenomatous Polyp Prevention on Vioxx) study was designed to examine the efficacy of the drug to prevent colorectal polyps, in hopes of expanding Vioxx's FDA licensure. The authors, all of whom reported conflicts of interest with Merck, reported an increased risk of cardiovascular events - but only after 18 months of use. This piece of the puzzle later made it difficult for plaintiffs to claim Vioxx caused their cardiovascular problems until the methodology was again found to be

flawed and the *New England Journal of Medicine* printed a correction. With these data public, Merck "graciously" took the drug off the market in September 2004 (Krumholz et al. 2007).

It sounds like a typical tragic story of corporate greed. But Vioxx would not have been so successful were it not for a complete failure of the FDA and the academic peer review process. Whether Vioxx should have been approved in the first place is highly questionable. Pre-approval trials lasted less than 12 months, even though patients who might take a drug like Vioxx would likely use it for much longer periods (Culp & Berry 2007). Furthermore, the populations with arthritis and coronary disease greatly overlap, yet the FDA failed to mandate a trial examining cardiovascular risks. And despite FDA warnings over Merck's marketing, the FDA never required additional safety data from the company (Topol 2004).

Perhaps most shocking is the silencing of various researchers concerned with Vioxx, including FDA scientist David Graham. Graham became concerned with Vioxx after the VIGOR study, and performed an epidemiological analysis on a population of 1.4 million. He found that 27,000 heart attacks and sudden cardiac deaths could have been avoided if the patients had used Celebrex (a competitor) instead of Vioxx. Graham was "pressured to keep quiet." By Merck, of course, but also by the FDA's Office of New Drugs, who said that because the FDA was not considering a warning against the use of Vioxx, Graham should change his conclusions on the drug (McGoey 2009). He was warned by a senior Merck executive that he would face "serious consequences" if he continued to publicly express concerns over the Vioxx (Culp & Berry 2007: 27). Other researchers raised a red flag, however each time Merck ironically responded by saying their data was flawed (Topol 2004).

Vioxx would not have been so successful were it not for academic journals rallying its support. Many highly respected journals, including the *New England Journal of Medicine*, *Circulation*, and the *Annals of Internal Medicine* published articles in support of Vioxx that contained flawed methodologies (Krumholz et al. 2007). Many of these were ghostwritten by Merck, while lead or sole authorship was attributed to an academic researcher. A review of ghostwritten articles on Vioxx, Ross et al. (2008) finds that only half included a disclosure of Merck sponsorship or financial compensation. Some "authors" of these articles were not even aware they were listed as lead authors until this fact went public during the Vioxx trials. Not only did Merck falsify research reports, but the company went so far as to create a series of fake journals, publishing six editions in Australia through academic publisher Elsevier (Edwards 2009). The depth to which Merck went to promote a known dangerous drug is almost inconceivable. Yet Krumholz et al (2007) succinctly explain Vioxx's unfortunate success:

> With billions of dollars at stake, Merck conducted the trials, stored and analyzed the data internally, paid academic researchers as consultants to the investigative teams and the safety monitoring boards, and maintained heavy involvement in the writing and presentation of findings. The journals published the studies, and the academic community accepted the findings without expressing much concern." (Krumholz et al. 2007: 122).

Fool Me Twice…? The Mainstream Gardasil Story

In June of 2006, the FDA approved and recommended a new vaccine to protect girls and young women ages 9-26 against four strains of sexually-transmitted human papillomavirus. Manufactured by Merck, Gardasil is reported to provide 100% protection against "low-risk" strains 6 and 11, which are associated with 90% of genital wart cases, and "high-risk" strains 16 and 18, which are associated with 70% of cervical cancer cases (CDC 2008). The vaccine may

also provide some cross protection against other types of HPV (Herrero 2009). Approval has since been expanded to include protection against vaginal, vulval, and anal cancers and for use in males ages 9-26 (FDA 2013). Gardasil has been approved by 121 countries worldwide (Haupt and Sings 2013). Gardasil is administered in three doses, at 0, 2, and 6 months and costs $120 per dose, for a total of $360.

According to clinical trials, designed and funded by Merck (Tomljenovic, Spinoza and Shaw 2013), Gardasil has an impressive safety and efficacy profile. FUTURE I and FUTURE II were randomized, placebo-controlled, double-blind Phase 3 studies. Enrolling 5,759 and 12,167 female participants ages 15-26, each study was approximately 3 years in duration. Compared with placebo, Gardasil showed 100% efficacy against vaccine types in the "per protocol" analysis, which included participants that received all three doses, were HPV-negative at day 1 and completed the study according to protocol (VRBPAC 2006). The most common adverse reaction reported in the Gardasil include syncope (fainting), headache, fever, nausea, dizziness, and injection site reaction (Merck 2009).

With these data, Gardasil was approved, highly publicized, and widely celebrated. Before Merck's educational and advertising television and print campaigns, the public had little knowledge or awareness of HPV and its relationship to cervical and anogenital cancers. In just months after Gardasil's FDA approval, public knowledge jumped by 60% (Kelly et al. 2009). Gardasil is technically a HPV vaccine, though it has been branded as a cervical cancer vaccine. One study found that nurses described the HPV vaccine as a "prophylactic cure" for cancer" and a way to "cure cancer before it happens" (Mishra and Graham 2012: 62). Indeed, no other pre-

cancer risk-reduction drugs currently exist for the general population, though Gardasil has not been documented to prevent a single case of cancer (Tomljenovic, Spinoza and Shaw 2013).

Be One Less: The Social Production of Human Papillomavirus Risk

Environment of Pharmaceuticalization

Medicalization is the process through which problems come to be viewed as medical illness or disorder, and medical interventions are deemed the appropriate solution (Conrad 2007). For example, Conrad and Schneider (1980) trace cultural shifts in approaches to madness, alcoholism, and opiate addiction from deviance, crime, or sin to that of sickness. Medicalization works to legitimize social problems by providing medical and pharmacological solutions, and often results in a proliferation and expansion of medical and diagnostic categories (Conrad 2007). Other examples include attention deficit hyperactivity disorder (ADHD), erectile dysfunction (Conrad 2007), childbirth (Rothman 2000), menopause (Bell 1990) and depression (Thomas-MacLean and Stoppard 2004).

Medicalization became a sociological concern in the 1970s, and is often the subject of critique (Conrad 1992). Critics of medicalization view this process as negative, repressive, and coercive and argue for the de-medicalization of various "medical" problems (Lupton 1997). Many have accused pharmaceutical companies of "disease mongering" to increase profits (Moynihan, Heath and Henry 2002). However, medicalization is not entirely oppressive. Riessman (2003) demonstrates that women often collaborate in medicalization. Middle- and upper-class women have historically fought for the alleviation of childbirth pain and the legalization of abortion and contraception – forms of medicalization that have benefited women's

lives.

The pharmaceutical industry plays an ever-increasing role in the medicalization of social life. Conrad (2007) suggests that as emerging "engines of medicalization" (10), the pharmaceutical industry and market interests are driving the conceptualization of disease by marketing illnesses to promote pharmacological solutions. Andrew Lakoff (2005) suggests disease is increasingly defined in relation to the drugs to which it responds, driven in part by the FDA requirement that drugs be approved for specific diagnoses. The medical profession still contributes to medicalization, though medical markets and consumers, as well as insurance companies, are growing as the primary forces (Conrad and Leiter 2004). *Pharmaceuticalization* may be a more appropriate term to describe the growing use of pharmaceuticals for purposes that are not strictly medical (Williams, Gabe, and Davis 2008). Pharmaceuticals are increasingly used not only to treat, but [possibly] prevent, disease (Greene 2007). "Protodisease," or pre-disease, is a major source of profit for the pharmaceutical industry (Rose 2006) as risk factors themselves are increasingly framed as diseases (Moynihan, Heath, and Henry 2002).

An increasing proportion of pharmaceuticals are "preventative," aimed at reducing risk of potential future disease. Pharmaceutical advertising has become commonplace, where drug companies now teach the public about the risk of disease while simultaneously presenting their risk-reduction solution. In 1957 at the American Drug Manufacturer's Association, Pfizer Chief of Operations Planning Charles Mottley planted the seeds for the pharmaceutical industry shift from disease treatment to disease prevention and risk reduction with "lifestyle" drugs. The pharmaceutical industry's success in antibiotic production proved paradoxical – as antibiotics

reduced infectious disease, so did the pharmaceutical companies' market value (Greene 2007). Pharmacologist David Healy (1997) describes, “drug companies obviously make drugs, but less obviously they make views of illness.” As Big Pharma focuses its efforts on reducing the risk of disease, so too do doctors and patients.

Vaccines have always been pharmaceutical inventions, but their role is increasingly changing in the pharmaceuticalized environment. Historically, vaccines were created to limit infectious disease. Yet vaccines are increasingly developed for non-infectious disease including various cancers, Alzheimer's disease, Type 1 diabetes, gastroesophageal reflux disease (GERD), and even cigarette smoking and cocaine abuse. As of 2012 there were 295 vaccines in development by various drug companies (PhRMA 2012), many of which are intended to reduce individual risk of *potential* disease more than *contain* infectious disease for the population. Gardasil was created in this environment, and is a prime example as both “a drug against risk” and a vaccine (Aronowitz 2010: 22).

As an example of pharmaceuticalized disease risk, Gardasil's famous “One Less” campaign was launched in 2006 shortly after gaining FDA approval. Television and print advertisements promoted a sense of cervical cancer risk: “Each year in the US, thousands of women learn they have cervical cancer. I could be one less” (Buttweiler 2009). One Less “emphasizes potential loss while providing empowerment to take preventive action...narrowing down to 2 choices. Get vaccinated or risk HPV and cervical cancer” (Grantham 2011: 320). The vaccine is presented as a rational choice in the context of individual risk and protection (Hobson-

West 2003), aligning with the goals of public health promotion and echoing feminist rhetoric (Chananie 2005). In this context, the "choice" is to utilize Merck's risk-reduction drug; the parallel choice *not* to vaccinate is elided. Indeed, to put pharmaceuticals into a healthy body necessitates a perception that the body is inherently *at risk*, and that the pharmaceutical is the answer (Mamo et al. 2010). Drugs are not only intended to address the "objective" danger of disease, but promoted to reduce the fear, discomfort and hassle – or "experience of risk" (Aronowitz 2010: 28). Similar to mass childhood immunization, the message to parents and young women is "vaccinate and all will be well" (Rogers and Pilgrim 1995: 77). Missing from discussion is the risk *of* Gardasil. Commercials and advertisements list some side effects, such as "pain, swelling, itching and redness at the injection site, fever, nausea or dizziness" (Merck & Co., Inc. 2006), but not the most severely reported.

Medical Expertise, Public Health and the Social Construction of Vaccines

As Foucault describes, today's regime of truth puts science and scientists on a social pedestal, particularly the study and practice of medicine. The history of medicine can be characterized as a "struggle for the supremacy of one type of knowledge and one model of diagnosis over a number of others... various forms of heterodoxy constantly arise to challenge the course of medical orthodoxy" (Jones 2004: 704). Dominant forms of medicine are backed by state legislature and capital investment with a "consensus among the educated public and a strong link with a paramount form of knowledge housed in universities" (704). The priestly class of physicians and public health workers uphold this canon of knowledge through the health education and the practice of medicine. In some ways, medical orthodoxy takes on religious

undertones, encouraging unquestioning belief and adherence to prescribed practices. The American Medical Association originated with, what McCoy (2008) terms, a sense of medical paternalism. This can be seen in the 1847 Code of Ethics, which required complete patient obedience in the pursuit of medical care.

Public health emphasizes disease prevention, regulating the individual to conform to the medically-defined "normal" body (Petersen and Lupton 1997). Nicholas Rose (2006) asserts that "health is not normality but normativity" (84), and that medical measures are used to bring the body in line with socio-medical norms. Central to public health is the concept of risk – who is at risk, for what, and what is the appropriate response to being "at risk"? "Risk factors" may lead to, but do not necessarily produce future illness. Rather than a black and white diagnosis, illness is a "perpetual becoming" (Armstrong 2002: 113) that theoretically *can* – and from the public health perspective – *should* be halted in progress. It is assumed in this paradigm that doctors and public health agencies know the "true" risks and promote the best options for alleviating risk. Risk reduction strategies are prescribed, literally and figuratively. Jasanoff (1987) characterizes risk communication as a "one-way street extending from experts to the public" (116). "Responsible citizens" appear to nothing more than idealized children, seeking out experts knowledgeable in risk and acting in perfect compliance without question (Mishra and Graham 2012).

But does doctor always know best? What happens when risk reduction techniques carry risks themselves? According to the FDA, adverse drug reactions result in approximately 2,216,000 hospitalizations and 106,000 deaths per year, making pharmaceuticals the fourth

leading cause of death in the United States (2009). Risk-reduction, particularly pharmaceutical interventions, are therefore "vulnerable to data suggesting that they carry their own risks. How can one aggressively sell peace of mind...when the very same product shows evidence of producing further risks?" (Aronowitz 2010: 27).

Vaccination is a cornerstone of public health risk-reduction as well as pharmaceutical industry profits. Culturally, vaccines may be viewed as magic bullets. Minutes from an FDA meeting report, "People expect a risk of zero from vaccines, even if it is theoretically impossible" (2002: 40). It is generally accepted that disease is far more dangerous than vaccination (Dew 1999). Because vaccination is typically seen as the most important medical development in history, resistance is scientifically puzzling (Hobson-West 2003), a challenge to medical establishment and expertise. Questioning the safety and efficacy of vaccines is frequently met with "taboo reactions" (Dew 1999: 382). Within the realm of scientific research, skepticism is always directed toward new theories, never the currently accepted lines of thought – even if emerging theories explain existing scientific knowledge better than their predecessors (Feyerabend 1987). As a vaccine AND a risk-reduction technique, Gardasil has thus enjoyed the benefit of the doubt.

Delegitimizing Opposition and the "Anti-Vaccine Movement"

> "Discourse transmits and produces power; it reinforces it, but it also undermines and exposes it, renders it fragile and makes it possible to thwart it" (Foucault 1978: 101).

The discourse of medical expertise exists because of as well as operates to privilege the

institution of medicine, creating a division between medical truth and falsehood. Backed by infallible science, medicine is seen to be on the cutting edge, the leading technology of truth. Yet within that space exists a parallel discourse of resistance, commonly called the "anti-vaccine movement," which also claims to have science on its side. Yet lacking the institutional support of mainstream medical associations, public health organizations, and regulatory agencies, while questioning vaccines has become more common in the last several decades it remains on the fringe.

Typically termed "antivaccinationists," those who question the safety and efficacy of vaccines would not characterize themselves as such. A more appropriate term would be vaccine safety & choice advocates (VSCAs). Mainstream medicine and VSCAs differ in their beliefs on health and the body. While mainstream medicine frames health as the absence of disease, VSCAs take a holistic approach, relying on complementary and alternative medicine that considers the balance between mind, body, emotions and spirit (Hobson-West 2004). Believing that vaccines contain toxic materials that stress the immune system, VSCAs prefer developing an individual's natural immunity (Blume 2006). As controversial vaccine safety advocate Andrew Wakefield says, "To question the safety of the product is not to be anti-product. Those who ordered the recall of Toyota cars in 2009 for sticking gas pedals were not anti-car" (Wakefield 2011). Many VSCAs do not trust the very centers of power-knowledge supporting widespread vaccination. They assert the expression of their free choice and civil liberties by reducing or refusing vaccines for themselves and/or their children (Blume 2006; Hobson-West 2004).

The concerns of those questioning vaccines have remained remarkably similar throughout

the history of vaccination. "Antivaccinationists" of the 1920s claimed that vaccines caused injury and death, that declines in disease were due to improvements in sanitation and standard of living – not vaccines, that compulsory vaccine policies were not in the interest of public health but rather a collusion between doctors, the state and vaccine manufacturers for profit via the threat of civil or criminal penalty, and that mandatory vaccination was a violation of civil liberties and bodily autonomy (Colgrove 2005). This is very similar to the debates rising in the 1980s and through today beginning with the DPT vaccine and developmental disorders like autism.

Those who question vaccines are viewed as scientifically ignorant, conspiracy theorists, hysterical parents and even a radial fringe that deliberately falsifies data to campaign against vaccines (Poland and Jacobson 2011). From a mainstream perspective, VSCAs simply lack medically correct information, so public health organizations create "fact based" educational campaigns to address these knowledge deficits. Yet programs are generally unsuccessful at changing beliefs, as they typically do not trust the organizations involved, questioning whether the information promoted is "fact." Keelan (2004-2005) notes, "Any attempt to increase compliance by a reiteration of the expert's interpretation of risk ignores the social, institutional and cultural context in which the data itself is co-produced and this lies at the core of resistance. Resistance lies at the surface of a profound cultural skepticism in the autonomy, accuracy and vested interests of those producing data about vaccination" (95).

The vaccine debate is heavily emotional, yet both sides ground their claims in science.

Most health professionals assume there is no factual basis to "anti-vaccine" arguments and dismiss competing claims as "junk science." The most well-publicized vaccine debate is of course the thimerosal-autism debate. Though the CDC and FDA consider the debate settled, many parents, researchers and VSCAs are not so certain. As journalist David Kirby (2006) illustrates in his firsthand account of VSCAs, the crux of the scientific debate is primarily methodological in nature. Differences in population selection and statistical techniques may yield wildly different results even from the same dataset. As we saw in the Vioxx scandal, manipulating data and selective reporting to yield desirable outcomes is not unheard of for the pharmaceutical industry.

Paul Offit says, "You have to convince people that a choice not to get a vaccine is not a risk-free choice; its just a choice to take a different risk" (Quoted in Shetty 2010: 971). The same can be said in reverse. Vaccination is not risk-free, as vaccines bring a different "different risk," the risk of the vaccine itself. Colgrove (2005) describes the construction of risk in 1920s vaccine resistance that remains apt today: "Anti-vaccinationists based their arguments in large measure on a careful reading of available data on the safety and efficacy of vaccination and if they did so with strong biases in favor of an *a priori* assumption, the same accusation could be made against defenders of the practice" (190). Not every claim against Gardasil, or any vaccine for that matter, will be true but accusing VSCAs as unscientific in order to discredit will not go very far when one probes deeper into the literature. As a vaccine, Gardasil piggybacks on institutionalized notions of disease risk and vaccination, thus undermining questions of safety, efficacy and necessity.

The Practice of Pharmaceutical Science and the Construction of Gardasil Certainty

Exploring the reasons Merck survived the Vioxx debacle, McGoey (2009) highlights the strategic use of uncertainty in Merck's legal defense. She says, "By stressing the uncertainty of the facts surrounding the safety of drugs such as Vioxx, regulatory hesitations in removing the drug from the market seem prudent rather than negligent." Merck attempted to capitalize on the uncertainty of correlation, claiming that age, weight, and family history of cardiac issues must have been the cause of heart attack, not Vioxx (Culp and Berry 2007). Pharmaceutical companies and regulatory agencies use uncertainty when it is is convenient to justify their actions or lack thereof (Abraham 1995).

Conversely, certainty may also be attributed to research studies and drug safety, when convenient. Gardasil was released with a handful of uncertainties - its efficacy beyond 5 years, the possibility of long-term adverse effects, and even whether it will truly prevent cervical cancer. Nonetheless, branded as a cervical cancer vaccine with 100% efficacy, Merck instilled a sense of certainty where there was none. This section will explore how the certainty of Gardasil's safety and efficacy were constructed through its clinical trial data, revealing a consistent picture much different from the one painted by Merck, the FDA and public health agencies.

– Safety – Is Gardasil Safe?

Serious adverse events are those which result in death, life threatening conditions, hospitalization, disability or permanent damage, birth defects, or require medical or surgical

measures to prevent permanent damage (FDA 2013). In the last seven years, the following serious adverse events (AE's) following Gardasil vaccination have been reported in the medical literature: autoimmune diseases like Guillian Barre syndrome and lupus, nervous system disorders and many others, including and death (Little 2012; Perez-Carmona 2010; Gatto 2013; Tomljenovic, Spinoza and Shaw 2013; Tomljenovic and Shaw 2013). Any medical intervention is bound to generate some side effects, so the question is not *whether* Gardasil has the potential to cause serious AEs but *how frequently*.

Clinical trials aim to determine whether a drug is as safe as yet more effective than placebo. By definition, a placebo should be a biologically inactive substance (like saline) so the effects of the control may be observed. In clinical trials, Gardasil reportedly caused no more serious AEs than placebo. However in the case of Gardasil, the "placebo" was not inert – Gardasil trials, like many vaccine studies, utilized an aluminum-based "placebo" containing the adjuvant used in the vaccine – amorphous aluminum hydroxyphosphate sulfate (AAHS). Adjuvants are added to vaccines to stimulate the immune system and make the vaccine more effective (Tomljenovic and Shaw 2011).

Though aluminum has been utilized as an adjuvant for over 70 years and is currently used in 26 different vaccines, its mechanisms are poorly understood (Brewer 2006; FDA 2012; Exley, Siesjo and Eriksson 2010). The FDA's upper limit of 850 μg/dose is not based on safety evaluations but rather amounts that enhance a vaccine's antigenicity (Baylor, Egan & Richman 2002). Non-clinical toxicological studies on vaccines are rare because "vaccines have not been viewed as inherently toxic" (FDA 2002: 11). Yet aluminum has been theorized to contribute to

various disorders, including but not limited to multiple sclerosis, Crohn's disease, Gulf War Syndrome, Alzheimer's disease, autism and ALS (Lerner 2012; Exley et al. 2006; Exley 1999; Shaw and Tomljenovic 2013).

The average adult orally consumes 2-3 mg of aluminum every day, yet the gastrointestinal tract and kidneys will eliminate this amount relatively quickly. Entering the blood stream via injection or IV, the protective barriers of the gastrointestinal tract are bypassed and aluminum may accumulate in bone, the liver and the brain (Klein 2005). Aluminum can cross the blood brain barrier and is eliminated more slowly than from other organs, with a half life of approximately 7 years. Becaria, Campbell and Bondy (2002) explain how accumulated aluminum can lead to neurological problems:

> Chronic exposure to Al leads to the accumulation of the metal in the brain. This then triggers activation of glial cells, which then produce proinflammatory cytokines and ROS to resolve a stimulus that the cells perceive as pathogenic. Prolonged secretion of these factors can diminish neuroprotective mechanisms such as antioxidant defense mechanisms, which lead to neuronal cell loss, eventually culminating with neurodegeneration. (316)

If Gardasil was not compared to a true placebo, how can we know it is safe? The only published record comparing Gardasil to a saline placebo exists in a single table within the package insert (Merck 2009). Participants receiving the aluminum-based "placebo" or Gardasil had 2-5 times more injection site AEs than those receiving the saline placebo. Yet in presenting more serious AEs, Merck pooled the aluminum and saline placebo groups as one (see Table 1). Both control and the combined placebo groups presented with the same rate of serious AEs – 2.3 percent. This strategic reporting is similar to how Merck handled Vioxx data that conflicted with their assertions that it is safe. Without separating the two "placebo" groups, Gardasil's safety (or

lack thereof) remains uncertain. Were we to compare Gardasil to saline placebo, however, it seems safe to hypothesize Gardasil would have had significantly more serious AEs. Why else would Merck have presented the data in this fashion?

Placebo issues aside, other methodological concerns make it difficult to gauge the safety of Gardasil, or any other vaccine. Due to limited sample size and time participants are followed (especially for Gardasil, which was fast-tracked by the FDA), most clinical trials do not have the power to elucidate rare yet serious AEs (Neels et al. 2013). Particularly for autoimmune disorders, a latent period between vaccination and development of disorders can range from days to years. Sometimes a temporal relationship is obvious, but often a direct causal connection cannot be established. Most scientists, public health workers and pharmaceutical companies conclude that serious AEs are rather coincidental, and that true serious AEs are thus extremely rare (Tomljenovic and Shaw 2012).

Post-licensure data are another valuable source of safety analysis, helpful in examining more long-term effects. Several researchers have conducted analyses of Vaccine Adverse Event Reporting System (VAERS) data with varying results. VAERS has several limitations which render it more speculative than definitive for statistical analysis, including (1) the reporting system is passive, not mandatory, and AEs are thus highly underreported, (2) reports are not systematically validated, (3) some reports are incomplete and of low quality, and (4) biases in reporting, for example if a physician does not believe vaccines cause AEs he or she may not file a report (Wilyman 2013). Despite these limitations, VAERS is one of a few sources of post-licensure data outside of pharmaceutical funded studies, as a majority of research on Gardasil has

been funded by Merck.

In a VAERS analysis funded by the CDC and FDA, Slade et al. (2009) report no greater risk of serious AEs with Gardasil than other vaccines, except for an increased rate of syncope and venous thromboembolic events. However 80% of Guillian-Barre syndrome (GBS) cases were excluded due to poor report quality, likely leading to an underestimation of autoimmune disorders. For all AEs, number of events were compared to the number of doses *distributed*. Not all doses distributed are administered, so a more accurate calculation would use the latter (Debold and Hurwitz 2009).

Examining doses *administered*, Tomljenovic and Shaw (2012 annals) find the rate of serious AEs is 2.5 times higher than the US cervical cancer death rate of 1.7/100,000, at 4.3/100,000 - seven times higher than calculated from *distributed* doses. Of 20,663 AEs reported to VAERS 2006-2012, 1,592 – or 8% – were serious. This includes 73 deaths, 348 requiring lifetime treatment and 581 with permanent disability. In addition, 438 cases of abnormal pap smear, 143 cases of cervical dysplasia and 16 reports of cervical cancer can be found in VAERS data. The rates of serious AEs per 100,000 doses *administered* is similar across various nations, suggesting a consistent pattern independent of limitations within VAERS data (Tomljenovic and Shaw 2012 annals).

Diane Harper, a principal investigator for Gardasil trials, and a paid consultant from Merck has compared the level of serious adverse events from Gardasil to Menactra, the meningitis vaccine which is known to have an increased risk of Guillian-Barre syndrome. She says:

> "The tolerance for serious adverse events in a vaccine that prevents a disease that can kill within 24 h after contracting the bacteria is different to the tolerance for serious adverse events in a vaccine that prevents disease from a virus that is mostly cleared by the body within 2 years of infection and does not progress to advanced stages of cancer unless there has been no screening for years. What tolerance level is acceptable?" (1614)

She believes in countries where routine Pap screening is not available and mortality from cervical cancer is high, the risk of Gardasil may be acceptable. However in a country where the incidence of cervical cancer is low and Pap screening is readily available for a majority of the population, there may be more risk from Gardasil than HPV (Harper 2009; Yerman 2009).

– Efficacy – Does Gardasil Work?

Gardasil advertising boasts a 98% effectiveness rate, impressive for any medical measure. Even aspirin does not cure a headache 98% of the time. Particularly following Vioxx, the certainty with which Merck's advertising, public health and regulatory agencies speak of Gardasil's efficacy should raise a red flag. Probing deeper into clinical trial data reveals the vaccine is far less effective, and some researchers are concerned that it may lead to worse infections and a higher incidence of cervical cancer.

Clinical trials utilized surrogate end markers to determine efficacy. Surrogates are a "necessary evil" for epidemiologists, used when it is unfeasible or unethical to wait for the end-point disease to develop. For a surrogate to be methodologically useful, it must be valid and measure what is theorized. With Gardasil, the surrogate was mid-to-high grade cervical lesions (CIN 2/3). Yet CIN 2 infections rarely progress to cervical cancer and typically resolve on their

own. CIN3 is a better marker, though even a majority of CIN 3 infections will clear, particularly with Pap smears and treatment. Tomljenovic, Spinoza and Shaw (2013) believe that HPV of any severity is a poor marker for cervical cancer because most infections clear within 3 years.

Gardasil was 98% effective against HPV 16 and 18 CIN 2/3 infections among women who tested negative for HPV at the beginning of the study. However, unless vaccinated before beginning sexual activity, many women will contract HPV before being vaccinated. So this efficacy rate is not accurate for the potential treatment population. Among *all* women in the study population ages 15-26, efficacy against CIN 2/3 was only 7.8% in FUTURE I and 17% in FUTURE II trials (Gerhardus and Razum 2010). Furthermore, an increased rate of HPV 16 and 18 CIN 2/3 infections among HPV-positive vaccinated women is concerning because women are not tested for HPV prior to vaccination (Spinoza et al. 2011). Curiously, this information was included in the VRBPAC document reviewed prior to Gardasil's approval, noting "concern that subjects who were seropositive and PCR-positive for the vaccine-relevant HPV types had a greater number of CIN 2/3 or worse cases" (FDA 2006: 13) (see Table 2).

However efficacy against HPV infections of *any* type was only 17-44% depending on the study (Paavonon & Lehitnen 2008). The same women who tested negative for HPV at the start of trials saw only a 20.5% efficacy rate against CIN 2/3 infections from any HPV type (Spinoza et al. 2011). Why would efficacy dip so low accounting for all types of HPV? Several theories may explain. First is the possibility of viral type replacement. If HPV 16 and 18 are eliminated, other types of HPV could become more prevalent (Pons-Salor et al. 2013; Tota et al. 2013; Villa 2011). Choi et al. (2012) raise another related issue – the phenomenon of "unmasking."

Reported in pneumococcal vaccination, when more than 1 type is present, physicians use an "oncogenic hierarchy" to decide which type is causing the infection. Since 16 and 18 are associated with 70% of cervical cancers, when sampled it is assumed those types are causing the disease, but it may be caused by another (non-vaccine) type. When a type is removed, statistics show fewer infections due to those types, but may reveal more infections due to other types that had been previously "masked." Gardasil may result in a 3-10% increase in cervical cancer rates from non-vaccine types that would otherwise have been attributed to HPV 16 and/or 18.

Postlicensure data does not fare much better than clinical trials, and selective reporting again makes conclusions uncertain. Gardasil was shown to be 100% effective against HPV 16/18 CIN1-3 lesions. Note this is a *combined* efficacy against HPV 16/18 *CIN1-3*. CIN1 is the lowest grade cervical infection, only 1% of which progress to cervical cancer; a majority clear on their own, and the individual never even knew they had an infection. If CIN2/3 are weak surrogates, CIN1 is particularly flimsy. The 5-year follow up study also had a low number of cases with wide confidence intervals. Finally there was no data on efficacy against any HPV type, only HPV 16 and 18 (Tomljenovic, Spinoza and Shaw 2013). Diane Harper has suggested that Gardasil will only yield a public health benefit against cervical cancer if 90% or more sexually active females are vaccinated, and if the vaccine is effective at least 15 years. However there is a sharp decline in HPV 18 antibodies, and at 5 years cannot be detected in 35% of women (Harper 2009; Harper and Williams 2013). If a girl is vaccinated long before she becomes sexually active, say at age 9 or 10, she may not be protected against HPV 18 by the time she begins sexual activity. The efficacy against cervical cancer appears low, but remains

uncertain as only 7 years after Gardasil's FDA approval, cancer has not had time to develop.

Considering the questionable safety and low clinical efficacy, Gardasil's acclaim appears far from certain. If anything it appears safer to err on the side of caution, considering the widespread availability of Pap smears in the US, and that those without access are also unlikely to afford vaccination. Were cervical cancer widespread in the US, perhaps a better safe than sorry approach would be warranted. The risk of human papillomavirus may be high, though the risk of cervical cancer is low in the US. According to the FDA, when disease incidence is low, "there is low tolerance for significant adverse events...caused by vaccines" (2002: 13). The relationship between 'potential risk' and 'potential benefit' is central to public health and individual decision-making: "If the potential benefits are substantial, most individuals would be willing to accept the risks" (Haugh 2009: 796). Perhaps to combat the uncertainties of Gardasil's safety & efficacy, at best - Merck overstated its case. At worst - could Merck be playing the same games as with Vioxx? Merck's motive is as uncertain as Gardasil's benefits appear. Yet because medicine is generally trusted in the US, few doctors and even fewer patients are aware that the risk of Gardasil may well outweigh the risk of HPV.

Federal Level Institutional Support

As both a drug and a vaccine, Gardasil is of course subject to review and approval by the Food and Drug Administration. The FDA is generally trusted in American culture, and it is assumed that FDA approval means a drug is both safe and effective, that the risk of disease is greater than risk of the drug. Nonetheless, Vioxx is one of many cases where the FDA allowed

an unsafe drug to remain on the market. Careful to avoid negative press, the FDA is slow to respond to drug safety issues, even among their own scientists - as demonstrated in the Vioxx case. In the event a drug turns out unsafe, typically a consumer may sue the company (though not the FDA). However individuals are barred from directly filing suit against pharmaceutical companies and must first file a claim through the federal Vaccine Injury Compensation Program. Implicit behind this federal program is idea that vaccines are safe and beneficial enough for the population that they should be protected from litigation, lest they threaten the nation's vaccine supply. This is especially relevant for new vaccines that do not have a long safety record, like Gardasil. This is a significant difference between Vioxx and Gardasil, because Merck will never be subject to the type of lawsuits it endured with Vioxx. The federal government occupies a prime center of power-knowledge, with regulations constructing the truth of disease risk over drug risk - whether or not it is in the best interest of patient health.

Food and Drug Administration

> "FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation" (FDA 2013)

A significant literature has questioned whether regulatory agencies like the FDA act more in the interests of the pharmaceutical industry than in the interest of public health (Abraham 2009; Williams, Martin and Gabe 2011). Mirroring to the cultural construction of medicine, the FDA is seen as "ultimate authority," the "proverbial 'father figure'" not to question (Thompson

2010: 124). But little do his children know, Big Pharma has been padding Daddy's pockets. The 1992 Prescription Drug User Fee Act allowed drug companies to pay user fees to expedite the approval of new drugs. In 2002, this amounted to $576,000 per application, the lion's share of which is earmarked to expedite more drug approvals. Faster approval means it is more likely dangerous drugs appear on the market, as the FDA is quick to approve drugs but slow to remove. In 1997 diabetes drug Rezulin was removed from the UK market for causing liver failure. But it was not until 2.5 year slater that it was removed from the US market. Since most of the FDA's effort focuses on new drugs, other functions like safety monitoring, manufacturing standards and marketing review fall by the wayside (Angell 2005). The FDA's own report – *FDA Science & Mission at Risk* (2007) – concludes, "The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak" (3).

McGoey (2007) argues in the case of Vioxx, it was "strategic ignorance" that allowed the drug to stay on the market. For regulatory agencies, approving a drug that causes serious AEs can create public mistrust. This is especially true when adverse events were reported in clinical trial data. She argues that silence may be a "survival tactic" to save face. Clearly pharmaceutical companies have what regulatory agencies refer to as "honest bias," intending to present their data in a positive light. Agencies assert their drug reviews take this bias into account. However time and again pharmaceutical companies are taken at face value and "honest biases" go undetected. Triazolam, a sleeping pill prescribed for insomnia in the 1980s, was found in 1985 by two FDA epidemiologists to result in 8 to 30 times more psychiatric problems than its competitors following numerous reports of adverse events. Nonetheless, the drug

remains on the market at a lower dose. The UK finally removed triazolam after 13 years (Abraham and Shepherd 1999). The examples of Vioxx, triazolam, and many others demonstrate that the FDA places far more emphasis on the risk of disease than the risk of drugs, allowing documented unsafe drugs to stay on the market.

This phenomenon likely explains how Gardasil was approved by the FDA, given the construction of certainty discussed in the previous section. The task of the FDA appears to bring drugs to the market but only to remove them under pressure, if at all. In the Vioxx trials, FDA scientist David Graham stated:

> I could bore you with a long list of prominent and not-so-prominent safety issues where CDER and its Office of New Drugs proved to be extremely resistant to full and open disclosure of safety information, especially when it called into question an existent regulatory position. In these situations, the [office] that approved the drug in the first place . . . typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues (Graham 2004, quoted in McGoey 2009).

By the time the FDA moves to take action on unsafe drugs, they have likely already caused unnecessary human suffering and even death - the exact opposite of their mission statement.

Vaccine Injury Compensation Program

With ordinary drugs, any individual my file a lawsuit against the company for experiencing serious adverse events - unless that drug is a vaccine. Then individuals must file a claim through the Vaccine Injury Compensation Program (VICP). VICP is a run through the Department of Health and Human Services to compensate individuals and parents of children

who have suffered serious AEs from vaccination. As of March 7, 2013, over 200 claims have been filed for HPV vaccine injuries and 49 have been awarded $5,877,710, amounting to approximately $122,000 per claim. 92 are still pending and 49 have been denied (Judicial Watch 2013).

VICP was created after traditional lawsuits in the early 1980s against DPT vaccine manufacturers skyrocketed. Amounts requested by plaintiffs exponentially increased from $25 million in 1981 to $655 million in 1983, to $3.2 billion in 1985. According to Paul Offit, co-developer of the rotavirus vaccine, had this program not been founded under the National Childhood Vaccine Injury Act (NCVI) of 1986, the pharmaceutical industry would have gone bankrupt, with no one left to produce vaccines. Unlike any other private industry wrought by litigation, the government "saved vaccines" in the name of public health and "had taken the burden of litigation off the backs of vaccine makers and put it on its own" (2010: 21-22). The VICP was created with the notion that "awards [could] be made to vaccine-injured persons quickly, easily, and with certainty and generosity" (Currier 2009-2010).

The Vaccine Injury Compensation Trust Fund, is funded by a $0.75 tax on each CDC-recommended routine vaccine dose (HRSA). For injury, a petitioner may receive the costs of future medical care, up to $250,000 for pain and suffering, lost wages and/or attorney's fees. For death, up to $250,000 may be awarded in addition to legal fees. Claims for injury must be filed within 3 years of the first symptoms, or 2 years of death and 4 years after initial symptoms (HRSA).

VCIP was intended to be a no-fault, non-tort alternative to traditional litigation - easier, faster and less costly. However Miller (2009-2010) believes petitioners are "institutionally disadvantaged." Petitions may take 1-2 or more years to be processed (Miller 2009-2010). An attorney is not required, but many claimants utilize legal counsel (Henson 2007-2008). This is a high cost to petitioners who are already managing the expense of medical care, often with no guarantee of compensation. Experienced attorneys are few and far between (Miller 2009-2010), though experienced attorneys win compensation for their clients 20% more than inexperienced (Currier 2009-2010). Award, however, is not likely. As of October 2006, 11,916 claims had been filed, yet only 16 percent (2,011) were awarded compensation. 79 percent (9,445) claims were denied and 460 were pending (Henson 2007-2008).

The VICP relies primarily on the "Vaccine Injury Table" listing common injuries that may be caused by particular vaccines and the onset of illness. If the petitioner demonstrates they received a vaccine and presented with symptoms listed in the Table in the program's set timeframe, vaccine court assumes the injury was caused by the vaccine and awards compensation. In the late 90s, HHS added more vaccines to the original Table, though it removed those previously involved in a high number of claims. After, "on table" claims decreased from 74 to 55 percent of total claims filed (Henson 2007-2008).

If a vaccine, like Gardasil, is not listed, an "off table" claim may be filed demonstrating a "preponderance of evidence" establishing a causal role for the vaccine. Often medical literature and/or expert testimony is presented in support and results in a higher likelihood of award. In

one study, 64 percent of cases that included medical literature were compensated, compared with only 35 percent who did not. Including an experienced medical expert witness increased the likelihood of compensation by 20% (Currier 2009-2010). Vaccine injured persons may file a civil suit against the vaccine manufacturer, but only after a claim is heard through the VICP. By the time their case is heard through the VCIP, they have likely already waited several years and thousands of dollars on legal fees.

Sack (2010) has argued that Gardasil plaintiffs should be allowed to file a traditional tort claim. Because Gardasil has not been on the market very long, there is little data available to establish a causal link, making the VICP process even more challenging than usual. Gardasil, Sack suggests, has several characteristics that differentiate it from existing vaccines: it protects against a "disease process" rather than a disease that can immediately cause harm, there is not a critical health need for Gardasil in the US because other options for preventing cervical cancer are readily available, and Gardasil is new, without appropriate safety data, and without long-term patient experience for comparison. Including Gardasil on the vaccine table, Sack asserts, benefits Merck more than patients by shielding the company from liability for a vaccine that was not properly tested. Sack argues those injured by Gardasil would have a better opportunity to gain compensation through a traditional tort claim, yet doing so may be too legally dangerous for the pharmaceutical industry. If Gardasil is removed from the table, it may set precedent for other vaccine injuries to proceed through a tort claim, which would compromise the pharmaceutical industry's safety net in the VICP.

Of existing Gardasil awardees, 47 were for injury and 2 for death. Specific injuries have not been released. Of the 92 claims pending, 87 are for injury and 5 for death. Anyone may submit a claim, so this does not necessarily mean the vaccine is at fault. However for those who do indeed have vaccine injuries – the process is expensive, cumbersome and uncertain – especially for Gardasil injuries. Far from supporting those who have experienced serious adverse events, the VICP appears to side with disease over drug risk.

Conclusion

In June 2013, Japan halted its recommendation of Gardasil for girls, citing concern over side effects. Vaccination is still available but public health organizations no longer promote vaccination. The Ministry of Health, Labor and Welfare is currently investigating whether to reinstate recommendation of Gardasil or to withdraw permanently (The Asahi Shibun 2013). Will Gardasil become the next Vioxx? It appears to have more serious adverse events than generally recognized, and some 73 girls have died (Tomljenovic 2013), but the damage may not be as acute. On the other hand, Gardasil is given to the general population, while Vioxx was only prescribed for particular purposes, usually arthritis. With a significant proportion of the young American (not to mention global) population being vaccinated, the potential for adverse effects is much greater. Particularly considering the long-term effects of aluminum, whether Gardasil recipients will face health concerns down the road remains to be seen.

As reviewed in this paper, risk as it is both popularly and medically understood is primarily in relation to disease. Despite disasters like Vioxx, which is merely one of many pharmaceutical failures, drugs get the benefit of the doubt at all levels - from patients and doctors

to researchers to regulatory agencies. If anything, disasters such as Vioxx should lead us to question drug safety and how agencies such as the FDA allow unsafe drugs onto the market. Yet Gardasil has thrived in this environment, the five sociological factors discussed producing and produced by our social understandings of risk.

Yet as Foucault describes, discourses also contain their own resistance, as is evidenced by the fact that this paper is being written. When I began this project in early 2007, serious questions of Gardasil's safety were relegated to internet blogs and conspiracy theories. In the six years since, various scholars have written papers published in respectable venues. While resistance to Gardasil on the level of safety & efficacy may not have delved completely into the mainstream yet, growing interest in "natural" health and alternative medicine seems to indicate a cultural shift. Nestled within a regime of truth that privileges scientific information, scientific and medical expertise has been used to back and justify the Gardasil vaccine. In time, perhaps we will see parallel methodologies reveal that Gardasil is merely "one less" drug fulfilling its promises.

Chapter 3

When Risk Reduction Carries Risks:

Gardasil Adverse Events and Shifting Objects of Risk

Drugs are not simply chemical formulations but encompass a "mythic image of what a drug is supposed to do (a concept)" (Healy 82). It is "common knowledge" that SSRIs like Prozac, for instance, restore unbalanced serotonin levels in individuals with clinical depression. Yet this concept is not rooted in science, it is "completely mythical. It arose in the marketing department of SmithKline Beecham, the maker of Paxil" (Healy 2012: 83). No relationship between serotonin levels and depression has ever been observed (Healy 2004; Lacasse and Leo 2005). Nonetheless this myth shapes an image that makes us feel drugs "work, creating "a spin that no data can overcome" (Healy 2012: 83). A marketing tactic or brand may or may not match the patient-consumer's experience and the biological mechanisms triggered by use of the drug.

The "mythic image" of Gardasil, the human papillomavirus vaccine, is as the "right tool" for the job of preventing cervical cancer in girls and young women. Gardasil is many girls' and young women's first experience of their bodies as potentially risky. Vaccination is a conduit through which girls mature into biomedical adults making "choices" as health consumers. It is the first step as a medical consumer-citizen via rational risk-reduction (Mamo, Nelson and Clark 2010). Via Gardasil marketing, Merck positions cervical cancer as an object of risk for the bodies of young girls, the object at risk. Indeed, Gardasil is central in the American public's

understanding and experience of HPV and cervical cancer. Before Merck's "educational" marketing campaigns, public knowledge of HPV and its connection to cervical cancer was low. A strong multi-pronged marketing campaign changed the face of cervical cancer and HPV in the US - commercials, print ads, public schools, universities, physicians organizations, medical journals, news media, politicians and attempts at mandates simultaneously framed cervical cancer as a central risk for young healthy girls who otherwise would never have thought about cancer (Rothman and Rothman 2009). Diane Harper, who was principal investigator on both Gardasil and Cervarix trials and worked on vaccine programs at the World Health Organization in 2006-2007, believes Merck's marketing communicated "a sense of panic that says 'You have to have this vaccine now'" (quoted in Rosenthal 2008: 1). The frenzy of Merck's advertising campaign took on a character of risk that paralleled the way Merck presented the dangers of HPV. Merck appeared as eager to sell the risk as the risk was supposedly risky. And the bigger the risk, the more likely states might mandate, as Merck attempted until 2007 (Mello, Abiola and Colgrove 2012). What could guarantee customers more than a legal requirement to purchase a specific product?

Yet a risk reduction tool is only as good as it is safe. The reduction of risk is compromised when new risks are introduced (Aronowitz 2010). As reviewed in chapter 1, Gardasil carries its own set of risks that are not widely acknowledged in either the public, academic or clinical spheres. While advertised as 100% effective against 6/11/16/18, Gardasil is really 17-44% effective against any HPV, most of which comes from elimination of CIN 1 and 2 infections that are unlikely to progress to cancer (Paavonon & Lehitnen 2008). Far from

complete effectiveness, 129 women must be vaccinated to prevent one case of CIN2/3 (Sawaya and Smith-Cune 2007), 90% or more sexually active females must be vaccinated to yield true public health benefit, and HPV 18 antibodies are undetectable in 35% of consumers after 5 years, so vaccination of young girls has limited benefit. Considering Pap smears catch most HPV infections before they progress to cancer, the tolerance for adverse events is low (Harper 2009; Harper and Williams 2013). Yet adverse events occur up to 2.5 times higher than the rate of cervical cancer (1.7 vs. 4.3/100,000 cases) (Tomljenovic and Shaw 2011). Trials appear little more than tools for marketing - the placebo contained the aluminum adjuvant used in the vaccine rendering comparisons between drug and placebo effects only partial, few safety studies were provided or required by the FDA, methodology was questionable with selective presentation of data and methods masking important adverse events – all while Merck and public health agencies proclaim Gardasil's higher-than-usual 100% efficacy and high safety rates (Little 2013; Sack 2010). Faulty methods aside, clinical trials illuminated a negative impact on existing HPV infections, problematic because women are not routinely tested prior to vaccination. With two (recently) former Merck employees serving on the FDA panel that approved the vaccine (Allen 2007), a vaccine containing potentially harmful ingredients like aluminum and polysorbate 80 passed review with flying colors (Coors et al. 2005; Gajdova, Jakubovsky and Valky 1993; Tomljenovic and Shaw 2011). Despite advertising with confidence, Gardasil is uncertain at best, dangerous at worst. Yet this is framed as the appropriate tool to reduce the risk of cervical cancer in young women.

As with any drug, some users will handle it perfectly fine. Others will experience risk

from the very tool they are using to lower their risk. Sidestepping the calculation of risk ratios characteristic of public health and modern medical research, this paper examines the experiential framing of risk itself. What happens to our notions of risk when the tool to reduce risk causes new health problems? How does a patient-consumer's understanding and experience of risk change following an adverse drug reaction? And what are the implications for future engagement with the healthcare system? I draw on the concept of "risk object" and Boholm and Crevellec's (2011) notion that risk is a relationship between "objects of risk" and "objects at risk" (see also Hilgartner 1992; Kendra 2007). I compare the experience of HPV, cervical cancer, and Gardasil risk for healthy female university students and young women who have experienced serious adverse events following Gardasil vaccination. Healthy females experience cervical cancer is the object of risk, their young active bodies the potential future object at risk. However experiencing an adverse event shifts the object of risk from cervical cancer to the Gardasil vaccine, as the experience of risk expands from a vague possibility of cancer down the road to present-tense side effects with intense physical discomfort, pain and disability. The object at risk, however, remains the patient-consumer's body. This paper contributes to the sociological literature on risk by examining the nuance of risk as an experience. Risk is not simply a calculation of probability or perception that can be right or wrong. Rather risk is an embodied experience, it is physiological as well as emotional and sociological.

Risk as Experience

As Robert Aronowitz suggests, "Drugs are not only intended to address the 'objective' danger of disease, but promoted to reduce the fear, discomfort and hassle - or 'experience of

risk'" (2010: 28). Risk, Nettleton argues, acts as a psychological mechanism for containing disease (1997) but is also emotional and physical experience**.** While epidemiologists calculate population-based statistical probabilities, individuals experience fear, anxiety, and "ticking time bomb[s]" (Gillespie 2012: 199). Yet unlike the "sick role" identified by Parsons, there is no "risk role" and thus no clear way to respond to risk emotionally and behaviorally aside from further engagement with surveillance medicine (Gillespie 2012). Some individuals may rationalize away any experience of risk while understanding they were technically at increased statistical risk . Patients use different measures of risk than epidemiological risk factors, relying on physical appearance, eating habits, drinking, smoking or gender to evaluate their sense of risk (Ruston and Clayton 2002). As disease is increasingly defined in terms of risk, individuals juggle multiple risks and prioritize those that cause the most anxiety, which may of course differ from the largest risk statistically (Altschuler and Somkin 2005).

Exploring the risk experience of individuals with elevated cholesterol or PSA (prostate-specific antigen) levels, Gillespie (2012) documents a phenomenon he calls "measured vulnerability." Unlike some risks, such as the risk for HPV or cervical cancer, PSA and cholesterol levels are particularly measured numbers to compare one's health status. Being informed about elevated levels designates one as "at risk," a space between illness and health but definitely no longer "healthy." When one's identity as a healthy person is challenged, the individual can no longer determine their health status through self-monitoring. Instead, "the risk experience leads to a compromised ability to trust one's own body to communicate health status," highlighting the continued need for diagnostics and medical surveillance (199).

Risk Objects and Relational Risk Theory

"Risk object" is a concept defined by Hilgartner (1992), elaborated on by Boholm and Corvellec (2011), that acts as a framework for understanding the social phenomenon of risk. These authors argue that what we call risk represents a relationship between a risk object, or an object of risk, and an object at risk or the target of risk. A risk object can include "physical, cultural or social artifact that can be delineated and singled out" (Boholm and Crvellec 2011). A risk object can be a literal object, such as a gun, a natural phenomenon like lightning, a cultural representation like a nationalist ideology or a behavior like consuming alcohol. A risk object "has a value that is at stake" of harm, damage or negative consequence. Risk objects are linked to objects at risk through a narrative of probability and structured by time.

What is designated as a risk object or object at risk and the relationship between the two is culturally and historically contingent. Definitions are shifting with the social landscape and multiple frameworks of risk relations can exist concurrently. Risk objects vary in their proximity. Risks may be "experience-far" or "experience-near," those near having a larger impact on one's experience of risk (Boholm 2003). As Mairal states, "I can say that a «tsunami» is very dangerous but I never say that a «tsunami» is risky. Nevertheless I can describe my proximity to the «tsunami» as risky. So the risk is not derived from the object but from my relationship to the object" (Mairal 2008: 44). From this perspective, risk does not exist in an objective sense, waiting to be perceived accurately or inaccurately. Rather risk is a narrative often tied to the opinions of "experts" disseminated throughout culture.

Nonetheless, risk objects are not inherently tied to popular interpretation. As Aronowitz

(2009) observes, when the risk of a drug becomes common knowledge, its utility as a risk-reduction technique is compromised. Vioxx promised to reduce the risk of gastrointestinal side effects from existing anti-inflammatories, yet was ultimately found to increase cardiovascular risk. Thus its position as a risk object shifted in the public eye as the drug became a source of new risks. Aronowitz notes, risks are "easy come, easy go" as "it is hard to promote the efficacy of a risk-modifying intervention as reducing fear and uncertainty when the very same intervention causes fear and uncertainty" (2009: 437).

Safety, Efficacy and New Drugs

We tend to assume new drugs are safer and work better than their predecessors, that progress has served us in the medical field. Yet from the 1970s to the 1990s, only 11-15.6% of new drugs provided therapeutic gain over existing treatments. Even more problematic, Americans experience up to 2.7 million adverse events from prescription drugs, an an estimated death rate of 128,000 per year, leaving prescription drugs the 4th leading cause of death (Light, Lexchin and Darrow 2013). Drug companies have been trying to get around safety and testing since at least the 1600s - but changes in regulations have allowed practices to proliferate in recent years (Light 2010). When a 1962 FDA amendment required testing drugs for safety and efficacy before approval, about half the existing drugs on the market were found ineffective, yet were targets of heavy marketing and pharmaceutical company resources (Light 2010).

The 1992 Prescription Drug User Fee Act (PDUFA) allowed drug companies to pay "user fees" of $500,000 per drug for priority review (Angell 2005). Between 1998 and 2008 the FDA gave priority review to almost 47% of new drug applications. Yet between 1995 and 2005

adverse reactions reported to the FDA almost tripled. Whereas only 38,000 reports were filed in 1985, the figure jumped to 156,000 in 1995 to 460,000 in 2005, rising 15% each year. A recent review found one in five new drugs causes enough serious adverse events to receive a severe warning or be removed from the market (Light, Lexchin and Darrow 2013). Drugs approved by priority review fare even worse; one in three drugs reviewed in just over half the normal time have serious side effects. For every 10 months less spent in review, there is an 18.1% increase in serious side effects, a 10.9% increase in the likelihood of hospitalization and a 7.2% increase in the chance of death (Olson 2012). The closer the review deadline, the more likely a drug is to receive a black box warning (by 3.27 times) and be withdrawn from the market (6.92 times higher) (Carpenter et al. 2012).

The startling danger of new drugs is not inherent but a function of the drug testing and approval process. Though the FDA's mission is to protect "the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation" (FDA 2013), safety is not a primary focus in drug reviews. All that is needed for a drug to be approved is two clinical trials showing statistically significant positive results compared to placebo, regardless of whether 98 negative studies exist in the literature (Healy 2012). Rather than engage in formal hypothesis testing, drug companies will sometimes run batches of correlations searching for statistically significant results to identify possible diseases a drug may treat. Yet when correlations are run en masse, searching for a relationship significant at the .05 level, there is a 1 in 20 chance any relationship will be statistically significant (Light 2010). The diseases

designated as the object of risk do not emerge from academic literature and the 'evidence base' as patients may imagine. Furthermore, results based on statistical significance are not inherently meaningful to patient health. While changes in blood levels or rating scores may be statistically significant, these do not automatically indicate a qualitative improvement in patient health (Healy 2012). Thus shiny and new is not always better when it comes to pharmaceuticals, and the dazzle of the latest blockbuster may be distracting both physicians and patients from working to improve health and well-being.

Contextualizing Adverse Drug Reactions

In 1976 Ivan Illich conceptualized the unwanted effects of illness, pain and death arisen from the medical system as medical iatrogenesis (Illich 1976). Yet the dangers of drugs have long been recognized. The word "pharmaceutical" comes from the Greek work "pharmakon," which meant remedy, poison and magical charm (Delbaere 2013). Adverse reactions have not always been so high; before the early 90s, new drugs were approved in other countries first, and if side effects emerged while the product was on the market it was not approved in the US. Thanks to the PUDFA, over 60% of drugs are approved in the United States before any other country. Once a drug is on the market, the FDA lacks legal authority to require additional safety studies, though drugs are reviewed every 5 years in Europe (Okie 2005).

While not popular knowledge, experts in the field of drug testing readily admit new drugs receive "only a superficial evaluation of safety" (Corrigan 2002: 502). Determining whether side effects are related to a drug during clinical trials is not based on a formal analysis. A criteria for determining a causal link is that the event "corresponds to what is known about the drug," yet

findings in pre-clinical and Phase I trials are tentative. Research investigators use their own judgment to determine a link, and bias exists if they believe a side effect cannot be related to the drug. Further, adverse events may look similar to the disease being treated, masking the effects of the drug. Finally adverse events can occur after long periods of time on the drug or after treatment has stopped, and such events are not typically considered causally related to the drug. Therefore most initial reports are treated as "conditional" or "doubtful" in its relationship to the drug and are only investigated further if more reports occur. Yet most studies lack statistical power to discover more rare adverse events. For an event estimated to occur in 1/10,000 patients, the trial requires 30,000-65,000 participants, yet most studies are much smaller (Corrigan 2002).

The public does not react well to adverse events. Stults and Conrad (2010) describe how a "risk scare" occurs when it becomes public knowledge that a medication carries adverse events and often results in lower use of the drug. After a link between HRT and cancer was made public in 1975, there was a 40% decrease in prescriptions among menopausal women. Later the drugs were rebranded and promoted to reduce the risk of other diseases, including osteoporosis. Yet in 2002 the same drug was found to significantly increase risk of breast cancer (with highly advanced cases), alzheimer's, and dementia. This resulted in a 50% decrease in prescriptions. Yet more surprising is that even after a black box warning, about half of women continued taking HRT. Does this indicate a degree of trust in pharmaceuticals, an "it won't happen to me" attitude, were they unaware of the label changes, or did patients enjoy the benefits enough that it was worth the risk of side effects? Regardless, adverse drug reactions mean bad PR for

pharmaceutical companies, who work tirelessly to promote their drugs as safe and effective.

Constructing Gardasil: Becoming One Less

Normal, Healthy Girls…

Contrary to earlier sexual health promotion that focused on "deviant" and "promiscuous" women at risk for STIs and unwanted pregnancy, Gardasil targets the pre-sexual female body as the object at risk (Mamo, Nelson and Clark 2010). It is not aimed at those with the highest cervical cancer rates, such as African Americans in the South, Latinas living near the border and Appalachian Caucasians, but rather framed every girl as having an equal risk and an equal chance of becoming "one less" (Rothman and Rothman 2009). The girl at risk is young, healthy and active. She is featured in Gardasil commercials playing sports, designing clothes, and enjoying time with friends. Gardasil is the tool promoted to "guard" that girl from squamous intraepithelial lesions (SIL) that may cause cervical cancer in the future. Reacting to Gardasil commercials, some girls believe they could "stay the way they were" if they got Gardasil. Identifying with the ad, one girl observed, "[the girls in the commercial] were all active and healthy seeming. So because of that, I felt that if I got the vaccine, I would be able to stay that way" (Vardeman-Winter 2012: 298). Thus the object at risk is the healthy female body with messages like this Canadian advertisement: "I chose Gardasil become I'm smart and I look after my health" (Connell and Hunt 2010: 73).

…threatened by the specter of [future] cancer

Various scholars have observed Merck's strategy to avoid discussions about sexuality and human papillomavirus by focusing on cervical cancer as the object of risk. Cancer's cultural

character is sneaky, developing without our awareness, an object of fear and uncertainty (Clarke and Everest 2006). Contrasted with images of healthy active girls, "It is significant that the 'evil' that the HPV project is directed against is a cancer, today's most dreaded disease. This provides a powerful motive for compliance even though the risks lie far into the future; as a risk management strategy, the HPV vaccine is a technology that aims to control the future" (Connell and Hunt 2010: 67).

Risk messages in Gardasil promotion are more implicit than explicit (Aronowitz 2010). An apt example comes from the "My Voice" marketing campaign as described by Malkowski (2013). The cover of an advertising booklet instructs the reader to "spin the wheel below to find out who is at risk for HPV." The package includes headphones to "hear a story from a girl like you" named Kristen. She is "a girl with cervical cancer," who is also white, mid-20s and thin with brown hair. The wheel designates "all of these people could be at risk, including male and female friends, and most importantly 'you.'" There is "so much to learn" including there is "no way to predict who will or won't clear," "8 out of 10 women will have had HPV in their lifetime" and "half of all women who develop cervical cancer are between 35 and 55 years old, many of these women were probably exposed to a cancer-causing HPV type in their late teens or 20s" (6). Scary statistics are contrasted with images of health, communicating impending fear and uncertainty. Cancer is framed as potential to destroy the happy healthy lives of innocent girls.

Methods

This project evolved through a grounded theory approach. Grounded theory is inductive,

whereby analytic codes and theoretical sampling are developed from the data (Charmaz 2001). The project grew from the intention of analyzing how the pharmaceutical industry and Gardasil have influenced young women's understandings of HPV and cervical cancer risk. This section will trace how this project methodologically evolved throughout the process of data collection along an emerging academic literature similarly pointing to Gardasil - not just HPV and cancer - as a possible risk object.

Although Gardasil was FDA approved for boys and men ages 9-26 in 2009 (FDA 2009), the vast majority of its marketing and media attention has centered on its use in females against cervical cancer. In addition, while HPV can cause anogenital cancers in men (and other genital cancers in females), they are even less common than cancer of the cervix. Various scholars have written about the "feminine" branding of Gardasil via Merck's marketing and the initial female-only FDA approval (Casper and Carpenter 2008; Malkowski 2014; Mamo and Epstein 2014; Thompson 2010; Vardeman-Winter 2012). I opted to focus on females as HPV, cancer and risk are likely to be more salient than for males, though the latter may provide a fruitful avenue for future research.

Theoretical sampling led to three sources of data: (1) interviews and surveys of female university students, (2) interviews and surveys of females who believe they have experienced a serious adverse event following Gardasil vaccination, and (3) YouTube videos of young women describing their experience with serious side effects after Gardasil. I will discuss each data source and the analytical process by which I arrived at the data below.

(1) I began by interviewing 23 female college students enrolled at a university in the

southwest between 2010 and 2011. These women were recruited through fliers at the University Health Service center, listserv emails, and brief presentations in Sociology, Family Studies and Women's Studies courses aiming to recruit participants. Participants were required to be between ages 18 and 26, the adult age range for which Gardasil is approved. 22 were current students, and one had just graduated the semester prior. Participants completed a paper questionnaire that took approximately 10-15 minutes, then an interview lasting 15-45 minutes. All interviews were recorded except two, at the participants' request; I instead took detailed notes. I asked these young women questions about their HPV and Gardasil knowledge, where they learned about HPV and Gardasil, whether they got vaccinated and why/why not, their opinions on the vaccine, and their own sense of HPV and cervical cancer risk. Participants were also asked about Cervarix, the competing HPV vaccine manufactured by GlaxoSmithKline, but only one had ever heard of the vaccine. See Appendices A and B for the questionnaire and interview schedule. Interviews were transcribed by a research assistant and reviewed for accuracy, then analyzed using Atlas.ti. Questionnaire results were tabulated into Stata for analysis.

In a grounded theory approach, early analyses and memo-writing shape additional data collection (Charmaz 2001). Within the first 10 interviews, I observed that HPV and cervical cancer were not the only object of risk, rather Gardasil had the potential to be risky for some participants. Academic literature at the time was generally in favor of the vaccine and downplayed any risk, though important exceptions began to emerge (most notably Tomljenovic 2011, but also Gerhardus and Razum 2010; Harper 2009; Haugh 2009; Debold and Hurwitz

2009; Spinoza et al. 2011; Yerman 2009). Internet blogs and news articles also pointed to important questions on Gardasil's safety and efficacy. Thus, I continued interviews with university students as I began collecting data on the population most likely to frame risk in germs of Gardasil - young women who have experienced serious adverse events (AEs) they believe to be the result of Gardasil vaccination.

(2) The second data source includes surveys with 7 females who believe they have experienced a serious adverse event following Gardasil vaccination, and interviews with 2 of these individuals. Being a difficult group to access, I made contact with several gatekeepers of "vaccine critical" (Hobson-West 2007) websites such as SaneVax and TruthAboutGardasil.org (a website dedicated to young women who have suffered serious AEs and/or died after using the Gardasil vaccine). I came into contact with several Facebook groups, such as Families Affected by Gardasil, Gardasil Awareness, Help & Healing From Gardasil Injury, and Post Gardasil/Cervarix HPV Vaccine Syndrome Group. These groups allowed me to email and/or post a call for participants on their webpage. The study population included females over age 18 who live in the United States and believe they experienced serious AEs following Gardasil vaccination, a serious adverse event defined as life-threatening, hospitalization, disability or permanent physical damage, birth defects, conditions requiring medical treatment or surgery, and/or conditions that do not require medical treatment or surgery now but may in the future to avoid one of the above outcomes (FDA 2014). Participants were invited to participate in an online survey hosted by SurveyMonkey.com. At the end of the survey, participants had the option of filling in their name, email and phone number to participate in a telephone interview.

Though I had 26 responses to the survey, only 7 fit the inclusion criteria. A majority of respondents were disqualified because they did not experience any adverse events after Gardasil, and others had not been vaccinated. Two respondents did experience adverse events but were under 18, which disqualified them from the study. Of the 7 remaining, several expressed interest in a telephone interview, but I was only able to schedule and complete two interviews. Both interviews were recorded. One interview participant experienced "brain fog" quite heavily, and her mother assisted her during the interview to help communicate when she had trouble. Participants in the adverse event group were asked similar questions as the university students regarding their knowledge of HPV and Gardasil, where they learned about HPV and Gardasil, why they got vaccinated, their opinions on the vaccine, and their own sense of HPV and cervical cancer risk. I also asked about the side effects they experienced. Survey and interview schedules can be found in Appendices C and D. SurveyMonkey data was exported into Stata for analysis. Interviews were transcribed by a research assistant and reviewed for accuracy, then analyzed with Atlas.ti.

There are several reasons why qualified response to the survey may have been so low. First, the population experiencing serious AEs is relatively small. As of December 2011, there were 20,098 adverse event reports filed in VAERS. This included death (71), life threatening conditions (338), permanent disability (567), hospitalization (982) and existing hospitalization extended (199). At the time of data collection there were just over 2,000 reports of serious adverse events among living patients all across the United States. VAERS is subject to both underreporting and reporting bias; a report does not necessarily indicate causality, yet

simultaneously reporting rates are notoriously low (Wilyman 2013). Thus it is difficult to estimate how large the Gardasil serious adverse events population is, but needless to say it is a fairly small population. Second, because the vaccine is approved from ages 9-26, a large proportion of females receiving the vaccine are under age 18. Third, the response rate may be a function of my recruitment locations. It may be that parents are more likely to be part of Facebook and support groups, or that affected members are underage and thus not qualified for the survey. I may have also had a low rate of follow-through on interviews because potential participants may have been dealing with health concerns. For instance, one woman I interviewed had to reschedule after having a "bad day" health-wise, so life with Gardasil adverse events may have prohibited some participants from sharing their experiences.

(3) To supplement my survey and interview data, the third data source includes 6 YouTube videos of young women over age 18 talking about their experience of AEs after Gardasil vaccination. A research assistant searched YouTube with the following combinations of keywords: Gardasil, HPV vaccine, HPV shot, cervical cancer vaccine and human papillomavirus vaccine with side effects, adverse events, adverse effects, victims, reaction, injury. Examining the first 5 pages of results, hundreds of videos were found under these keywords. Videos that emphasized first person accounts of the young woman "telling her story" about her experiences with Gardasil were selected for analysis. Many of these videos covered similar topics as interviews and surveys, making the two data sources complementary. News stories, physicians' opinions, documentaries, photo montages, lectures, and other videos were excluded. One additional video was excluded because the female said she was only 11 years old. Interestingly,

in every video the young woman introduced herself by name and noted her age. One claimed she was a participant in Gardasil's clinical trials at age 21, the rest were presumably vaccinated as consumers. Videos were uploaded between February 6, 2009 and January 4, 2014 and ranged from 1 minute to almost 17 minutes, most between 4 and 7 minutes long. There was obviously less demographic information available about each YouTube woman than in surveys, but more rich detail about her experiences. A research assistant transcribed the videos. Transcriptions were checked for accuracy and analyzed with Atlas.ti.

Demographics and Characteristics

The university student group had 23 participants. The age range was 18-26, with a mean of 21.39, most between 20 and 22. 17 were white, three Latina, two black and one Asian. 20 considered themselves heterosexual or straight, two bisexual and one queer. 13 described their socioeconomic background as middle class, 3 working class, 6 upper-middle and 1 upper class. 15 were sexually active, 13 of whom only had male partners. 19 received one or more Gardasil shots, 14 got all three. Of those not vaccinated, one did not plan to get the vaccine and the additional three were unsure. 10 paid with insurance, 4 said their parents paid (which may have been through insurance as well), three paid out of pocket and two were unsure. Most side effects were mild: 11 experienced pain at the injection site, two had a fever, one experienced amenorrhea (no period) the month following vaccination, and one had a thyroid condition diagnosed after vaccinating, which she did not believe was related to the vaccine (though her mother did). 14 had a positive view of Gardasil, 7 were unsure and only two had a negative perspective. A majority of participants learned about HPV and Gardasil at the same time, and

when I asked separate questions about where they learned about HPV and Gardasil, most could not distinguish between the two. Advertisements (21), family members (10), doctor (20), and school (9) were the primary sources of HPV and Gardasil information. Paralleling other Gardasil studies, physicians were most influential in their decision to get vaccinated, followed by family members (usually mother) (Ratanasiripong 2012). Of the 13 who said they were most influenced by their doctor, 12 were vaccinated, while all 5 most influenced by family members got the vaccine. 14 knew family and/or friends who got Gardasil, and all of these participants were vaccinated themselves. Seven had previously experienced abnormal pap smears, and five had been diagnosed with cervical HPV, one of whom had first been incorrectly diagnosed with cervical cancer by her physician.

The AEs group had seven participants. The age range was 18-25, with a mean age of 20.5. Six were white, one was half white/half American Indian. Two described their social class as lower-middle, four as middle class, and one as upper class. Only two of the seven were sexually active, with male partners, and all reported a heterosexual orientation. All lived in the United States. Educationally, 1 had completed some high school, four graduated from high school, one had some college education and one had a college degree. Three were currently students, one worked as a receptionist, another as an RN, one was disabled and unable to work, and the last did not respond to the question. Four participants received all three Gardasil shots, two had two, and one had only one shot. Two indicated they received multiple vaccines at once - one also got a flu vaccine, while the other got a flu, hepatitis A, and meningitis vaccine simultaneously. Four paid with insurance, one said parents (who may have paid with insurance),

one paid out of pocket and the last participant was unsure. Six of seven had friends who received the vaccine, though none had any family members who were vaccinated. Participants learned about HPV and Gardasil from Gardasil advertisements (5), doctor (5), friends (3), news (3) and only one from family members. All had a negative perspective on Gardasil.

Side effects happened quickly: two were immediate, four within two weeks of vaccination, and one more than four weeks later. All participants saw a physician about their AEs. All seven required medical treatment or surgery, six will require future medical treatments, six had been hospitalized, five experienced life threatening conditions, and six became disabled or had permanent physical damage. Four reported their AEs to the Vaccine Adverse Event Reporting System, three did not. The side effects were primarily neurological and gastrointestinal in nature, and five of seven experienced autoimmune diseases (according to the American Autoimmune Related Diseases Association 2014). All indicated they were previously healthy with no previous health problems, except one who had mononucleosis the year prior. See Table 3 for the complete list of reported side effects for each participant. Both as a sociologist and due to the methodology of this paper, I am unable to confirm or deny whether these adverse events were indeed caused by the Gardasil vaccine, and such an analysis is far beyond the scope of this paper. Nonetheless, all participants believed their health conditions were caused by Gardasil vaccination; one who received multiple vaccines at once believed it was Gardasil in combination with the other shots that caused her health problems. No participants ever experienced an abnormal pap smear, HPV diagnosis or HPV-related cancer.

Less is known about the creators of each YouTube video. The YouTube women were

between age 18 and 31, most in their late teens and early 20s. Based on skin tone, five appear to be Caucasian and one may be Latina. Two said their side effects began after the first shot, and worsened with the second. The clinical trial participant said her side effects became an issue after the third shot. Table 4 shows the side effects each woman listed in her video. All 5 had neurological effects, others included gastrointestinal, autoimmune, reproductive, and other side effects. Across both sets of adverse events participants, the most common side effects included muscle pain/weakness/tremors (7), numbness/tingling in limbs (6), gastrointestinal problems (6), autoimmune disorders (6), headaches/migraines (6), seizures (5), syncope (fainting) (4), rash (4), weight loss (4), and reproductive system disorders (3).

Becoming One Less Girl Affected by Cervical Cancer?

Before Gardasil: Healthy Girls

The University Student group of young women generally experienced themselves as healthy. A majority simply did not feel at risk for HPV or cancer; these diseases were not relevant to their lives as teens. They felt uninformed about the vaccine, HPV and cervical cancer. Either their mother, or their doctor, recommended the vaccine. Though commercials advocate girls "choose to be one less," for 7 participants it was not so much a choice as they did as they were told:

> I wish I knew what I was getting shots for… I was 16 and more concerned about getting good grades and getting into college. And so like something like Human Papillomavirus like I didn't even know what that meant so I was just like, okay well if my doctor says I need to get it, then I'll get it (University Student #6, vaccinated)

> They didn't really tell me much about it, they just said it was something I should get so I mean I would not have gotten it if my mom hadn't let me because I don't like drugs (University Student #3, vaccinated)

Some had reason not to feel at risk because they or their partner had never been sexually active, or because they were in monogamous relationships. Others felt "young and invincible" (University Student #21, vaccinated). For 3 students, being offered Gardasil made them aware they could be at risk for HPV or cancer, a feeling of uncertainty hat was quickly mitigated by getting vaccinated. The vaccine both raised their risk awareness but resolved the issue at the same time, leaving them with a little more knowledge than prior but not much sense of risk. One woman said, "because [my doctor] seemed to think that getting these shots were important and that made me feel at risk. Because if she did not think it was not important then I would not have. I mean if I was not at any risk right she would have not thought it was important to do" (University Student #7, vaccinated).

If students felt generally healthy, what motivated them to get vaccinated? Four themes emerged: that of protection or "better safe than sorry" (15 participants), that of precaution or "just in case" (7 participants), unaware of any drawbacks (8 participants) and the last set saw no reason not to be vaccinated and thought "Why not?" (6 participants). In the first theme, Gardasil was seen as providing protection from HPV or cervical cancer, with statements such as:

> I felt a little more protected like kind of like when you get the Tuberculosis vaccines or whatever they are. Before you come to college and kind of feels like well now I know I won't get that so I kind of felt like a little more protected, more like okay at least I know this strains am protected against for the most part. So it was a little more different, I mean it was kind of like a little relief, a little tiny one. (University Student #5, vaccinated)

Protection is about keeping the current state of health in tact, protecting oneself as is. The focus is on the self. In the second theme, precaution is more external and focused on what Gardasil is a precaution against. That is, something external might happen, it emphasizes what is occurring

outside the body. However, these women spoke in general, not about HPV or cancer in particular:

> It's a precaution with anything else, when a paramedic comes out and helps someone who is bleeding, there's a chance they may get something from the blood, that doesn't mean you *always will*. So just like with anything, its precautions, so I don't feel at risk (University Student #17, vaccinated)

The third theme is about a lack of information that conflicts with the notion that the vaccine will keep them healthy. These women are unaware of any reason not to get the vaccine, pointing to the possibility that they are open to the idea that there may be reasons not to get vaccinated. Here is one example:

> Um, for people who are sexually active I think, anything they can do to keep from getting an STI is beneficial, um people know if they have practices that could lead to them, there's no harm in getting it. (#17, vaccinated)

The fourth theme has a sense of indifference. It is not that participants were itching to get the vaccine, rather it seemed like a simple step to take that might benefit them in the future. As one participant said, "if you can do it to be healthy, why not? (University Student #15, vaccinated). These last two themes are more passive; the former are more active. Overall, HPV and cervical cancer did not explicitly play a large role in their current state. Rather the focus was on maintaining the present healthy body - keeping the girl in the commercial active and safe.

Risk of Future Cancer

Risk did not feature largely in most girls' decisions to get vaccinated. Only 9 participants indicated ever feeling significant risk for HPV or cervical cancer. 4 described feelings of risk as they were learning about HPV, primarily with the emotion of fear.

Interviewee: Just like, the way the commercial is, I guess a little scared. Like, "A virus

that causes cancer!" like the idea of that is a little scary, so that's what I got from the commercial. (#14, vaccinated)

Sarah: And did what you learn [in school sex education] make you feel at risk for HPV?
Interviewee: A little bit more because there were graphics [laughter]
Sarah: Okay they showed you the pictures.
Interviewee: Yeah.
Sarah: And how do you describe that feeling of risk?
Interviewee: Kind of like I don't ever want to do it. *[Laughter]*.
Sarah: By 'do it' you mean…?
Interviewee: Have sex. (#2, vaccinated)

However for most, these moments of risk were minor and passing. There was a range in the experience of risk, from more intense to minimal. Only 4 felt at risk for HPV at the time of the interview, and only 1 for cervical cancer, all of whom are vaccinated. 3 of the 4 (including the one who felt at risk for cervical cancer) were previously diagnosed with HPV. For this group, the experience of having HPV heightened their awareness of the negative consequences that could come from an infection. Fear is understandable given their prior experiences. Scholars have identified receiving an abnormal pap smear as a liminal space between illness and health (Forss et al. 2004); it appears this space continues well beyond treatment. 4 women became interested in the vaccine only after being diagnosed with HPV, wanting to prevent having to go through that experience again. Three got the vaccine, one was age 26 and in a monogamous marriage when it came out and her doctor [incorrectly] said she was too old.

For others, risk was a logical calculation, a scientific fact more than an emotional experience. As Aronowitz (2010) notes, awareness of a statistical risk does not automatically translate into an individual feeling, emotion or experience of risk. These respondents were more matter-of-fact in their risk discourse:

If it's a chance to lower a risk for future health problems, do it. That's kind of my take on

it. (#18, vaccinated)

> It doesn't seem like people really know, um, what the risks are for lesbian women or women who have sex with women, so it seemed important to go ahead and get it, in case we found out later I'm at risk, without even realizing it. (#22, vaccinated)

Cancer was not something they were actively concerned about; the object of risk was well in the future. This reflects research demonstrating teenage girls describe health in terms of weight. To a teenager, and even to many adults, appearance is taken as an indicator of one's health status (Ruston and Clayton 2002).

To the extent that risk was presently relevant to young women, it was typically tied to personal experience with HPV or in a more objective sense. For most, risk did not play into their emotional or lived experience of surrounding Gardasil.

Is Gardasil the Right Tool?

What is interesting about the above themes is that each indicates that the individual is currently healthy and wants to preserve that state. Rather than addressing a state of risk and fear, Gardasil was a buffer between their present self and what could happen down the road were they not vaccinated. Gardasil was generally perceived positively and without risk, and could only be perceived as a precaution or protection if Gardasil itself were considered safe. After all, "How can one aggressively sell peace of mind… [if] the very same product shows evidence of producing further risks?" (Aronowitz 2010: 27).

There was a subset of women who either raised concerns about Gardasil themselves, or noted that a friend or family member had warned them against taking the vaccine. Curiously, those who were warned about Gardasil were not typically worried about its safety and efficacy

themselves. All 8 participants who were warned about the vaccine got vaccinated. 6 saw the vaccine as positive, and 2 were unsure.

> "[My mom] was working, so I just like, "Hey, there's this Gardasil thing that prevents against like uterine cancer and all this stuff." And she says "Be careful about that." And she tells me like when she was a kid, there were these vaccines, and then years later women would have babies that were born with birth defects… but after talking to my doctor, they're like, "Oh you should get it before you're sexually active, to best be protected." And I'm like "I'm gonna get it now then, "because-- I read some of the studies, it seemed pretty legit, so-- but yeah, she was um, more cautious and skeptical, and she was more telling me *not to do it*. (#17, vaccinated)

> "[My mom] has read some scary stories on the Internet about mothers saying "Oh, my daughter got this and that, and all these new health problems after getting the vaccine." But, I'm a big believer that correlation is not causation, and I think there needs to be more research done to know for sure if there are any dangerous side-effects or not, so far I don't think that it's negatively effecting me. (#21, vaccinated)

Another group of 7 participants expressed some concern about Gardasil's safety or efficacy themselves. However only 2 of these chose not to get vaccinated due to these issues. 3 saw Gardasil as positive, 2 were unsure and 2 had a negative opinion.

> I felt that, at first I didn't get it because my mum was very against it all the friends who were getting it, it was kind of brand new and I didn't want to jump on and get it and then it has some crazy negative side effects. I had been diagnosed with [HPV] so I knew that my chances of getting this again were pretty high… like if it came back again or anything like that and after like giving it like 3 or 4 years I figured alright, even if my mom hates it she doesn't have to know. And on top of that I haven't heard anything negative about it yet, so I figured I will just give it a try and see what happens so that's why I gave in. I still though think oh my gosh what if in a year all these girls start like dying or something from it, so it still kind of freaks me out a little bit because it is a new vaccine, but I don't know, I try not to think about it because I will go crazy. (#5, vaccinated)

> I am kind of scared about the side effects of it, so I don't think I will take it. (#9, unvaccinated)

The doctor played a big role in these participants' decision to get vaccinated despite safety concerns. They opted to trust their doctor's opinion, and with a physician recommendation, agreed to get vaccinated and did not search for any additional information. One participant said, "I guess I'm kind of a slave to do what doctors kind of tell to do. Like they say, "Get a flu shot," so I got a flu shot. So they recommend getting the HPV shot so I was like, "I should get one" (#23, vaccinated).

There was one risk of Gardasil identified by a significant minority of women. 8 participants expressed concern that Gardasil only prevented infection from 4 strains of HPV, out of the 40+ that can affect the genital area. To these women, the risk was of Gardasil not being a silver bullet, and failing to prevent *every* HPV infection. As one woman described,

> I think drawback is of course they want to push their products so they don't want you to know that… it only covers four of the hundreds [of HPV strains]. So I think sometimes they just give a false sense of security you know people think they are totally protected and that is not really the case. But you know it is way something. (#10, vaccinated)

As several scholars have highlighted, Gardasil's efficacy against any HPV type was low, especially in women already exposed to the virus (Tomljenovic and Shaw 2011). Nonetheless, 7 of 8 got the vaccine and felt it was better than not getting vaccinated at all.

Overall, young women saw few risks of the Gardasil vaccine, and when they were worried, it did not stop them from getting vaccinated. While Gardasil is more like a risk-reduction drug than a traditional vaccine, it appears that it benefits from the general cultural and medical assumption that vaccines are safe and effective (FDA 2002). Despite a history of unsafe drugs passing FDA review (Abraham 1994; Abraham and Sheppard 1999; McGoey 2009),

approval is taken as evidence of Gardasil's safety for one participant:

> "I'd rather do some more experimentation and know for sure that it's not going to cause any side effects, because I know there are some people who believe that it does. Um, but, it passed the FDA requirements, so - so it doesn't keep me up at night" (#21, vaccinated).

Summary

For University Students, Gardasil may have risks itself, but these are seen as minor in comparison to the possibility of protection. Were Gardasil not connected to "the dreaded C word" (Clarke and Everest 2006), would women be so quick to trust Gardasil? Braun and Phoun (2010) note, "it is difficult to argue with the public health goal of 'One Less.' Why not just get vaccinated, after all?" (45). The object of risk for healthy girls is a vague notion they may one day get cervical cancer, if not vaccinated. Yet we can also ask, if Gardasil were not a vaccine, but rather a daily medication, would it be so readily trusted? Although Gardasil includes three shots over the course of 6 months and requires several doctor's visits to complete, it is only a few steps until she is allegedly "protected" for the forseeable future, unlike a daily medication. Administered as a vaccine, Gardasil may benefit from the broader cultural assumption that vaccines are safe and effective (Dew 1999; FDA 2002). Though voices have publicly questioned Gardasil's safety since at least 2007 (FoxNews.com 2007; Huffington Post 2009; Kotz 2008; Krueger 2009; Mullen 2008), a woman's doctor plays an important role in vaccination. Physician was the most influential source of info on HPV & Gardasil for 13 university students, and 5 more named family members, most often mothers. Doctor plays an especially important role in reassuring patients that Gardasil is safe and effective, encouraging even some who are skeptical to vaccinate. Thus mom and doctor help most young women take

their first steps into biological citizenship (Charles 2012), making a "choice" to be one less. Yet this path may represent less a conscious decision and more a move to go with the flow of the status quo for addressing risk. Through the process of vaccination, university students assimilate cervical cancer as the object of risk and their future bodies as the object at risk, with Gardasil as the "right tool" to protect the young healthy girl in the commercial.

"It Makes You One Less Person": How Gardasil Becomes the Object of Risk

For University Students, the vaccination narrative involved a decision to vaccinate and three visits to the doctor's office. The story concludes with Gardasil. Yet for girls who experienced serious AEs, vaccination was the beginning. Any concerns about HPV and cervical cancer were far surpassed by the serious health conditions they dealt with on a daily basis, including doctors appointments, laboratory tests, hospitalization, severe pain, and physical disability.

For these women, HPV and cervical cancer take a backseat to Gardasil as the object of risk. The hazy possibility of cancer in the future pales in comparison to the health issues experienced right now. However the transition did not occur over night. For most, it was a period of months of symptoms before they connected their problems to the Gardasil vaccine. Not questioned right away, the vaccine was implicitly trusted. Thus becoming a "Gardasil victim," as one woman described it, followed a social process and encompassed a typical narrative identified below. Not every survey, interview and YouTube video covered every point, but each woman's story carried pieces of this overarching narrative. It is through this story of Gardasil injury that the object of risk shifts from cervical cancer to Gardasil, while the object at

risk - the young female body - remains. Their side effects represent an experience of risk, only not an experience of fear and discomfort for a future health problem, but rather an experience happening right now. Dealing with side effects from the risk of Gardasil is present-tense. It ironically begins in the same place as the university students and advertisements - with a healthy girl.

Prologue: Before Gardasil…

The story begins with young, active, happy women. They were dancers, athletes, cheerleaders and gymnasts who at times performed under a demanding - yet enjoyable - schedule. They were involved in after school activities and hobbies like photography:

> I was involved in softball , basketball, volleyball, track, show choir, and I loved being in school, I loved having, just high school surroundings, being around my friends, I was very active. (YouTube Video #2)

> Before the shot, I was an extremely active and healthy young girl. I had not a single medical issue and participated in many sports. (AE Survey Participant #7)

Chapter 1: Getting Vaccinated

For most, vaccination was assumed to be a positive step for one's health. Like the university students, HPV and cervical cancer did not play a big role in their decision specifically. They thought Gardasil would be a "great thing" or a "good idea." A minority of participants felt pressured or scared into taking the vaccine. One said her doctor said she could get HPV by "bumping into people who are sweating," or "shaking hands and by a lab accident." The participant was set to take dance and chemistry courses the following semester at community college, so she felt "frightened into taking it." She had mononucleosis the year prior and was concerned it would not be good for her immune system; later she believes the vaccine

"reactivated" her mono. No other participants identified any specific objections to the vaccine. As studies of "anti-vaccination" parents have found, most come this way through experience. None of the survey participants or YouTube stars indicated prior "anti-vaccine" attitudes; otherwise they probably would not have been vaccinated.

Chapter 2: Confusion - Something's Not Right

> "God, I don't know what's wrong with me, I hate this. I said, I just wanna cry." (YouTube Video #2)

Side effects were unexpected and were met with confusion. Often beginning with fatigue, headache or fainting, a vaccine reaction was not obvious. In this stage, the young women and their families struggle to make sense of their symptoms, which typically worsen over time. First they engage "lay diagnoses" (Zinn 2009), for instance attributing symptoms to allergies.

> I started having really bad headaches, I was tired all of the time, I would always be inside when everyone was playing in the pool and, I would just lay on the couch and sleep all the time because my headaches were that bad…and Tylenol, or aspirin didn't do anything for it. And we always thought it was just my allergies, and I had sinuses or something. (YouTube Video #3)

One girl fainted while with friends. When she came to her friends were crying because, "I was cold and my eyes had been fixed and staring" and they thought she had died.

Once they engage with the medical system, either through their family doctor, a specialist or hospitalization, the women enter liminal space of "something's wrong but we don't know what or why." This experience was met with confusion and fear on top of pain or fatigue interfering with daily life.

> You name it I had it. I thought I was dying. (AE Survey Participant #1)

Attaining a diagnosis (or for most, diagnoses) was a struggle. Many were subjected to numerous diagnostics over the course of weeks or months. Doctors were just as puzzled, assigning one diagnosis then another, prescribing antibiotics or insisting it was just a flu. Two were frustrated by physicians who believed the problem to be purely psychological.

> We were kind of like in the dark. Because very few people we knew, had ever gotten it. It was still very, very new. (AE Survey/Interview Participant #3)

A sense of desperation and at times, hopelessness, occurred at this point in the story. Unable to figure out what is happening, it was difficult to make any progress:

> I had been to all these big hospitals before and they couldn't find what was wrong with me. How in the world could a hospital here help me? (AE Survey/Interview Participant #3)

Chapter 3: Is Gardasil the Risk?

After a period of confusion, each young woman came to the conclusion that Gardasil was the source of her health problems. For three participants, this revelation came through a doctor: "I finally saw an infectious disease specialist and he told me not to get the third shot or I would not be here" (YouTube Video #5). Others implied it was they or their parents who came to suspect Gardasil.

> [After hospitalization] Well, Me and my mom knew in our heart that it was Gardasil. (YouTube Video #5)

> All seeing their daughter all of a sudden having a seizure of course they are gonna think of Gardasil. My dad is always gonna point fingers at it, its like a poison. (YouTube Video #3)

Even when a woman attributed Gardasil as the cause, uncertainties remained. One survey participant received Garadasil along with two other vaccines. Her mother suspected it

was the vaccines, and she told ER doctors this when hospitalized. Hospital staff agreed she had a vaccine reaction, but the young woman was unsure whether Gardasil was the culprit or whether it was the combination. She read about other girls' Gardasil experiences online and found her symptoms matched theirs, but said, "There's no way of knowing but just one of the questions that I have" (AE Survey/Interview Participant #5). Another said she is certain the vaccine caused health problems for her and her best friend, though lamented it could not be proven.

Chapter 4: Physical Pain and The Embodiment of Gardasil Risk

"I would be in tears. It was just so, painful" (YouTube Video #4)

After the Gardasil vaccine, the once active healthy girl is now as one YouTube video said, a "sick child." She is thrust into a world of pain and discomfort. Most experienced multiple side effects at once, which meant managing multiple illnesses and medications, sometimes experiencing additional side effects from the drugs. The risk of cervical cancer is now embodied through a series of new health conditions that can easily overwhelm a teenager and her family.

> There's two different types of episodes in one would be having the back pain and the inflammation of my muscles. How I describe the back pain is more like, being stabbed in the back with a knife and at the same time having someone put a lighter under the muscle and another person taking my muscles and stretching them and twisting them and it it's just a horrible pain. Its - I would never wish it on anyone its extremely painful. I have trouble breathing, I breakout in a rash all around my neck down my neck and all around at my face which we later found out it was because blood vessels were popping in my face And the second episode, is, I just get really tired and its kinda hard to move and then I just, my legs go numb. I can't just feel anything, I can't walk I can't feel someone touch me. And that is one of the scariest feelings in the world seeing someone your leg that you have been able to walk on your entire life and not feel it. (YouTube Video #2)

> A few of the the things that I have dealt with after Gardasil are seizures, passing out, aggression, weight loss, excruciating body pain, migraines, and those are just a few to name including paralysis. I have over 80 of this symptoms from after the Gardasil shots. (YouTube Video #1)

> My legs they will turn a dark purple where they almost look black and that goes all the way down to my feet, and my feet are the darkest. And that does that every occasion, and when it does that, my legs get really, really tingly. (YouTube Video #5)

Because these are serious adverse events, side effects lasted months or years. A 19 year-old cried as she spoke in her YouTube about her seizures, even though she was "seizure free" for almost 3 years. The experience had been so traumatic that even after getting her new epilepsy diagnosis under control, she was upset and angry.

Chapter 5: Treatments - Managing Pain and Uncertainty

As many have argued that engaging in risk-reduction creates lifelong patients and good medical citizens (Charles 2012), the same is ironically true when experiencing the risk of the risk reduction method. While many experienced acute events requiring hospitalization, they were also burdened with discomfort and pain that altered their daily lives. Most AE participants had some form of ongoing medical treatment, including medications and supplements.

> This is my home health kit, basically we'll to try to do this before something happens. This is the blood sugar tester thingamajigger. I have oxycodone is what I take, when I have really bad back pains, Promethazine is pretty much taken daily. It's for nausea and if I don't take one before I eat, I throw up and get sick…This is a nebulizer. And I have to take it with, when I have back inflammation and I have trouble breathing. And then we have, a blood pressure monitor. (YouTube #2)

> I live on medicine every single day and its just a struggle and I just, its terrible. I've had 8 epidural steroid injections, 4 of them which I was put to sleep. And I had 4 which 2 of them they didn't use the Lidocaine before they put the epidural needle in my back. And the other two I was awake. (YouTube #5)

The pain and discomfort of side effects requires continued interaction with the medical system. Some turned to alternative treatments or combined those with traditional methods.

Chapter 6: I'm Not Alone

It was important for over half of the surveys and YouTube videos to describe others who share their or similar conditions. One began her video saying, "I am one at the thousands of girls who had an adverse reaction to Gardasil." Thus, women who experienced serious adverse events after Gardasil are actively situating their health problems a broader context. They are "not a coincidence," as one woman asserts. Participants mentioned friends and acquaintances in the "Gardasil community" suffering from seizures, autoimmune disorders, and even cervical cancer in a 9 year-old and 12 year-old girl.

Some of those experiencing serious AEs have become one another's support system through Facebook groups, where they share their stories and day-to-day advice on dealing with side effects, talking with doctors who do not believe the vaccine caused any damage, and ways to improve their health through both mainstream and alternative approaches. Parents of children with Gardasil side effects are the most frequent posters, but occasionally girls and young women would participate in the discussion.

Ch 7: Life After Gardasil

"I can just be screaming, and saying I want it to stop I want it to be over"

(YouTube Video #4)

In these women's biographies, Gardasil marks a turning point, after which life was never the same again. Post-Gardasil life was characterized in three ways. First, participants emphasized things they are no longer able to do because of their side effects from Gardasil. They recall the active, healthy girl they used to be, the one they were trying to protect from

cancer. School was missed during extended periods of hospitalization, switching medications or being bed ridden from exhaustion.

> If I had never gotten the shot, I would be a normal teenager. And I wish I could go back to when, I could ride my bike, from one side of our small town to the next. And I just can't do that now. (YouTube Video #2)

> I'm constantly thinking of "Okay, Am I gonna be light headed in 10 minutes or am I okay to drive? And do I need to have someone come pick me up for am I gonna be fine to walk all day long?" Because I don't know. And then there's other times when I am sick for an entire month, and in the middle of an episode, I can just be screaming, and saying I want it to stop I want it to be over. (YouTube Video #2)

At least for a period of time, if not indefinitely, life revolved around managing their side effects, which made it difficult to get through each day.

> It destroyed my life. It has ruined so many dreams and so many hopes (AE Survey/Interview Participant #3)

> And its just been, this whole situation has been a struggle, to struggle to live every day is a struggle to deal with these doctors, its a financial struggle, everything is a mess. (YouTube Video #5)

> Since my diagnosis, I have been struggling with maintaining my health on a daily basis. My immune system seems to be that over someone going through chemotherapy. (AE Survey Participant #7)

Dealing with the pain and struggle of Gardasil side effects, several participants and YouTube users aimed to help others. One teen enjoyed knitting hats for other girls who experienced Gardasil side effects. Many on YouTube noted they were sharing their story so that others may avoid getting injured by Gardasil, or to give viewers somewhere to turn if they have experienced side effects. One survey and interview participant who seemed to have the most difficulty in her day-to-day life reached out to media and told her story every chance she got. Even though she had difficulty concentrating during our interview, her passion for helping

prevent other girls from her experience was obvious.

Finally several participants had recovered from or successfully managed at least some of their health problems and tried to get back to their "normal" life. Several were able to graduate high school despite long periods of absence, because they had understanding teachers. While some health problems remain ongoing, symptom improvement was welcome after months or years of suffering:

> I still get occasional severe back pain. I still have fatigue.There is, I had night time incontinence until about three months ago which finally stopped. I still have trouble emptying my bladder at times. Bowel control is an issue sometimes still. I've got it under control where I can live my life normally, but there's still lingering symptoms. (AE Survey/Interview #5)

To summarize, Gardasil became the object of risk for young women who suffered serious adverse events following vaccination. The transition in the object of risk occurred through a sociological process. Beginning as a healthy active girl featured in the Gardasil commercials, vaccination leads to "one less" out on the field or in the high school halls. Attributing symptoms to Gardasil vaccination typically took several months and many visits to doctors and hospitals. Suddenly thrust into the patient role, these young women struggle not only with their physical symptoms but to make sense of an experience they never expected.

New Opinions and Attitudes

Going through this experience of Gardasil risk therefore creates new opinions and attitudes toward HPV vaccines and the practice of medicine more broadly. The most frequent theme was that Gardasil is not worth the risk. That ironically, like cancer, the vaccine can cause damage before one is even aware:

> This vaccine is basically, playing Russian roulette with your child or yourself. Would you allow your child to have one bullet, one bullet in his gun. And and that one bullet could blow your head off. Why would you want to take that chance? And, that's exactly the way I look at Gardasil. (YouTube Video #5)

> Sometimes you know the preventative measures with the vaccine can be worse than the actual disease. (AE Participant #5)

> I think that you're in more danger with the vaccine than you are without it. (AE Survey/Interview Participant #3)

Referring to the HPV vaccine as "poison" or "false hope," many expressed anger and frustration toward the vaccine. Some believe the vaccine needs additional testing, while others say it should be taken off the market.

Physical pain aside, most difficult was breach of trust in their doctor. While the CDC, FDA and Merck were also blamed, women were most upset that the physician they trust gave them the vaccine, usually without any warning about possible side effects.

> Well partially its either [doctors] don't know or they are being paid by the pharmaceutical companies with kickbacks and all these different things like vacations and dinners… my mom used to work for a doctor's office and she knows how they work. And so, I know that they do get kickbacks and they do get bonus stuff from them when they give so many vaccines or medications or what not. So I think it's that and I think another part is fear. That they will lose their jobs. It's ignorance too. They don't know enough about the reactions and this is the sad part… The unknown and being told by the CDC and the FDA, this is a safe vaccine, they may take them at their word regardless. They're not going to think outside the box. (AE Survey/Interview Participant #3)

The participant who received multiple vaccines at once believed her doctor was inept and should not have administered them all simultaneously.

> I feel the doctor made a mistake on giving… [Menactra and Hepatitis A] with Gardasil. It was just basically overloaded me and I think the doctor should have been better informed. (AE Survey/Interview Participant #5)

One young woman felt especially betrayed by her childhood doctor. As a Christian who does not

believe in sex before marriage, she felt embarrassed and angry to have taken a vaccine for a sexually transmitted disease she would have had minimal exposure to. Though her doctor knew her values, and she even participated in Girl Scouts with the doctor's children, she felt the vaccine was pushed on her needlessly.

Ultimately, reframing the object of risk from cervical cancer to Gardasil was not a positive one. One survey participant agreed with the premise of the vaccine but asserted it needed to be tested before released on the market. Yet HPV and cervical cancer were even farther from the adverse events women than the university students. A possible risk in the future is less relevant than the risk happening right now. Had these women not experienced serious adverse events, we can imagine their stories may have been similar to the university students. Gardasil may have just been a passing health choice they, their mother or doctor made for them. Perhaps they would have seen Gardasil as offering protection or safety. But a "better safe than sorry" approach quickly becomes irrelevant when the action taken in the name of safety may create a massive health problem affecting their daily lives.

While we cannot know what these women would have thought of Gardasil otherwise, a shift in thinking demonstrates that an individual's understanding of risk is shaped by personal experience. A negative experience can lead to a conscious reframing of risk, as Hobson-West (2007) finds among "vaccine critical groups." One of the ways the UK groups she studied interacted with the concept of risk was to reframe risk away from diseases we vaccinate against and toward the new health risks created by vaccination. A similar process occurs for women with AEs from Gardasil through their experience. Nonetheless, the object at risk - the female

body - remains the same.

Discussion

This paper uses risk as an analytic strategy to highlight a shift in risk object framing due to divergent experiences of risk. While the "mythic image" (Healy: 62) of Gardasil is as the tool to prevent cervical cancer in girls and young women (Mamo, Nelson and Clark 2010), the experience of cervical cancer risk and Gardasil varied depending on what happened after vaccination. If side effects were minimal or nonexistent, Gardasil remained the "right tool" for the job of cervical cancer risk. Yet when side effects were severe, the object of risk shifted to Gardasil.

Trust was a big factor for both university students and females with adverse events. Trust in doctor was a main motivator for women to get vaccinated. Though the pharmaceutical industry is often portrayed negatively in the public sphere, its massive profits demonstrate an "apparent confidence in its products" (Brown and Calnan 2012: 57). Big Pharma, Brown and Calnan suggest, is nameless and faceless, and thus cannot win the trust of patient-consumers directly. One's personal physician, however, is highly trustworthy. Doctors are mediators between patient and pharmaceutical company. Yet what patients do not realize is that physicians take risk on their behalf by trusting products made by the pharmaceutical company and recommending them to their patients. With a history emphasizing patient "obedience" and "compliance" with doctor's recommendations, the institution of medicine is paternalistic and takes on an almost religious fervor amongst its practitioners (Jones 2004; McCoy 2008).

Yet as Brody (2010) asserts, the profession of medicine has "betrayed the public trust"

(71). Perhaps physicians would not be so trustworthy if patients knew how easily influenced they are by pharmaceutical companies. Prosser and Walley (2006) find that physicians' decisions to prescribe a new drug are just as subjective as a patient's desire to use a drug. Instead of deciding based on statistics, advertisements or personal relationships with drug reps were cited as the reason to prescribe. While patients assume physicians are making recommendations based on clinical evidence, doctors are notoriously resistant to change when new research contradicts established beliefs. As David Healy (2012) documents, Pierre Louis was among the first to statistically test for the effectiveness of medical treatments and found many common practices did not alleviate pain and suffering across cases. Physicians argued against his findings, claiming "it was not possible to practice medicine by the numbers" (Healy 2012: 69). Today physicians regularly prescribe standard practices such as glucose control for type 2 diabetes patients using insulin. As evidenced in clinical trials - yet 'spun' to describe a positive outcome in study abstracts - this monitoring has no real-world impact on a patient's health outcomes while such drugs are FDA approved and prescribed to thousands of individuals across the US (Havas 2009; McCormack and Greenhalgh 2000). Statin drugs are readily prescribed to those with elevated cholesterol on the notion that lowering cholesterol will reduce the risk of heart attack. Yet being physically unfit leads to more deaths than elevated cholesterol, and reducing numbers via medication has no impact on one's likelihood of death (Abramson 2008; Light 2010). When met with information that conflicts with standard practice, physicians will explain away contradictory findings, as Liebert and Gavey (2009) demonstrate physicians "rhetorically mitigate" the risk of SSRIs and suicide, meanwhile an elevated risk was detected in early clinical

trials (Healy 2012). It is not to say physicians are intentionally mistreating patients, rather their trust is based on a misunderstanding of how the medical system functions in our pharmaceuticalized society.

As a first step in medical consumer-citizenship, Gardasil operated to file girls down the line toward their first of many risk-reduction methods and diagnostics to come. When Gardasil became the risk, women with serious adverse events were forced to become even greater medical consumers, interacting with the medical system to attain diagnosis and provide treatment to be able to live day to day. Gardasil is thus highly successful in creating medical consumers. While university students are happy they took a step to protect their current state of health - the happy active girl - adverse events participants work within medical system attempting to get that same girl back. When risk reduction methods generate new risks, they also generate new points of medical consumerism. Lifelong customers are created on both sides - those avoiding risks and those living with risk as the result of risk-reduction.

This paper also demonstrates a dimension of temporality within the experience of risk. As Vardeman-Winter (2012) finds in her study of teen girls' response to Gardasil commercials, health was often conflated with weight, implying a 'fat' person is unhealthy and a 'skinny' person is healthy. Cancer is far from the minds of most teenagers, a distant possibility they do not want, yet are not actively afraid of either. As a risk object cancer is worrisome, perhaps American culture's most feared disease, yet contrasting with images and experiences of health the risk is distant. On the other hand when the object of risk shifted to Gardasil, the risk was immediate and their state of health uncertain. When some struggle with basic issues like

headaches, incontinence, medications, fainting, dizzy spells, and food intolerances - the possibility of cervical cancer in the future pales in importance to taking care of oneself right now. Nettleton (1997) suggests that risk functions psychologically as a way of controlling disease, confirming our faith in mainstream medicine. Perhaps for this group, framing Gardasil as the risk gives these women the opportunity to gain control over their experience. Not by confirming faith in medical science, but rather by giving them a framework to explain their experiences and to identify a cause of their health problems.

Risk objects, therefore, are not fixed. As Kendra (2007) observes, "powerful entities have the ability to define risks, to define something as risky, and to resist being defined as risk objects in their turn" (31). The pharmaceutical industry is indeed a "powerful entity" with both mainstream media marketing and regulatory agencies backing their framework of disease risk, positioning their products as the solution. The industry has a strong financial motivation to direct all sense of risk to disease, as stock prices fall when a drug is publicly known to cause harm (Gale 2009). Regulatory agencies are institutionally biased to keep drugs on the market, and even warnings from within the FDA go unheeded. In addition to financing speedy drug approvals with industry user fees and allowing industry insiders on drug approval boards, the FDA seeks to maintain the appearance of upholding public safety and thus officials are hesitant to admit any wrongdoing (Healy 2012). On the individual level in the absence of any contradictory experience, young women tell a typical Gardasil story of protection from a far-off threat – of guarding against squamous intraepithelial lesion (SIL). Yet when personal experience counters prevailing constructions of risk, the risk object is reoriented to reflect a new and

unexpected experience of risk.

Limitations

It is first important to highlight the use of risk as an analytic strategy in this project rather than as an empirical result (Zinn 2006). While generally accepted as safe and effective, vaccines remain a controversial topic within the scientific community. Medical journals regularly emphasize increasing vaccine uptake and characterize those concerned with vaccine safety as ill informed. As Dew (1999) observes, social scientists have taken "the medical model's claim to scientific truth" for granted when it comes to vaccines. Thus for the widespread controversy on vaccine safety, there is relatively little scientific research exploring individual experience. Whether the adverse event participants indeed suffered an adverse event or whether it was coincidental is irrelevant to the study. This project is unable to determine whether Gardasil risk is empirically "real" and instead focuses on the lived experience of those who believe they are vaccine injured, which allows us to examine the structuring and experience of risk.

Second, some scholars have characterized Gardasil as a feminist issue, concerned about patriarchal social forces treating young women's bodies as an object of biomedical intervention. Gardasil was initially approved for females only, gaining FDA approval for males in 2009 (FDA 2009). However most research, including this project, has focused on the opinions, attitudes and experiences of young women or feminist readings of pharmaceutical marketing and public policy (see Mara 2010). Yet for almost 5 years the vaccine has been available to males as well, though advertised far less. Thus while the experience of risk may be gendered, it is important to consider the experiences of males before drawing a feminist conclusion. How are their

experiences different or the same considering how Gardasil has been branded as a female cancer tool? What motivated their decision and (how) did their opinion change if they experienced side effects? Gender is an important variable to consider, given that men are more likely to engage in "risky" behaviors and less likely to care for their health and well-being. Masculinity is traditionally associated with risk-taking while femininity is related to care-taking (Courtenay 2000). Thus there are likely important gendered distinctions in becoming vaccinated and experiencing risk from the vaccine. Exploring the experience of males, both healthy and those who have experienced adverse events, may help scholars understand gendered dimensions Gardasil and the risk experience.

Third, while data collection was informed methodologically through grounded theory, these findings are not generalizable to all university students or women experiencing adverse events from Gardasil. Speaking to more women with adverse events would be useful in understanding the risk object narrative identified in this paper. Including more participants who chose not to get vaccinated may reveal an alternative construction of risk. With only 4 in the sample it is difficult to make any generalizations, but it could be interesting to explore whether they still consider cervical cancer to be an object of risk or like parents who refuse vaccines for their children, if they have perhaps more holistic attitudes toward health that emphasize attentiveness to the entire mind-body system (Hobson-West 2004). Most research on Gardasil's target market has taken a traditional public health approach, seeking to identify reasons for non-compliance with the prescribed risk-reduction method, and miss the nuance of the experience of risk (or lack thereof). Whether and how the concept or experience of risk plays in deciding not

to get vaccinated may be theoretically useful in identifying the limits of "powerful entities" (Kendra 2007) constructions of risk objects and the experience of living in a socially "risky" world while subscribing to a different framework of health entirely.

Conclusion

When physicians, public health agencies, and researchers talk and write of risk, they do not attempt to understand risk and risky behavior but rather control it. The risk object framework destabilizes the 'what' of risk and allows for investigation into the social forces shaping the experience of risk. Framing the "good citizen" as risk-averse, and mainstream medical methods as the appropriate response privileges "expert opinion" as truth and alternative formulations as deviant. Yet not everyone wants to be healthy, at least not in the way defined by their doctors and the CDC. On the individual level, risks are not necessarily to be avoided but rather navigated (Zinn 2008). Attention to consumers' experiences with risk reduction highlights the distinction between sociological norms, the structure of modern medicine and the lived experience of risk. Hobson-West articulates, "further empirical research is needed to assess whether the public uses risk at all in relation to vaccination decision making" (2004: 97). As highlighted in this paper, risk can play a role, but consumers are not motivated to avoid risk as much as maintain health. As adverse events participants demonstrate, risk does not necessarily end with the decision to vaccinate or use a risk reduction method. Rather vaccination was the beginning of their risk narrative. Thus, decisions about whether to use any pharmaceutical or risk-reduction product involves both the risk of disease, the risk of the drug, and the experience of risk in the process of decision-making and use of the drug. Disentangling the experience of

risk is both theoretically and practically important in an era that frames risk-reduction as medicine while potentially risky drugs are allowed onto the market with ease. Perhaps the experiences of young women who experienced adverse events after Gardasil can illuminate the rocky terrain of risk and that social life and medical decisions take place within the context of a rich field of social understandings and experiences.

Chapter 4

Impact of Disease Education, Social Relationships, and Experience of Risk on Gardasil Vaccination and Opinion

Introduction

Ask your doctor about getting vaccinated with the only cervical cancer vaccine: Gardasil

Though questions about Gardasil's safety and efficacy were first documented in 2007 in both academic literature and news media reports, Gardasil's $1.2 billion sales in 2012 speak volumes to its success (Abdelmutti & Hoffman-Goetz 2009; Merck 2012). While Gardasil has been critiqued on the grounds of profiteering, biocitizenship and governance, surveillance, feminism, globalism, moralism, individual and parental autonomy (Casper and Carpenter 2008; Charles 2012; Connell and Hunt 2010; Javitt, Berkowitz and Gostin 2008; Mara 2010; Mishra and Graham 2012), millions of young women still seek to become "one less." This paper seeks to explore how patient-consumers come to get vaccinated and have a positive opinion on a drug whose safety and efficacy is questionable at best (Harper 2009; Harper and Williams 2013; Sack 2010; Sawaya and Smith-Cune 2007; Tomljenovic and Shaw 2011).

With a rise in medicalization and in recent years, pharmaceuticalization, pharmaceuticals are becoming ever more consumer-oriented. We live in the age of the patient-consumer, where health decisions have become purchasing decisions. We have moved away from traditional care and pushed toward shopping drugs and medical services. These days, we can buy everything from "designer vaginas to optimal cholesterol levels" (Healy 2012: 190). With three shots to be

administered, Gardasil vaccination is not a one-time (or even three-time) decision but part of a larger social process.

What motivates a young woman to get vaccinated? Early public health research on risk made the assumption that education was the key; if an individual knows about their objective, calculated risk they will seek to alleviate with the methods prescribed. For instance, adolescent sexual health education programs are often based on academic theories for changing human behavior, such as social learning theory, theory of reasoned action, health belief model and theory of planned behavior, which highlight sexual transmitted infections alongside recommendations for condoms (Kirby, Laris and Rolleri 2007). Public health agencies try to convince parents who opt against vaccinating their children by presenting risk statistics, yet numerous scholars have demonstrated that risk does not enter decision-making the way the public health model assumes (Altschuler and Somkin 2005; Gillespie 2012; Lupton 1994). Rather individual beliefs, values, emotions, identities and experiences play a role, as well as social and historical context. No longer an issue of patient compliance, we are in the age of the "empowered" consumer.

So what "empowers" girls to choose Gardasil? Various studies have demonstrated that a high level of HPV and cervical cancer knowledge does not automatically translate into vaccination. Cohen and Head (2013) find striking similarities between vaccinated and unvaccinated women with respect to their HPV and cervical cancer knowledge, or lack thereof. Some women even "choose" Gardasil knowing very little, if anything, about HPV and cervical cancer. Prompted by healthcare providers, women consent to vaccination with relatively little

information. Consumer understanding and use of drugs is a more complex process than a top-down dissemination of risk "facts." Presented as if vaccination is an either/or choice - get Gardasil or get cancer - a woman's decision to get vaccinated and her opinion on the vaccine are a more complex social process than simply choosing to be one less. This project examines three documented areas of influence on women's Gardasil use: direct-to-consumer advertising, social influences, and perception and experience of risk.

Disease and Drug "Education": Direct-to-Consumer Advertising (DTCA)

The FDA Modernization Act of 1997 facilitated television direct-to-consumer advertising (DTCA) as well as "educational" advertising of diseases or disorders (Conrad 2007). That is, drug companies can now market directly to consumers, including "educating" consumers on diseases their drugs are meant to help. 2007 spending for consumer advertising was four times higher than in 1996, and twice as high for physician advertising (Kaiser Family Foundation 2008). Proponents view DTCA as a form of patient education that may empower patients to make decisions regarding their health. Opponents argue that DTCA generates demand for medications that do not necessarily improve health, and potentially compromise the physician-patient relationship, health policy, and prescribing practice (Gilbody, Wilson, and Watt 2005).

A variety of studies have found that DTCA directly influences patient demand for pharmaceuticals (Gilbody, Wilson, and Watt 2005). Between 1997 and 2007, there was a 72% increase in the number of written prescriptions (Kaiser Family Foundation 2008). Weissman et al. (2000) find that in visits where patients discussed DTCA, the advertised drug was prescribed 39% of the time. About 20% of physicians who prescribed the advertised drug did not expect the

drug to positively affect patient health. DTCA also frequently omits important safety information and overemphasizes drug benefits (Lexchin and Mintzes 2002). On a broad scale, it is currently unclear how DTCA and increasing consumer demand for prescriptions affects patient health (Gilbody, Wilson, and Watt 2005).

In 2005 Merck began an aggressive educational and advertising campaign to educate women about HPV and cervical cancer and encourage Gardasil vaccination (Weeks 2008). Educational campaigns included "Make the Connection" (2005), highlighting the causal link between HPV and cervical cancer, "Tell Someone" (2006) recommending women tell their female friends and family about the HPV-cervical cancer relationship, and "Make the Commitment" (2007) encouraging women to discuss cervical cancer with their physicians. Gardasil was also directly marketed in the most famous advertising campaign, "One Less" which included television commercials depicting girls and young women engaged in physical activities, such as baseball, skateboarding, and drumming (Weeks 2008). Women were urged to "Become one less life affected by cervical cancer" (Gerend and Magloire 2008). The "I Chose" (2009) campaign was aimed at both young women and mothers with daughters. In 2006, Merck was awarded Brand of the Year by *Pharmaceutical Executive* magazine for creating a "market out of thin air" (Herskovits 2007: 60). A higher level of HPV and cervical cancer knowledge suggest that these campaigns have been successful in raising awareness (Gerend and Magloire 2008)

How consumers respond to pharmaceutical marketing is another story. One study of Gardasil recipients found that only 4% said that Gardasil advertisements were a primary motivation behind receiving the vaccine. But two-thirds said ads motivated them to talk with

their doctor about vaccinating, so its impact may not be direct, but does appear significant in the process of becoming a Gardasil consumer (Manika, Ball & Stout 2014).

Social Influence: Doctors, Moms and Friends

The nature of Gardasil and its marketing means that consumers do not make their vaccination decision in a vacuum. Most obviously, the vaccine must be administered by a physician or other licensed medical professional. A vaccine aimed at women ages 9-26 necessarily means parents or guardians are involved in the decision for many girls and young women, whether the decision is made for them or more jointly. And unlike other vaccines, Gardasil being heavily marketed on television, in print and on college campuses (Polzer and Knabe 2009) means that Gardasil has become a topic of conversion among some groups of pre-teens, teenagers and college students.

The impact of conversations about Gardasil with doctor, mom or friends depends on the content of the conversation. Social contacts can either support or recommend against vaccination. For instance, the doctor of one young woman in Cohen & Head's (2013) study did not recommend the vaccine because she was not yet sexually active; this influenced her decision not to get vaccinated. Another said her mother was concerned about the side effects and thus influenced her daughter's risk perception (risk of the vaccine), "Mom said that when she was younger, I don't know, there was some vaccine that a lot of girls were injected with but then their children were affected by it you know later on. And so I just, I'm kind of leery" (1229).

Most studies on Gardasil "acceptance" have found that young women encouraged to get vaccinated by doctor, family members or friends are more likely to get vaccinated than those

who are not. Manika, Ball & Stout (2014) find that supportive discussions with friends and family were seen as a main influence on vaccination. Positive communication with mothers about Gardasil as well as sisters and other female social networks like the cheerleading squad, were heavily influential (Cohen & Head 2013). Doctors, however, seem to be the most important source of support across a variety of studies. Some women are prompted by their doctors to get vaccinated and agree to get the vaccine with little or no knowledge or perceived risk of HPV (Cohen & Head 2013). One study found that when a woman's doctor discussed and recommended the vaccine, she was 93 times more likely to get vaccinated than if the doctor did not discuss and recommend. Over 80% of participants rated the strength of their doctor's recommendation 4-5 on a 5-point likert scale, and when the recommendation was perceived as strong, these women were 4 times more likely to get vaccinated than a "not strong" recommendation (Rosenthal et al. 2011).

Perception and Experience of Risk

The general goal of pharmaceutical marketing is to raise the consumer's awareness of risk to encourage patients to purchase their product that will alleviate the feeling of risk. This makes logical sense, if someone feels at risk for a disease they may be more likely to attempt to mitigate the risk than one who does not feel at risk whatsoever. HPV is an interesting disease in that most people who are sexually active will experience an infection at some point in their lives, but because most infections clear undetected HPV alone may not generate as big a sense of risk as other more visible STIs. This, in addition to the sexual nature of genital HPV, is likely why Gardasil's marketing emphasized cervical cancer, naming HPV infection as a precursor (Casper

& Carpenter 2008).

However when an individual or someone they know has experienced an abnormal pap smear and HPV infection, the may feel an increased risk for HPV and/or cancer. Miller-Ott and Durham refer to this as "experiential support," which they find to increase a woman's likelihood of vaccination (2011). Various scholars have found that receiving an abnormal pap can place women in a liminal space between illness and health, experiencing uncertainty, fear of cancer and confusion (Forss et al. 2004; Juraskova et al. 2007). If a woman or her social contacts have been through this experience, it may encourage her to get the vaccine. For some with a family history of cancer, relatives encourage vaccination (Cohen & Head 2013).

Yet experiential support alone is not enough. Some women in Miller-Ott and Durham's study had friends or personal experience with HPV, understood the experience of severe HPV infection, but this did not lead them to get vaccinated because they did not personally feel at risk (2011). In fact, unvaccinated women are more likely than vaccinated to feel at risk - not from HPV or cancer, but from the vaccine itself. Concerns include getting a brand new vaccine, the short period it was tested (5 years), how long the vaccine might work, and long-term side effects. If one is concerned about these issues and does not feel much risk for HPV, it is understandable why one may not get the vaccine. Thus, the perception and experience of risk can work both for vaccination and against it, depending on the individual's perspective.

Agenda and Research Questions

While various studies have identified factors influencing young women to get vaccinated with Gardasil, no studies have yet explored how they relate to one another. That is, causality is

complex and conjectural. As attractive and simple as it may be to input independent variables into a regression to calculate net effects, individuals do not make decisions based on their race, gender, or exposure to pharmaceutical marketing separately (Ragin 2008). Rather healthcare decisions are made within a social context containing each of these factors and many more.

Further, virtually all studies examine vaccination as the outcome. For researchers and healthcare professionals interested in increasing vaccination rates, the outcome is perfectly logical. However whether or not one gets the vaccine may or may not relate to their opinion. Consumer opinion is also important for drug manufacturers, particularly for a drug as "viral" as Gardasil and living in the "viral" era of the internet, because bad experiences may be spread like wildfire, such as the story of Jenny Tetlock who was almost completely paralyzed due to a degenerative muscular disease after Gardasil vaccination (Kotz 2008). Further, simply because one purchases a product does not necessarily mean they feel good about the decision and enjoy the product. Evaluating young women's opinions on Gardasil provides a useful angle to better understand the consumer experience.

This study will therefore explore four questions:

(1) How does where a young woman learned about HPV, cervical cancer and Gardasil impact their opinion on Gardasil and whether or not they get vaccinated?

(2) How do social relations influence a young woman's opinion on Gardasil and whether or not they get vaccinated?

(3) How does a sense of risk (for HPV, cervical cancer, or Gardasil) impact a young woman's opinion on Gardasil and whether or not they get vaccinated?

(4) For each of the above questions, how does each causal condition relate to one another in producing the outcome?

Methods

Data Collection

I began interviewing 23 female college students enrolled at a university in the southwest between 2010 and 2011. These women were recruited through fliers at the University Health Service center, listserv emails, and brief presentations in Sociology, Family Studies and Women's Studies courses aiming to recruit participants. Participants were required to be between ages 18 and 26, the adult age range for which Gardasil is approved. 22 were current students, and one had just graduated the semester prior. Participants completed a questionnaire that took approximately 10-15 minutes, then completed an interview lasting 15-45 minutes. I asked these young women questions about their HPV and Gardasil knowledge, where they learned about HPV and Gardasil, whether they got vaccinated and why/why not, their opinions on the vaccine, and their own sense of HPV and cervical cancer risk. See Appendices A and B for the questionnaire and interview schedule.

Analytic Strategy

To explore factors influencing Gardasil vaccination and opinion on the vaccine, I utilized a method called Qualitative Comparative Analysis. Created by Charles Ragin and using the fsQCA program designed by Ragin, Drass and Davey (Ragin 1987; 2000; 2006; 2008; Ragin, Drass and Davey 2009), QCA uses set-theoretic logic to explore combinations of conditions or "causal recipes" as subsets of the outcome. Unlike quantitative analysis, which results in a

single causal pathway, QCA allows for multiple pathways to the outcome. Qualitative case-oriented analysis is also limited by sample size, sacrificing depth for breadth, limiting generalization. QCA is a middle ground between qualitative and quantitative methods, combining in-depth case knowledge with systematic analysis in order to make theoretical generalizations. QCA is ideal for intermediate sample sizes of 5-50, requiring both in-depth knowledge and identification of cross-case patterns.

An assumption of QCA is that causality is complex and may be combinatorial, that is, causality may depend on certain conditions occurring or *not* occurring together. Causal complexity indicates that no single cause is either necessary or sufficient but rather that different combinations of causal conditions result in the same outcome. Several important measures in QCA include consistency and coverage. Consistency is the degree to which cases with a condition or combination of conditions display the same outcome. Scores range from 0 to 1, 0 meaning none of the cases agree on the outcome (perfect inconsistency) and 1 meaning all cases agree (perfect consistency). Similar to statistical significance, consistency demonstrates whether an empirical relationship is strong enough to explore, but does not guarantee a theoretically meaningful relationship exists. Coverage is the degree to which the causal condition or combination of conditions represents a subset of the outcome, or what proportion of the outcome can be explained by each condition or combination of conditions. Coverage measures the empirical importance of each solution. Scores range between 0 and 1, the closer the value to 1 the more the outcome is explained by the condition or recipe, and thus the more theoretically important the solution (Ragin 2008).

In "crisp set" QCA, used here, causal conditions are binary measures in which 1 (or capital letters) indicates presence and 0 (or lower case letters) indicates absence. Unlike dichotomous variables in quantitative research that are either 'on' or 'off,' these set-theoretic causal conditions are carefully constructed based on theoretical and substantive knowledge. For instance, one may have an "income" variable from a dataset. This single variable could be formed into multiple causal conditions depending on the research question. One could compare "high income" versus "not-high income." This analysis would compare those with high income to those with low + middle + upper middle income combined. Alternatively, one could study "low income" versus "not-low income," not-low including middle, upper middle and high incomes collectively compared to those with low income. Causal conditions may be related by logical *and* (*) and logical *or* (+) based on Boolean algebra. Conditions must be selected carefully, if *k* is the number of conditions there are *2^k* logically possible combinations of conditions. The more possible combinations, the more complex the analysis and more more lines on the Truth Table to minimize. Therefore it is in the researcher's best interest to select as few causal conditions as possible while drawing on theoretical work and case specific knowledge.

The analytical process of QCA follows several important steps (Ragin 2012): (1) identify cases, causal conditions, and outcomes. (2) Construct the dataset, in which causal conditions are columns and cases are rows, each condition receiving a 0 or 1 for presence or absence per case. (3) Test for any individual conditions that may be necessary. For a condition to be considered necessary, it must have a consistency greater than 0.9, meaning 90% or greater cases with the

outcome also have the condition. It must also make theoretical sense. (4) Construct the Truth Table, which includes all logical possible combinations of conditions. Assess the consistency of each combination and resolve contradictions where consistency is less than perfect (0 or 1). Use a consistency cut off of at least 0.75 to indicate outcome presence, and mark which rows are present and absent for the outcome. (5) Run the Truth Table analysis using the Quine algorithm in the fsQCA program. This algorithm identifies matched pairs of truth table rows that differ only by the presence or absence of one causal condition. The algorithm makes paired comparisons until the data cannot be simplified any further. Sometimes remainders, rows without any cases, are used to further reduce based on theoretical and substantive knowledge. Analysis produces three possible solutions - complex, parsimonious and intermediate - the latter of which Ragin recommends using. And (6) evaluate the results. How do the findings relate to theory? What causal mechanisms are implied? How do they relate to case knowledge? Which cases follow which recipes and how do they group together? The analysis is brought back to case knowledge, which allows for theoretical generalizations.

Measures and Expectations

This study utilizes two outcomes. The first is *Vaccinated*, whether or not the participant has received one or more doses of the Gardasil vaccine. The second is *PositiveOpinion* on Gardasil, indicating whether or not one had a positive view on the vaccine. Opinions ranged from negative to mixed to positive; negative and mixed responses were joined as the absence of a positive opinion.

Based on the three areas of influence in question (education, social, risk experience), I

conducted six total analyses - one for each area of influence on each of the two outcomes. Causal conditions are explained on Table 5 with their expected impact on the outcomes in question. Unlike traditional statistical analysis, it is not possible to make hypotheses because the expectation of QCA is that causality is complex and recipes will be revealed through analysis. However it is possible to identify how each condition would contribute to the outcome based on theoretical and substantive knowledge. For instance, because as explained earlier, the content of a participant's conversation with her doctor or mother could be supportive of vaccination or against it. Thus learning about Gardasil from one's doctor or family could theoretically have a positive or negative impact on vaccination, or in QCA terms could be present OR absent for the outcome of vaccination. Yet learning from Gardasil advertisements or pamphlets is expected to be present for the outcomes because pharmaceutical ads are aimed at promoting the drug and carry only minimal information to dissuade particular consumers (i.e. listing side effects or possible co-indications).

Analysis

Demographics

The study population included 23 participants. The age range was 18-26, with a mean of 21.39, most between 20 and 22. 17 were white, three Latina, two black and one Asian. 20 considered themselves heterosexual or straight, two bisexual and one queer. 13 described their socioeconomic background as middle class, 3 working class, 6 upper-middle and 1 upper class. 15 were sexually active, 13 of whom only had male partners. 19 received one or more Gardasil shots, 14 got all three. Of those not vaccinated, one did not plan to get the vaccine and the

additional three were unsure. 10 paid with insurance, 4 said their parents paid (which may have been through insurance as well), three paid out of pocket and two were unsure. Most side effects were mild: 11 experienced pain at the injection site, two had a fever, one experienced amenorrhea (no period) the month following vaccination, and one had a thyroid condition diagnosed after vaccinating, which she did not believe was related to the vaccine (though her mother did). 14 had a positive view of Gardasil, 7 were unsure and only two had a negative perspective. A majority of participants learned about HPV and Gardasil at the same time, and when I asked separate questions about where they learned about HPV and Gardasil, most could not distinguish between the two. Advertisements (21), family members (10), and doctor (20) were the primary sources of HPV and Gardasil information. For 13, doctor was the most important influence on their current opinion on Gardasil; family was ranked most important for 5. 14 knew family and/or friends who got Gardasil, and all of these participants were vaccinated themselves. 7 had previously experienced abnormal pap smears, and 5 had been diagnosed with cervical HPV, one of whom had first been incorrectly diagnosed with cervical cancer by her physician. Participants were also asked about Cervarix, the competing HPV vaccine manufactured by GlaxoSmithKline, but only one had ever heard of the vaccine.

Necessary Conditions

Vaccinated had two necessary conditions, meaning these causal conditions are required for the outcome to occur. The first is *learngardads*: 94.7% participants who learned about HPV and Gardasil from Gardasil ads received the vaccine. As noted above, *learngardads* was expected to be present for the outcome; the necessity test indicates it is indeed present for almost

all cases of the outcome. However *learngardads* was not sufficient to produce the outcome by itself, as 2 participants who learned from Gardasil ads did not get the vaccine. This makes sense because with commercials on major television networks, even a person not interested in the vaccine may still see the advertisements. *Learndr* was the other necessary condition, meaning every person who talked with their doctor about HPV/Gardasil was vaccinated. This makes logical sense, because if a young woman wants the vaccine a doctor (or healthcare professional) must administer the shot. In this population, no one learned about HPV/Gardasil from their doctor and did not get vaccinated, so *learndr* was therefore also sufficient to produce the outcome. While various causal configurations will be discussed below, this finding indicates a causal path of *learndr* is sufficient in itself without any other conditions to lead to vaccination for some participants. *Learngardads* and *learndr* are also both necessary for *PositiveOpinion*, though neither are sufficient as several who learned from ads and their doctor did not have a positive view.

Truth Tables

I constructed truth tables listing all possible configurations present in the dataset. All rows with a frequency of 1 or more were included. A consistency threshold of at least 0.75 was set to indicate the presence or absence of the outcome in each analysis. Exploring the truth tables for analyses 4-6, one contradictory case became problematic and subsequently dropped. Ragin recommends using a consistency cut off of 0.75; these rows had a consistency of 0.667, or 2/3 cases conforming to the outcome. Across analyses 4, 5, and 6, the same case created rows with the same consistency level. Because 0.667 is still relatively close to 0.75, but not close

enough to warrant lowering the consistency threshold, I followed Ragin's advice to explore case knowledge further. The contradiction occurred because of a situation particular to this individual case. The participant was the oldest in the study at age 26. She had just graduated and was married with a child. At age 20 her physician mis-diagnosed her abnormal pap smear with cervical dysplasia as cervical cancer. The diagnosis was eventually cleared up but the experience was emotionally traumatic. When Gardasil came on the market, the participant asked her current physician about the vaccine, who said she was "too old" to receive it. The physician was incorrect, as Gardasil is approved for young women up to age 26, but the participant took her doctor's word and did not pursue the vaccination any further. Thus she was not vaccinated and had mixed feelings about Gardasil, but primarily due to several physicians acting in error. Because she was so curious about the vaccine, and very interested in discussing her experience in the interview, it is not unlikely she would have been vaccinated had her situation been different. Given this unique situation and her demographics being much different from the typical college student population, I dropped her case from analysis. The results, discussed below, are virtually or almost the exact same for analyses 1-3 whether or not this case was included. For analyses 4-6, the results were the same as if I had lowered the consistency cut off to 0.667 to include her, which were more parsimonious and theoretically sound than leaving the dataset intact with the 0.75 cut off. Thus removing this case only strengthened the analysis. The final truth tables after resolving this inconsistency can be found in Tables 6-11.

Causal Recipes

Causal recipes for each analysis can be found in Tables 12-17. I will discuss each set of

findings one by one. Analyses 1 and 2 address research questions 1 and 4 - How does where a young woman learned about HPV, cervical cancer and Gardasil impact their opinion on Gardasil and whether or not they get vaccinated? and How does each causal condition relate to one another in producing the outcome? Causal conditions include learndr, learnfamily, learnfriend, learngardpamphlet, and learngardads, with the outcome *PositiveOpinion*. The assumptions input into fsQCA, as explained in Table 1, included *learngardads* and *learngardpamphlet* set to present. There were 13 of 32 rows present on the truth table, yielding a diversity index of 40.6% (Grant, Morales and Sallaz 2009). Analysis yielded two solutions or causal recipes, together with perfect consistency (1.0) and perfect coverage (1.0), meaning these solutions account for all instances of the outcome with absolute consistency. The first solution had high unique coverage of 0.737 - *LEARNGARDADS*LEARNDR*. This means a large subset of those with a positive opinion learned about HPV and Gardasil from both ads and their doctor. Solution 2 was *learnfriend*learnfamily*LEARNDR* (coverage 0.053), indicating a subset who learned from their doctor but not from friends or family. Because *learndr* is a necessary condition, its presence in both solutions is expected. The combination of *learndr* and *learngardads* makes logical sense - if a young woman saw a Gardasil commercial, the logical step would be to talk to her doctor to get the vaccine. Alternatively if she did not ask her doctor, she may have simply seen the commercial on TV or in print, and then later was asked by her doctor if she wanted the vaccine. Contrary to expectations, *learngardpamphlet* was not included in any causal configurations, indicating it could be present or absent to result in the outcome.

The outcome for analysis 2 is *Vaccinated*. The causal conditions and assumptions were

the same as for analysis 1. The diversity index was slightly lower, 13/32 truth table rows available (34.4%). Overall solution coverage and consistency were high, at 0.857 and 0.923 respectively, indicating most instances of the outcome are covered by two solutions and most configurations were consistent. With unique coverage of 0.643, solution 1 was *LEARNGARDADS*learngardpamphlet*LEARNDR*. This means a subset of vaccinated women learned about HPV and Gardasil from advertisements and their doctor, but not from pamphlets. The absence of *learngardpamphlet* was unexpected. Solution 2 was *LEARNGARDADS*LEARNFRIEND*LEARNFAMILY*LEARNDR* and had a unique coverage of 0.143. This subset of vaccinated women learned from everywhere except *learngardpamphlets* - the lack of this condition from the solution indicates its presence or absence has no relation to the outcome. *Learngardads* and *learndr* were both necessary conditions for *Vaccinated*, which is why they are part of both solutions.

Analyses 3 and 4 examine research questions 2 and 4 - How do social relations influence a young woman's opinion on Gardasil and whether or not they get vaccinated? and How does each causal condition relate to one another in producing the outcome? The outcome for analysis 3 is *PositiveOpinion*, with causal conditions *learndr*, *learnfamily*, *learnfriend*, *friendfamcancerhpv*, and *friendfamvax*. *Friendfamcancerhpv* and *friendfamvax* were assumed to be present. The diversity index was lower in this analysis with 13/32 rows present (40.6%). During analysis the algorithm was unable to fully reduce the truth table, requiring the selection of prime implicants. Prime implicants are created through minimization combining rows that differ on only one condition. But often there are more prime implicants logically possible than

are necessary to continue minimization, leaving the researcher to select that which makes the most theoretical and substantive sense (Ragin 2008). I selected *LEARNDR*LEARNFAMILIY*LEARNFRIEND*FRIENDFAMVAX* as the prime implicant because the presence of each condition was the most theoretically feasible option based on previous research.

Overall solution consistency was a perfect 1.0, meaning all cases agreed on the outcome, but with a coverage of only 0.428 almost 60% of the outcome remains unexplained. Each of the three solutions had the same unique consistency of 0.143. The first solution was *friendfamcancerhpv*LEARNFRIEND*learnfamily*LEARNDR*, meaning a subset of participants who learned from a friend and their doctor, but not family and knew no one with cancer or HPV, had a positive opinion on Gardasil. Here the social contact with doctor and friend were very important. Solution 2 was *learnfriend*FRIENDFAMVAX*learnfamily*LEARNDR*, which means a subset of participants who learned about HPV and Gardasil from a doctor, had a friend or family member vaccinated, but did not learn about HPV or Gardasil from their friends or family had a positive opinion. The absence of learnfriend and learnfamily was striking paired with the presence of *FRIENDFAMVAX*, meaning that for cases falling under this solution, knowing a friend or family member was also vaccinated was important but they did not learn about HPV and Gardasil specifically from these individuals, only from their doctor. Solution 3 was *friendfamcancerhpv*LEARNFRIEND*learnfamily*LEARNDR*, meaning a subset of participants who learned about HPV and Gardasil from friends and doctor, but not family and did not have any friends of family with cancer or HPV, had a positive opinion on the vaccine. The inclusion

of *LEARNFRIEND* with *friendfamcancerhpv* in both solutions 1 and 3 is interesting, learning about Gardasil and HPV from friends was significant but only if the friends did not have HPV or HPV-related cancer. Because as discussed earlier, *learndr* is a necessary condition, its inclusion in each solution is expected. The absence of *friendfamcancerhpv* in solutions 1 and 3 was counter to expectations, though the presence of *friendfamvax* in solution 2 was expected.

Analysis 4 explored the same causal conditions and assumptions with the outcome *Vaccinated*. The diversity index was again 13/32 (40.6%). The three solutions together resulted in perfect coverage (1.0) and consistency (1.0). The solution with the highest coverage (0.421) was *FRIENDFAMVAX*LEARNDR*. This is a more simplified version of solution 2 from analysis 3 above, meaning for a subset of vaccinated women, a friend or family member was vaccinated and the participant learned about HPV and Gardasil from her doctor. This makes logical sense as learndr is a necessary condition and I expected having friends or family vaccinated would positively influence vaccination. Solutions 2 and 3 included *learnfamily*LEARNDR* and *FRIENDFAMCANCER*LEARNFRIEND*LEARNDR*. With a coverage of 0.211, solution 2 is a subset of vaccinated participants who did not learn from family but did from their doctor. Solution 3 indicates a subset of vaccinated women had friends or family with HPV or HPV-related cancer, learned about HPV/Gardasil from friends and their doctor. The presence of *friendfamvax* and *friendfamcancerhpv* was expected.

Analyses 5 and 6 address research questions 3 and 4 - How does a sense of risk (for HPV, cervical cancer, or Gardasil) impact a young woman's opinion on Gardasil and whether or not they get vaccinated? and How does each causal condition relate to one another in producing the

outcome? The causal conditions included *hpvdiagnosis*, *friendfamcancerhpv*, *everatrisk*, and *sideeffectworry*. The assumptions included *hpvdiagnosis* - present, *friendfamcancerhpv* - present, *everatrisk* - present, *sideeffectworry* - absent. The diversity index was higher than other analyses, with 9/16 rows present (56.3%). Three solutions were found, overall yielding a consistency of 0.909 and a coverage of 0.714, indicating analysis 1 solutions are both fairly strong and theoretically important. Findings were surprising - the solution with the highest unique coverage (0.357) was *everatrisk*SIDEEFFECTWORRY*, meaning not feeling at risk and being worried or warned about side effects was the most common path to a positive opinion on Gardasil. The other two solutions, with smaller unique coverages, included *HPVDIAGOSIS*FRIENDFAMCANCERHPV*sideeffecworry* and *hpvdiagnosis*FRIENDFAMCANCERHPV*SIDEEFFECTWORRY*. Solution 2 means a subset of those with a positive opinion were diagnosed with HPV, had friends or family members with HPV or cancer, and were not worried about side effects. Solution 3 means no HPV diagnosis, having friends or family members with HPV or cancer, and being worried about side effects leads to a positive opinion. *FRIENDFAMCANCERHPV* was the only condition that behaved as expected; *hpvdiagnosis* and *sideeffectworry* were both present and absent in different solutions, and everatrisk was only absent in one solution.

Analysis 6 looked at the same causal conditions and assumptions, only for the outcome *Vaccinated*. There were 9 of 16 rows present on the truth table, yielding a diversity index of 56.3%. Three solutions had a combined coverage of 0.947 and consistency of 1.0, meaning the results are very strong and theoretically important; almost every instance of the outcome can be

explained by these recipes with perfect consistency. The causal path with the highest unique coverage (0.631) was *SIDEEFFECTWORRY*, meaning being worried or warned about side effects was sufficient enough to lead to vaccination. This is similarly surprising as analysis 1. The two other solutions included *HPVDIAGNOSIS*FRIENDFAMCANCERHPV* and *FRIENDFAMCANCERHPV*EVERATRISK*. These two make logical sense, one being diagnosed with HPV plus having a friend or family member with cancer or HPV, the other feeling at risk while having a friend or family member with cancer or HPV. The conditions in solutions 2 and 3 all behave as expected in Table 1.

To better elucidate the relationship between side effect worry and the outcomes in question, I ran several additional analyses (see Tables 18-23). I separated *sideeffectworry* into two causal conditions: *sideeffectconcern* (participant was concerned about side effects herself) and *sideeffectwarn* (participant was warned about side effects from friends or family). These were largely separate groups; each causal condition had seven cases, with only two sharing both conditions. I ran analyses substituting each of the new causal conditions for *sideeffectworry* for each outcome, and analyses with both conditions for each outcome.

Analyses with *sideeffectconcern* revealed that in combination with other conditions, the absence of personal concern for side effects led to both a positive opinion and vaccination. In fact, in analysis 8 ~*SIDEEFFECTCONCERN* was itself a path to the outcome, with a unique coverage of 0.316 and consistency of 1.0. Conversely, analyses with *sideeffectwarn* demonstrated that being warned about potential side effects, in combination with other conditions, constituted a recipe for positive opinion and vaccination. That is, when a woman

questions Gardasil safety herself, she is less likely to get vaccinated and have a positive opinion. Yet when someone else warns her about safety, she is more likely to get vaccinated and have a positive opinion. Analysis 10 shows *SIDEEFFECTWARN* as a causal pathway by itself, with a unique coverage of 0.211 (the highest of all solutions) and a consistency of 1.0. Analyses 11 and 12 included both *sideeffectconcern* and *sideeffectwarn* and demonstrated the same overall pattern. Of particular interest is solution 1 for Analysis 11 - *~SIDEEFFECTCONCERN*SIDEEFFECTWARN* for the outcome *PositiveOpinion*. Unique coverage was low for this solution (and two others), yet it is striking because it highlights the important distinction between self-worry and other-worry about Gardasil's safety. In the context of causal recipes, self-worry made a participant have a lower opinion and less likely to get vaccinated, yet other-worry was associated with positive opinion and vaccination.

Discussion

In this section I will address each set of research questions one by one. Research question 1 considered, *How does where a young woman learned about HPV, cervical cancer and Gardasil impact their opinion on Gardasil and whether or not they get vaccinated?* and also *How does each causal condition relate to one another in producing the outcome?* Analyses 1 and 2 highlighted the importance of the girl's physician and having seen Gardasil commercials or advertisements in both having a positive opinion and getting vaccinated. Both of these were necessary conditions. This makes both logical and theoretical sense. Logically speaking, a patient has to get the vaccine from a healthcare provider, who would likely inform them to some degree about HPV, cervical cancer and the vaccine. With such widespread mainstream

marketing, it would be hard to avoid Gardasil advertisements. Therefore exposure to Gardasil marketing was a necessary causal condition indicates that the marketing campaign worked as intended.

Various scholars have demonstrated the importance physicians play in healthcare decisions. Physicians are met with a high level of trust:

> I honestly take my doctors word of saying like this is what you need to get. I don't really look into stuff that I need like vaccines that I get for myself. (#6, vaccinated)
>
> I guess I'm kind of a slave to do what doctors kind of tell to do. Like they say, "Get a flu shot," so I got a flu shot. So they recommend getting the HPV shot so I was like, "I should get one." (#23, vaccinated)

But have physicians earned this level of trust? Though the internet has made medical information more readily accessible (Conrad 2007), physicians and healthcare professionals are still regarded as a key source of medical knowledge (Hesse et al. 2005). Physicians tend to think it is ethical to accept a variety of offers from pharmaceutical companies ranging from drug samples to consultantships (Morgan et al. 2006). Inexpensive gifts (pens, pocket antibiotic guides, meals at department conferences) are considered more appropriate than expensive gifts (travel, social events, textbooks), though many physicians accept gifts even when they consider them inappropriate (Steinman, Shlipak, and McPhee 2001). Physicians feel their prescribing practices are not affected by relations with pharmaceutical companies, though they believe other doctors are more easily influenced (Morgan et al. 2006; Steinman, Shlipak, and McPhee 2001). However, Wanaza (2000) finds that attendance at industry-sponsored presentations and accepting conference travel funding or lodging from pharmaceutical companies is positively associated with prescribing the sponsored medication, which may or may not be in the patient's best

interest.

Conversations with physicians may be "primarily one-sided and brief," relying on printed materials perceived as unhelpful, but are highly influential. Some young women describe their doctor as aggressive, "I think my doctor was a little too assertive too, actually. In terms of 'let's go ahead and set the appointment up,' but didn't sit down and discuss anything," or "I just went in for a yearly exam and [the doctor] said, "By the way, you should get the Gardasil shot." She was very adamant. She said, 'You should set up an appointment today.' She said, 'Get it taken care of'" (Miller-Ott 2011: 190). Considering the high rate of adverse drug events in the US (Light 2010) and controversy surrounding Gardasil's safety emerging in 2007, "trusting blindly can be the biggest risk of all" (Hobson-West 2007). Physicians serve as the familiar caring face, mediator between patient and pharmaceutical company. Trust in physician can at least partially explain continued pharmaceutical profits even as the industry is portrayed publicly in a negative light (Brown 2012).

Pharmaceutical marketing has not been found to have a direct impact on prescription drug decisions. In one study only 4% said that Gardasil advertisements were a primary motivation behind receiving the vaccine. But two-thirds said ads motivated them to talk with their doctor about vaccinating, so its impact may be more indirect (Manika, Ball & Stout 2014). Of course, many more individuals will see a commercial than purchase a product which explains why viewing ads alone was necessary but not sufficient to generate either outcome.

Question 2 explored *How do social relations influence a young woman's opinion on Gardasil and whether or not they get vaccinated?* and also *How does each causal condition*

relate to one another in producing the outcome? Learndr was also important in combination with other social factors. In analysis 4 the solution with the highest coverage was *FRIEDNFAMVAX*LEARNDR*. *Friendfamvax* may operate similar to learngardads, in that knowing someone else who got vaccinated beforehand may have primed them to be more open if the doctor brought it up. It is interesting that the second highest coverage combined the presence of learndr with the absence of *learnfamily*. Contrasted with the first recipe that includes the presence of *FRIENDFAMVAX*, it appears in this study, family's experiences with vaccination may be relevant but are not important in sharing information on the vaccine, HPV or cancer. It may be that we are more "monkey see monkey do" with family than we enjoy being told what to do. It is also possible that in some families all siblings are taken to the doctor and vaccinated at the doctor's recommendation, so it is not the parent's desire or opinion to get vaccinated but instead they are just following doctor's orders.

Analysis 3 had the lowest solution coverage, meaning there is a big proportion of the outcome that is not explained by the recipes generated. It also had the most complex causal recipes that are difficult to interpret. Perhaps social relationships are less important in shaping one's opinion of Gardasil than whether they get vaccinated. But consider that Analysis 4 has perfect coverage and consistency, and also less variation in the sample, with a vast majority being vaccinated. The murkiness of analysis 3 may be related to greater variation in the outcome; a more diverse sample size in analysis 4 would make it easier to determine whether this is the case. Nonetheless in analysis 3, *learndr* was also present in all recipes and interestingly, *learnfamily* was absent in all. it may be that in combination with other factors, families are more

sources of emotional and experiential support than information.

Turning to question 3, I evaluate *How does a sense of risk (for HPV, cervical cancer, or Gardasil) impact a young woman's opinion on Gardasil and whether or not they get vaccinated?* and *How does each causal condition relate to one another in producing the outcome?* The most interesting finding is that contrary to expectations, the presence of *sideeffectworry* is sufficient alone as a path to vaccination. Separating this condition into *sideeffectconcern* (self-worry) and *sideeffectwarn* (other-worry) demonstrated that in combination with other conditions, the absence of *sideeffectconcern* was related to vaccination and positive opinion, while the presence of *sideeffectworry* was associated with the outcomes.

A relationship between the absence of *sideeffectconcern* and vaccination or opinion is expected. Concerns that one may experience adverse events from a drug may be a logical deterrent. However it is important to note that 5/7 concerned were vaccinated. According to QCA and boolean logic, the absence of sideeffectconcern in these causal recipes does not conversely imply that the presence sideeffectconcern would have a negative relationship with the outcomes. Thus it is truly a *lack* of concern over side effects that contributes to a positive opinion and vaccination, not that concern over side effects contributes to a *not-positive* (or negative) opinion and non-vaccination. Then why did 5/7 participants concerned about side effects get vaccinated? It may be that despite concerns, vaccines and FDA approved drugs in general are given the benefit of the doubt on safety. The general population expects zero risk of vaccines (FDA 2002), and as a vaccine Gardasil benefits from this assumption:

> "I'd rather do some more experimentation and know for sure that it's not going to cause any side effects, because I know there are some people who believe that it

> does. Um, but, it passed the FDA requirements, so - so it doesn't keep me up at night" (#21, vaccinated)

Conversely, the relationship between s*ideeffectwarn* and the outcomes was unexpected. In Analysis 10, this causal condition constituted the third solution, with the highest unique coverage (0.211). For those warned about Gardasil's safety by others but not concerned themselves, perhaps being confronted by a contradictory belief in Gardasil's safety generated a reactionary response, rooting young women more deeply in their opinion that Gardasil is safe, leading them to be vaccinated. A trusted doctor's recommendation may also mitigate warnings from family and friends:

> I think that there was a lot of talk about it in the news, um, some people were thinking it would lead to baby birth defects, or something, like years from now; and my mom warned me against it, and I was like, "I'm getting it." So, well at first I talked to the doctor, and like, "I'm getting it," 'cause you know people got that stereotype, like "Vaccines can lead to all these *weird abnormalities*!" And, not true. (#7, vaccinated)

Additional research is required to determine how patient-consumers interact with safety information. Is the differentiation between self-worry and other-worry about drug safety generalizable or particular to this sample? Does other-worry ever lead to information seeking, and does this process shift consumer opinion and vaccination decision-making? Are personal concerns and the worries or friends and family qualitatively similar or different? Despite the frequency of adverse drug reactions, there is scant research covering patient-consumer perspectives on drug safety.

Limitations

The largest limitation to this project is known in QCA as limited diversity. Social

phenomena are necessary limited in their diversity, failing to exhibit all logically possible combinations of conditions. Counterfactual cases and outcomes are causal combinations that are logically possible but are not observed in the sample. Another term for empty rows on the Truth Table is remainders. The most conservative approach is to exclude remainders and treat them as false, as was done in these analyses (Ragin 2008). Limited diversity was a larger issue for analyses with the outcome *Vaccinated*, as only four were not vaccinated and one of those cases was dropped from the analysis. Therefore while this study illuminates combinatorial pathways to vaccination, it cannot make any conclusions about those who do not get vaccinated. The diversity index ranged from 34.4-56.3% and could be markedly improved with a larger sample size. I believe QCA remains an appropriate method of inquiry given the intriguing relationships identified between causal conditions, though given the limitation of the sample size other methodologies may provide additional insights.

Second is the limitation of crisp-set QCA analysis and relying on binary causal conditions. While analytically useful, practically speaking social life is more complex than a series of dichotomies. Crisp sets erect qualitative distinctions, either one is in the set or one is out. Using fuzzy sets may provide a more nuanced analysis. Rather than a score of 1 indicating membership or a score of 0 indicating non-membership, fuzzy sets allow membership scores between 0 and 1. This means a case can be partly in a set but not fully, having fuzzy membership. Fuzzy sets indicate degree of membership. For instance, perhaps it is not simply whether or not they learned about HPV, cervical cancer and Gardasil from their doctor but the degree to which the doctor was influential that matters for *Vaccination* and *PositiveOpinion*.

Collecting more diverse data could further disentangle and clarify the relationships explored here.

Finally I am unable to compare causal conditions across analyses. This means that the recipes generated from Analysis 1 cannot be directly contrasted with recipes generated from Analysis 3. While QCA has been helpful to explore possible combinations of causal conditions (educational, social, risk-related), I am unable to determine which of these models best fit the data, to best predict vaccination and positive opinion more broadly. Of course, that is not the goal of QCA, which emphasizes illuminating the multiplicity of causality. Exploring the same data with statistical analyses or qualitative analyses may be an interesting way to compare different types of causal relationships within the data.

Conclusion

Pharmaceutical marketing and a woman's doctor played the most important role in female university students opinions on Gardasil and decision on whether or not get vaccinated. In this study both were necessary, though not sufficient causal conditions. That is, neither led to vaccination or generated a positive opinion alone, but worked together with other causal conditions to lead to the outcomes under study. Worry about side effects also contributed interestingly to the outcomes. The absence of personal concerns, in combination with other conditions, was associated with positive opinion and vaccination. Yet being warned about side effects from others was also associated with positive opinion and vaccination. This seemed to cement a woman's decision to get vaccinated, and may have been bolstered by a supportive physician. Patients have a high degree of trust in their doctor and an implicit trust in the vaccine,

so much so that being warned about its safety actually encouraged some participants to get vaccinated. Subsequently not experiencing side effects confirmed they made the "right" decision. A couple expressed concerns about side effects in the future but these worries were not strong enough to prevent them from getting vaccinated.

Though discussing causal conditions individually allows us to compare to other variable-oriented research findings, I am not making a direct comparison of these factors, which QCA does not allow. Rather this discussion highlights how using combinatorial logic allows us to examine the context of these causal conditions in relation to one another. Contrary to public health assumptions that disseminating risk information will encourage individuals to take risk-reduction steps, a multiplicity of factors shapes any healthcare decision. Choosing to be "one less" was the result of a combination of conditions rather than any single causal factor.

Conclusion

This brief chapter will review the main contributions of this dissertation, explore avenues of future research, and speculate on the future of Gardasil.

Main Contributions

Chapter 2 calls attention to social structural forces, in the shape of norms and specific social institutions, that are responsible for Gardasil's success following one of the biggest drug disasters in history, Vioxx. In particular this chapter identifies how and why Gardasil's safety and efficacy have remained relatively hidden until recently. Positioned uniquely as both a vaccine and a risk reduction drug (Aronowitz 2010), Gardasil's success is due in part to the fact that it acts as a typical risk reduction pharmaceutical yet in the form of a vaccine and receives benefits from both angles. Receiving institutional support from public health and institutional protections through the FDA and the Vaccine Injury Compensation Fund are two examples; Gardasil also benefits from the social construction of "anti-vaccine" activists as crazy, stupid and unscientific. This chapter highlights how the construction of diseases as the source of risk is upheld even when drugs to treat the risk of those diseases carry their own health risks.

Chapter 3 identifies how diseases are constructed as risk objects through pharmaceutical marketing, relationally tied to objects at risk. This framework is highly useful in examining drugs and other sources of risk. Rather than speak of risk in general, as perception or as an undefined feeling, treating risk as a relationship between "objects of risk" and "objects at risk" makes the connection more clear. In this chapter I demonstrate how objects of risk can shift with

risk experiences, and that the experience of risk becomes significantly more urgent in experiencing adverse events from drugs. While one object of risk - cervical cancer - is only a future possibility and thus does not generate very much fear or worry, Gardasil becomes the object of risk as women experience serious adverse events resulting in pain, discomfort and disability right now. Chapter 2 highlights the temporality of the experience of risk and the shift from one object of risk to another. In addition, Chapter 2 illuminates a crisis in trust after experiencing serious adverse events, compromising the prior doctor-patient relationship, and subsequent difficulties navigating the medical system.

Chapter 4 explores how education, social relationships and risk perception and experience shape vaccination decisions and opinions. The strengths of this chapter include the use of a unique method, qualitative comparative analysis (QCA) to allow for multiple causal complexity and identify various causal recipes. This paper demonstrated the importance of physicians and marketing campaigns in shaping positive opinion on Gardasil and decision to vaccinate, in conjunction with other causal conditions. This chapter considers the curious finding that the absence of side effect concerns personally, and the presence of warnings from others may contribute to vaccination and Gardasil opinions positively. By and large, Gardasil is perceived as safe and effective, such that concerns over side effects may be easily mitigated by physician recommendation.

To summarize across all 3 chapters - Gardasil is neither as safe nor as effective as advertised. However due to a variety of normative and institutional structures, Gardasil is generally perceived as safe and effective. The system of medical orthodoxy is constructed

paternalistically and relies on patient trust, particularly in one's personal physician. As an individual gets vaccinated and remains seemingly healthy, trust is upheld and the construction of cancer-as-risk remains primary, even if she was concerned about side effects. Intriguingly being warned against the vaccine only further supports vaccination and positive attitudes toward Gardasil. This suggests that the social character of vaccines and FDA approved drugs in general as safe and effective is strong enough to mitigate any worries. Unless, that is, one experiences a serious adverse event. An adverse event is traumatic, not only physically but emotionally. Following Gardasil side effects, a young woman goes through a process of reorienting her understanding of cervical cancer risk to frame Gardasil as the object of risk. Trust in her physician and the medical system more broadly are compromised, yet ironically they must continually interact with the system as they have become lifelong patients, exercising a form of biomedical citizenship. Ultimately, this dissertation highlights that risk is not static but shaped by both macro cultural-structural forces and micro-level personal experience.

The Future of Gardasil

The FDA is notoriously quick to approve drugs and slow to remove them due to lack of resources and institutional pressures (Angell 2005). Between 1999 and 2001, 11 drugs were withdrawn from UK and US markets. Strikingly, 4 of these drugs were withdrawn based on spontaneous reports alone. 2 cited clinical trial evidence and 2 were based on data from other studies (Clarke, Deeks and Shakir 2006). This indicates that based on the studies and clinical trials reviewed in this dissertation (particularly Chapter 2), ample evidence already exists to support removing Gardasil from the market. It would not be the first time in recent years a

vaccine has been taken off the market. In October 1999, the manufacturer took the Rotashield vaccine off the market. Clinical trials included approximately 7,000 children and though a few cases of intussusception (bowel obstruction) were reported the difference between vaccine and placebo groups was not statistically significant. (Whether the company engaged in any of the selective reporting, trial design or other biases intended to make a drug appear more positive is not known.) After 1.5 million doses were administered, 15 cases of intussusception were reported and found related to the vaccine, which led the company to withdraw Rotashield from the market. What is notable about this case is that the vaccine was removed for a handful of cases, not due to statistics or any risk calculation even though unlike other vaccines, risk was quantifiable and documented. Instead the vaccine was removed for political purposes to maintain the appearance that vaccines are inherently safe as a category (Javitt, Berkowitz and Gostin 2008; Schwartz 2012). A doctor on the committee commented, "This was not viewed as rotavirus simply for rotavirus's sake but also the potential for maintaining public faith and credence in the overall immunization schedule" (Schwartz 2012: 298).

Whether Gardasil will ultimately be removed from the market remains to be unseen. The vaccine is controversial worldwide. In January 2013, the Indian Supreme Court gave notice to the government that Gardasil and its competitor Cervarix are "unsafe" and were licensed without proper research (ET Bureau 2013). In February of this year, EU Parliament member Michèle Rivasi called for a moratorium on Gardasil vaccination in Europe (Sautot 2014). Last summer the Japanese government stopped recommending the vaccine, citing safety concerns, but has kept Gardasil on the market, leaving the decision to vaccinate up to parents, young men and women

(Mulchay 2013). No such move has been suggested yet in the US. It is possible that close ties between the FDA and Merck, discussed in Paper 1, may prevent a deeper investigation into Gardasil's safety and efficacy. Institutional practices for drug review and recommendation also differ greatly by nation-state, and drugs removed from one market are not necessarily removed from another (Abraham and Shepphard 1999).

Avenues of Future Research

This dissertation has raised more questions about risk, patient-consumers and the pharmaceutical industry than it has provided answers. I will briefly discuss a few potential areas of future research.

First, what are the experiences of boys and men in HPV vaccination? Considering Gardasil was promoted as a cervical cancer vaccine several years before it was approved for males, it would be interesting to discover what is the object of risk for boys and men. Are they concerned with HPV-related cancers for themselves? Are they more interested in protection against genital warts? Or is the female body still the object at risk, and are (heterosexual) males getting vaccinated to prevent infecting female partners? Both healthy vaccinated and unvaccinated males could provide insight into these questions. Boys and men who have experienced serious adverse events after Gardasil are also important to investigate. Does their experience of risk follow a similar narrative as women? Or is their experience different in gendered ways?

Considering the alarmingly high rate of adverse drug reactions in the United States, I found very little research of individuals' experiences with drug side effects. Epidemiological

statistics are plentiful, but the lived experience is quite another issue, one appropriate for the social sciences. For instance, how does experiencing adverse drug events shape an individual's perspective on subsequent drugs and experience of disease risk? How do patient-consumers who have suffered serious adverse events continue to engage with the medical system that caused their side effects? How is the doctor-patient relationship affected, particularly when a doctor is resistant to the idea that drugs or vaccines can cause serious adverse events? Is the sociological experience of adverse events any different whether the object of risk is a drug or a vaccine? How do social understandings about the safety of vaccines more generally shape the experience of an adverse event?

Third, how has Gardasil's construction of cervical cancer risk impacted young women's experiences being diagnosed with HPV? Women have long blamed themselves for HPV diagnoses (Nack 2008), and has this worsened with a drug that provides the rhetorical possibility of avoiding infection? If effectiveness is as low as 17% (Paavonon & Lehitnen 2008), many vaccinated women will nonetheless face a HPV diagnosis in their lifetime. Will women still blame themselves, either for engaging in 'too risky' of behaviors, for not finishing the 3-shot series, or will they blame a faulty vaccine?

Fourth, how can risk object theory be furthered to more deeply explore relationships of risk? In Chapter 3 I documented how a traumatic health experience can cause a risk object to shift. What other areas of social life involve shifts of risk? This theory has broad potential for application, both in the field of medicine and elsewhere. This theory could also be utilized to how examine health narratives morph over the life course, how other adverse drug controversies

operate in both the public and personal sphere or how diagnostic testing illuminates invisible yet ever changing risks. Outside of medicine, risk object theory could useful in tracing the rhetoric of politicized social movements, identifying how objects of risk emerge and fade over time. While a wealth of research on risk exists, the risk-object perspective highlights how risk is not absolute but rather a relationship, which is inherently open to change.

How does trust operate in the experience of risk? Pharmaceutical companies are faceless conglomerates, but a doctor has a living, breathing, sensate relationship with a patient and his or her body. Were the doctor not the source of vaccination, if Gardasil were instead sold at drugstore pharmacies and administered by the pharmacist or assistant on duty, would vaccination rates be as high? Would young women and their guardians trust the vaccine without a specific personally known trusted authority encouraging its use? To what extent is a personal relationship necessary for an individual patient-consumer to become connected enough to a drug to take it? Does trust operate differently in relation to macro-level institutions such as the FDA or CDC than it does in micro-level interactions?

Finally, what are the implications of this dissertation for other vaccines? Vaccines have been controversial since their inception, yet questioning vaccine safety and efficacy is scientifically taboo (Dew 1999). While this project is limited to the investigation of Gardasil, the findings here have important implications for other vaccines on the market. Each vaccine is unique, yet the institutional practices of and relationships between pharmaceutical companies and regulatory agencies described here is not limited to Gardasil. Has data been selectively presented in other vaccine trials? Have side effects been obscured? Has efficacy for one

subgroup been presented as efficacy for all? Have FDA review boards included members from the pharmaceutical industry? An equally in-depth look as this dissertation would be required to answer these questions for any other vaccine. Further is the question of the impact of aluminum adjuvants, and their use as a "placebo" in clinical trials. It is common for vaccine clinical trials to utilize an aluminum-based "placebo," though some do use legitimate placebos containing saline or the antigen without the adjuvant (Exley 2011). Considering hepatitis A, hepatitis B, diptheria-tetanus-pertussis (DtaP), haemophilus influenza type b (Hib), and pneumonia vaccines all have aluminum-based adjuvants (CDC 2010), the cumulative and long-term impact of aluminum, as well as the ways in which vaccines are tested for safety, needs further investigation.

These are just six potential areas of future research, though there are many more possibilities. Particularly for a researcher interested in drug side effects, there is a wide open field of questions and concerns to address. This area may become more pertinent in the coming years as new risk-reduction drugs are developed every year, many taking the form of vaccines. As of 2012 there were 295 vaccines in development (PhRMA 2012), so while Gardasil is the first of its genre it will not be its last.

Conclusion

Technology has and will continue to shape our experiences of health, the body and risk. It has been my aim to provide a thoughtful, nuanced exploration into the relationship between risk and the pharmaceutical technology Gardasil, how it impacts young women's experience of the body, their decisions, and the lived experience of risk. Gardasil is emblematic of historian

and sociologist Robert Aronowitz's assertion that vaccine programs are "massive population experiments and should be treated as such" (2010: 26). As more risk-reduction vaccines are introduced into the market, controversy and debates over the safety and efficacy of vaccines will likely rise. What it means to be healthy, or sick, or somewhere in-between will continue to be an area of contestation.

Zinn (2009) reminds us, "Every risk is accompanied by a chance. If we sacrifice the risks we might forget about the chances and values we strive for" (521). Love, adventure, vulnerability and connection all require we take risks. Life, despite what the pharmaceutical industry may wish us to believe, is less about avoiding every possible risk and more about deciding which risks to actively take. Sometimes, the best response to risk is to do nothing at all. And other times, a risk is well worth taking. Though anxiety provoking and uncertain as any risk, I believe writing this dissertation is a risk that has served me both personally and professionally, one I hope will help others navigate the complex world of risk reduction and medicine. As C. Wright Mills states, "No social study that does not come back to the problems of biography, of history and of their intersections within society has completed its intellectual journey" (1959 [2000]: 6). I believe this journey is finally complete.

Appendix

Appendix A - University Student Questionnaire

PART A

We are interested in what you know about human papillomavirus (HPV). If you like, you can explain any of your answers in the area next to each question.

1. If someone is infected with HPV, they might give the virus to their partner. How can one person give HPV to another? Mark all that apply:

- ☐ Blood
- ☐ Semen and fluid from the vagina
- ☐ Skin
- ☐ From mother to child in the womb
- ☐ Sharing needles
- ☐ Toilet seat
- ☐ Vaginal sex (penis in vagina)
- ☐ Oral sex (mouth on vagina or penis)
- ☐ Anal sex (penis in anus)
- ☐ When partners rub their sex organs against each other
- ☐ Sex toys
- ☐ Warts on hands or feet
- ☐ Sores on the mouth or sex organs
- ☐ Don't know

2. How much do condoms protect against HPV infection?

- ☐ Completely protect
- ☐ Protect somewhat
- ☐ Rarely protect
- ☐ Don't protect at all
- ☐ Don't know

3. How is a woman diagnosed with HPV? Mark all that apply:

- ☐ Blood test
- ☐ Urine (pee) test
- ☐ Pap smear
- ☐ A doctor looks at the area
- ☐ When a sex partner has an HPV infection, the doctor assumes the woman has it too
- ☐ Don't know

4. How are men diagnosed with HPV? Mark all that apply:
- ☐ Blood test
- ☐ Urine (pee) test
- ☐ Pap smear
- ☐ A doctor looks at the area
- ☐ When a sex partner has an HPV infection, the doctor assumes the man has it too
- ☐ Don't know

5. Which of the illnesses below are related to HPV? Mark all that apply:
- ☐ Uterine (uterus) cancer (The uterus is where a baby grows.)
- ☐ Cervical (cervix) cancer (The cervix is the opening of the uterus.)
- ☐ Ovarian (ovary) cancer
- ☐ Vaginal (vagina) cancer
- ☐ Vulval (vulva) cancer (Vulva are the "lips" outside the vagina.)
- ☐ Penile (penis) cancer
- ☐ Prostate cancer
- ☐ Anal (anus) cancer
- ☐ Genital warts
- ☐ Abnormal Pap smear
- ☐ Don't know

6. Who is at risk for HPV? Mark all that apply:
- ☐ All women
- ☐ All women who have sex
- ☐ Women with a lot of sex partners
- ☐ Women who don't use condoms
- ☐ Women who don't get Pap smears
- ☐ HIV-positive women
- ☐ Women who have an abnormal Pap smear
- ☐ Women who have genital warts
- ☐ Women who take birth control pills
- ☐ Women who smoke cigarettes
- ☐ All women who have sex with men only
- ☐ All women who have sex with women only
- ☐ All women who have sex with both men and women
- ☐ All men
- ☐ All men who have sex
- ☐ Men with a lot of sex partners
- ☐ Men who don't use condoms

- ☐ HIV-positive men
- ☐ Men who have genital warts
- ☐ Men who smoke cigarettes
- ☐ All men who have sex with women only
- ☐ All men who have sex with men only
- ☐ All men who have sex with both men and women
- ☐ Don't know

7. Who is at risk for cervical (cervix) cancer? Mark all that apply:

- ☐ All women
- ☐ All women who have sex
- ☐ Women with a lot of sex partners
- ☐ Women who don't use condoms
- ☐ Women who don't get Pap smears
- ☐ HIV-positive women
- ☐ Women who have an abnormal Pap smear
- ☐ Women who have genital warts
- ☐ Women who take birth control pills
- ☐ Women who smoke cigarettes
- ☐ All women who have sex with men only
- ☐ All women who have sex with women only
- ☐ All women who have sex with both men and women
- ☐ Don't know

8. If a woman is diagnosed with genital warts, what are her chances of getting cervical (cervix) cancer (cancer on the opening of the uterus)?

- ☐ High
- ☐ Medium
- ☐ Low
- ☐ No chance
- ☐ Don't know

9. If a woman has an abnormal Pap smear, what are her chances of getting cervical cancer?

- ☐ High
- ☐ Medium
- ☐ Low
- ☐ No chance
- ☐ Don't know

10. If a woman is diagnosed with HPV on her cervix, what are her chances of getting cervical (cervix) cancer?

- ☐ High
- ☐ Medium
- ☐ Low
- ☐ No chance
- ☐ Don't know

11. What percentage of sexually active people will ever get an HPV infection?
    - ☐ 5 out of 100
    - ☐ 10 out of 100
    - ☐ 25 out of 100
    - ☐ 50 out of 100
    - ☐ 75 out of 100
    - ☐ Don't know

12. What are symptoms of HPV infection on a woman's cervix? Mark all that apply:
    - ☐ Pain or burning while urinating (peeing)
    - ☐ Lower stomach pain
    - ☐ Itching around the vagina
    - ☐ Painful sex
    - ☐ Bumps or warts
    - ☐ Discharge or dripping from the vagina
    - ☐ Sores
    - ☐ No symptoms
    - ☐ Don't know

13. What are symptoms of genital warts in women or men? Mark all that apply:
    - ☐ Pain or burning while urinating (peeing)
    - ☐ Lower stomach pain
    - ☐ Itching around the penis or vagina
    - ☐ Painful sex
    - ☐ Bumps or warts
    - ☐ Discharge or dripping from the penis or vagina
    - ☐ Sores
    - ☐ No symptoms
    - ☐ Don't know

14. If someone has an HPV infection, how long does it take for it to go away?
    - ☐ 2 weeks
    - ☐ 3 months
    - ☐ 6 months
    - ☐ 1-2 years

- ☐ 5 years
- ☐ Never, once someone has HPV it will not go away
- ☐ Don't know

15. What is Gardasil? Mark all that apply:
    - ☐ Genital wart vaccine
    - ☐ Herpes vaccine
    - ☐ Cervical cancer vaccine
    - ☐ HPV vaccine
    - ☐ HIV vaccine
    - ☐ Don't know

16. Who can get vaccinated with Gardasil? Mark all that apply:
    - ☐ Young girls (age 12 and under)
    - ☐ Young boys (age 12 and under)
    - ☐ Teenage girls (age 13-19)
    - ☐ Teenage boys (age 13-19)
    - ☐ Young women (age 20-35)
    - ☐ Young men (age 20-35)
    - ☐ Middle-aged women (age 36-54)
    - ☐ Middle-aged men (age 36-54)
    - ☐ Older women (age 55 and up)
    - ☐ Older men (age 55 and up)
    - ☐ Don't know

16. What is Cervarix? Mark all that apply:
    - ☐ Genital wart vaccine
    - ☐ Herpes vaccine
    - ☐ Cervical cancer vaccine
    - ☐ HPV vaccine
    - ☐ HIV vaccine
    - ☐ Don't know

17. Who can get vaccinated with Cervarix? Mark all that apply:
    - ☐ Young girls (age 12 and under)
    - ☐ Young boys (age 12 and under)
    - ☐ Teenage girls (age 13-19)
    - ☐ Teenage boys (age 13-19)
    - ☐ Young women (age 20-35)
    - ☐ Young men (age 20-35)
    - ☐ Middle-aged women (age 36-54)

☐ Middle-aged men (age 36-54)
☐ Older women (age 55 and up)
☐ Older men (age 55 and up)
☐ Don't know

PART B:
We want to know where you have learned about human papillomavirus (HPV), HPV vaccines, and whether you have ever had HPV. If you are not comfortable answering any questions, you may leave them blank.

Human Papillomavirus (HPV) Information

1. Before participating in this study, had you ever heard of human papillomavirus (HPV)?

_____

2. We want to know where you have learned about HPV. Did you learn about HPV from:

☐ Doctor or nurse?
☐ Family members?
☐ Friends?
☐ Gardasil commercials or advertisements?
☐ Cervarix commercials or advertisements?
☐ www.gardasil.com?
☐ www.hpv.com?
☐ Other websites?
☐ School?
☐ Books?
☐ News?
☐ Gardasil pamphlets?
☐ Cervarix pamphlets?
☐ Other? Please explain:

_____

3. Patients want health information they can trust. If you wanted to learn about HPV, how much would you trust each of these sources of information? Please rate your trust on a scale of 1-5, 5 meaning completely trusted and 1 meaning not trusted at all. Please leave it blank if you don't know or haven't heard of the source.

_____ Doctor or nurse
_____ Family members
_____ Friends

_____ Gardasil commercials or advertisements
_____ Cervarix commercials or advertisements
_____ www.gardasil.com
_____ www.hpv.com
_____ Other websites
_____ School
_____ Books
_____ News
_____ Gardasil pamphlets
_____ Cervarix pamphlets
_____ Other, please explain:
_____

Human Papillomavirus (HPV) Experience

4. Have you ever had an abnormal Pap smear? If so, when?
_____

5. Have you ever been diagnosed with HPV or genital warts? If so, when?
_____

If no, skip to Question 13.

6. Which of the following were you diagnosed with? Mark all that apply:
_____ HPV infection of the cervix
_____ Genital warts
_____ Other (fill in):
_____
_____ Not sure

7. Were you in a romantic or sexual relationship when you were diagnosed?
_____

If yes, was your partner a man or a woman?_____

Was your partner also diagnosed with HPV? _____

8. Have you ever been diagnosed with cervical cancer? _____

9. Right now, how much do you feel at risk for HPV? Please rate your feeling of risk on a scale of 1-5, with 5 meaning very much at risk and 1 meaning not at all:
_____

10. Right now, how much do you feel at risk for cervical cancer? Please rate your feeling of risk on a scale of 1-5, with 5 meaning very much at risk and 1 meaning not at all:

_____

Human Papillomavirus (HPV) Vaccine Information

11. Before participating in this study, had you ever heard of Gardasil?

_____

If no, skip to Question 14.

11. Where did you first hear about Gardasil?

_____

12. We want to know where you have learned about Gardasil. Have you learned about Gardasil from:

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Gardasil commercials or advertisements?
- ☐ www.gardasil.com?
- ☐ www.hpv.com?
- ☐ Other websites?
- ☐ School?
- ☐ Books?
- ☐ News?
- ☐ Gardasil pamphlets?
- ☐ Other? Please explain:

_____

13. Women want health information they can trust. If you wanted to learn about Gardasil, how much would you trust each of these sources of information? Please rate your trust on a scale of 1-5, 5 being completely trusted and 1 being not trusted at all. Please leave it blank if you don't know or haven't heard of the source.

_____ Doctor or nurse
_____ Family members
_____ Friends
_____ Gardasil commercials or advertisements

_____ www.gardasil.com
_____ www.hpv.com
_____ Other websites
_____ School
_____ Books
_____ News
_____ Gardasil pamphlets or brochures
_____ Other, please explain:

_____

14. Before participating in this study, had you ever heard of Cervarix?

_____

If no, skip to Question 18.

15. Where did you first hear about Cervarix?

_____

16. We want to know where you have learned about Cervarix. Have you learned about Cervarix from:

☐ Doctor or nurse?
☐ Family members?
☐ Friends?
☐ Cervarix commercials or advertisements?
☐ Websites?
☐ School?
☐ Books?
☐ News?
☐ Gardasil pamphlets?
☐ Other? Please explain:

_____

17. Women want health information they can trust. If you wanted to learn about Cervarix, how much would you trust each of these sources of information? Please rate your trust on a scale of 1-5, 5 being completely trusted and 1 being not trusted at all. Please leave it blank if you don't know or haven't heard of the source.

_____ Doctor or nurse
_____ Family members
_____ Friends

_____ Cervarix commercials or advertisements
_____ Websites
_____ School
_____ Books
_____ News
_____ Cervarix pamphlets or brochures
_____ Other, please explain:

_____

Human Papillomavirus Vaccination

18. Have you had the Gardasil or Cervarix vaccine? If yes, which one?

_____

If no, skip to Question 21.

19. Have you had all three shots?

_____

If no, how many shots have you had?

_____

20. How did you pay for Gardasil or Cervarix?

_____

Skip to Question 22.

21. Do you plan to get the Gardasil or Cervarix vaccine in the future?

_____

Do you have friends or family members who have had the Gardasil or Cervarix vaccine? If yes, who?

_____

Appendix B – University Student Interview Schedule

Background

How old are you?

What is your occupation?

What is the highest level of education you have completed?

- ☐ Some high school, high school, some college, college, graduate degree

What is your socioeconomic class?

- ☐ Working, lower-middle, middle, upper-middle, upper class

What is your race or ethnicity?

What is your religious background?

Are you currently practicing?

What is your sexual orientation?

- ☐ Heterosexual, lesbian, bisexual, other

Do you usually have sex with men, women, or both?

HPV Information Sources and Perspective

Generally, what do you know about HPV?

You said you have learned about HPV from Source 1, Source, 2, Source 3, etc.

Ask detail about each source marked:

What was the doctor or nurse's gender?
Which family members or friends?
Which Gardasil or Cervarix ads? TV, magazines, etc.?
Which websites?
What classes in school?
What books?
What news sources?
Where did you get Gardasil or Cervarix pamphlets?
Other?

Which of these sources was most important in learning about HPV?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was second most important in learning about HPV?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was third most important in learning about HPV?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

In your opinion, how big of a health problem is HPV for society? For women? For men?

HPV Diagnosis

Is your current doctor a man or a woman? At your doctor's office, do you usually see a male nurse or a female nurse?

If diagnosed with HPV/genital warts:

You were diagnosed with HPV/genital warts. Had you ever heard of HPV or genital warts before you diagnosis?

If so, where? What did you know?

Did you feel at risk for HPV or genital warts?

How would you describe this feeling of risk?

Did your current doctor diagnose you? If not, was that doctor a man or a woman?

How did your doctor describe your diagnosis to you?

What did your doctor tell you about HPV/genital warts?

Did your doctor give you any written information or pamphlets when you were diagnosed?

How did you feel about being diagnosed?

How did you feel about your body after your diagnosis?

If cervical HPV:

Did your diagnosis change how you think or feel about your cervix?

How did you think or feel about your cervix after being diagnosed?

Did your doctor tell you anything about cervical cancer? What did she/he tell you?

After diagnosis, did you feel at risk for cervical cancer?

How much did you feel at risk?

1. No risk, a little, some, a lot

How would you describe this feeling of risk?

After your diagnosis, did you look for information about HPV/genital warts? If so, where?

Did your doctor give you any advice about your sexual partner(s)?

If respondent reports male partners:

Did your doctor tell you about HPV in men?

If respondent reports both male and female partners:

Was your doctor's advice different for male versus female partners?

If respondent had a partner at time of diagnosis:

Did you tell your partner about your diagnosis? Why or why not?

How did you feel about your partner's risk for HPV? For cancer?

If respondent told partner:

Did your partner feel at risk for HPV? For cancer?

If respondent had an abnormal pap but was not diagnosed with HPV:

Did your current doctor diagnose you? If not, was that doctor a man or a woman?

How did your doctor describe your diagnosis to you?

What did your doctor tell you about abnormal pap smears?

Did your doctor give you any written information or pamphlets when you were diagnosed?

How did you feel about being diagnosed?

How did you feel about your body after your diagnosis?

Did your diagnosis change how you think or feel about your cervix?

How did you think or feel about your cervix after being diagnosed?

Did your doctor tell you anything about cervical cancer? What did she/he tell you?

After diagnosis, did you feel at risk for cervical cancer?

How much did you feel at risk?

2. No risk, a little, some, a lot

How would you describe this feeling of risk?

<u>Gardasil Information Sources and Perspective</u>

Generally, what do you know about Gardasil?

You said you have learned about Gardasil from Source 1, Source, 2, Source 3, etc.

Ask detail about each source marked:

What was the doctor or nurse's gender?

Which family members or friends?
Which Gardasil ads? TV, magazines, etc.?
Which websites?
What classes in school?
What books?
What news sources?
Where did you get Gardasil pamphlets?
Other?

Which of these sources was most important in learning about Gardasil?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was second most important in learning about Gardasil?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was third most important in learning about Gardasil?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

If discussed Gardasil with a doctor/nurse and says this was one of three most important sources, add these questions to those above. If doctor/nurse not one of three most important, ask these questions next:

What did your doctor/nurse tell you about Gardasil?

Did they recommend Gardasil?

In this conversation, did your doctor make you feel at risk for HPV? For cervical cancer?

How would you describe this feeling of risk?

What is your perspective on Gardasil?

What do you see as Gardasil's benefits?

What do you see as Gardasil's drawbacks?

Do you think boys and men should be vaccinated with Gardasil? Why or why not?

Cervarix Information Sources and Perspective

Generally, what do you know about Cervarix?

You said you have learned about Cervarix from Source 1, Source, 2, Source 3, etc.

Ask detail about each source marked:

What was the doctor or nurse's gender?
Which family members or friends?
Which Cervarix ads? TV, magazines, etc.?
Which websites?
What classes in school?
What books?
What news sources?
Where did you get Cervarix pamphlets?
Other?

Which of these sources was most important in learning about Cervarix?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was second most important in learning about Cervarix?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was third most important in learning about Cervarix?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

What is your perspective on Cervarix?

What do you see as Cervarix's benefits?

What do you see as Cervarix's drawbacks?

If discussed Cervarix with a doctor or healthcare worker:

What did your doctor tell you about Cervarix?

Did they recommend Cervarix?

Did this make you feel at risk for HPV? For cervical cancer?

How would you describe this feeling of risk?

<u>Vaccination</u>

If has been vaccinated or is planning to get vaccinated:

Why did you decide to get vaccinated with Gardasil or Cervarix?

If hasn't been vaccinated but is planning to get vaccinated:

Which vaccine will you choose, Gardasil or Cervarix? Why?

How do you feel about your decision?

Did you feel any different about your body after getting vaccinated?

How did you feel about your HPV risk after getting vaccinated? What about your cervical cancer risk?

If respondent has not been vaccinated and is planning on vaccination:

Why did you decide not to get vaccinated?

How do you feel about your decision?

Reflection

Has anyone close to you ever been diagnosed with HPV, genital warts, or HPV-related cancer?

What do you wish young women would know about HPV?

What do you wish young men would know about HPV?

Is there anything else you think is relevant to this study?

Do you have any questions?

Appendix C - Internet Survey for Females With Serious HPV Vaccine Side Effects

Background

How old are you?

What is your occupation?

Where do you live? (list of states)

What is the highest level of education you have completed?

Some high school, high school, some college, college, graduate degree

What is your social class?

Working, lower-middle, middle, upper-middle, upper class

What is your race or ethnicity? Choose all that apply:

White, Black, Hispanic/Latino, Asian, American Indian, Pacific Islander, Other

What is your religion?

Are you currently practicing?

What is your sexual orientation?

Heterosexual, lesbian, bisexual, other (please describe)

Have you ever been sexually active? (Have you ever had sex with a man or woman?)

Do you usually have sex with men, women, or both?

Human Papillomavirus (HPV) Experience: If you have ever been diagnosed with HPV, we would like to know about your experience.

Have you ever had an abnormal Pap smear? If so, when?

Have you ever been diagnosed with HPV or genital warts? If so, when?

Which of the following were you diagnosed with? Mark all that apply:

HPV infection of the cervix, Genital warts, Other (please explain), Not sure

Were you in a romantic or sexual relationship when you were diagnosed?

If yes, was your partner a man or a woman?

Was your partner also diagnosed with HPV?

Have you ever been diagnosed with cervical (cervix) cancer? (The cervix is the opening of the uterus.)

Right now, how much do you feel at risk for HPV? Please rate your feeling of risk on a scale of 1-5, with 5 meaning very much at risk and 1 meaning not at all.

Right now, how much do you feel at risk for cervical cancer? Please rate your feeling of risk on a scale of 1-5, with 5 meaning very much at risk and 1 meaning not at all.

Human Papillomavirus Vaccination: We would like to know about your experience with HPV vaccines and any side effects you believe are the result of Gardasil or Cervarix.

Have you had the Gardasil or Cervarix vaccine? If yes, which one?

Why did you decide to get the vaccine?
Both Gardasil and Cervarix include three shots. Have you had all three shots?
If no, how many shots have you had? Do you plan on getting all three shots?
How did you pay for Gardasil or Cervarix? (i.e., insurance, parents, cash, etc.)
Do you have friends or family members who have had the Gardasil or Cervarix vaccine? If yes, who?
How did you feel about your risk for HPV after getting the vaccine? Much Higher, Higher, Same, Lower, Much Lower, Not Applicable – Did not ever feel at risk for HPV
How did you feel about your risk for cervical cancer after getting the vaccine? Much Higher, Higher, Same, Lower, Much Lower, Not Applicable – Did not ever feel at risk for cervical cancer
Have you experienced any side effects you believe come from Gardasil or Cervarix? Please describe.
How soon after getting the vaccine did you begin feeling side effects? Immediately, less than 2 weeks, 2-4 weeks, more than 4 weeks. Please describe.
After which shot did you experience side effects? Mark all that apply: First, Second, Third.
Have you ever seen a doctor because of side effects from Gardasil or Cervarix?
Have you ever been hospitalized because of Gardasil or Cervarix?
Have you been diagnosed with a life-threatening condition because of Gardasil or Cervarix?
Have you had medical treatment or surgery because of Gardasil or Cervarix?
Have you been diagnosed with a condition that does not need medical treatment or surgery now but might in the future?
Have you become disabled or had permanent physical damage because of Gardasil or Cervarix?
Have you given birth to a child with birth defects because of Gardasil or Cervarix?
Have you, a doctor, or family member reported your side effects to the Vaccine Adverse Events Reporting System (VAERS)? Yes, no, don't know.
What is your opinion on HPV vaccines?
What do you see as benefits and drawbacks of HPV vaccination?
Do you think boys and men should get HPV vaccines?

HPV Knowledge: We would like to know what you know about HPV.

If someone is infected with HPV, they might give the virus to their partner. How can one person give HPV to another? Mark all that apply:

- ☐ Blood
- ☐ Semen and fluid from the vagina
- ☐ Skin
- ☐ From mother to child in the womb
- ☐ Sharing needles
- ☐ Toilet seat
- ☐ Vaginal sex (penis in vagina)
- ☐ Oral sex (mouth on vagina or penis)
- ☐ Anal sex (penis in anus)

- ☐ When partners rub their sex organs against each other
- ☐ Sex toys
- ☐ Warts on hands or feet
- ☐ Sores on the mouth or sex organs
- ☐ Don't know

How much do condoms protect against HPV infection?

- ☐ Completely protect
- ☐ Protect somewhat
- ☐ Rarely protect
- ☐ Don't protect at all
- ☐ Don't know

How is a woman diagnosed with HPV? Mark all that apply:

- ☐ Blood test
- ☐ Urine (pee) test
- ☐ Pap smear
- ☐ A doctor looks at the area
- ☐ When a sex partner has an HPV infection, the doctor assumes the woman has it too
- ☐ Don't know

How are men diagnosed with HPV? Mark all that apply:

- ☐ Blood test
- ☐ Urine (pee) test
- ☐ Pap smear
- ☐ A doctor looks at the area
- ☐ When a sex partner has an HPV infection, the doctor assumes the man has it too
- ☐ Don't know

Which of the illnesses below are related to HPV? Mark all that apply:

- ☐ Uterine (uterus) cancer (The uterus is where a baby grows.)
- ☐ Cervical (cervix) cancer (The cervix is the opening of the uterus.)
- ☐ Ovarian (ovary) cancer
- ☐ Vaginal (vagina) cancer
- ☐ Vulval (vulva) cancer (Vulva are the "lips" outside the vagina.)
- ☐ Penile (penis) cancer
- ☐ Prostate cancer
- ☐ Anal (anus) cancer
- ☐ Genital warts
- ☐ Abnormal Pap smear
- ☐ Don't know

Who is at risk for HPV? Mark all that apply:

- ☐ All women
- ☐ All women who have sex
- ☐ Women with a lot of sex partners
- ☐ Women who don't use condoms
- ☐ Women who don't get Pap smears
- ☐ HIV-positive women
- ☐ Women who have an abnormal Pap smear
- ☐ Women who have genital warts
- ☐ Women who take birth control pills
- ☐ Women who smoke cigarettes
- ☐ All women who have sex with men only
- ☐ All women who have sex with women only
- ☐ All women who have sex with both men and women
- ☐ All men
- ☐ All men who have sex
- ☐ Men with a lot of sex partners
- ☐ Men who don't use condoms
- ☐ HIV-positive men
- ☐ Men who have genital warts
- ☐ Men who smoke cigarettes
- ☐ All men who have sex with women only
- ☐ All men who have sex with men only
- ☐ All men who have sex with both men and women
- ☐ Don't know

Who is at risk for cervical (cervix) cancer? Mark all that apply:

- ☐ All women
- ☐ All women who have sex
- ☐ Women with a lot of sex partners
- ☐ Women who don't use condoms
- ☐ Women who don't get Pap smears
- ☐ HIV-positive women
- ☐ Women who have an abnormal Pap smear
- ☐ Women who have genital warts
- ☐ Women who take birth control pills
- ☐ Women who smoke cigarettes
- ☐ All women who have sex with men only
- ☐ All women who have sex with women only

- ☐ All women who have sex with both men and women
- ☐ Don't know

If a woman is diagnosed with genital warts, what are her chances of getting cervical (cervix) cancer (cancer on the opening of the uterus)?

- ☐ High
- ☐ Medium
- ☐ Low
- ☐ No chance
- ☐ Don't know

If a woman has an abnormal Pap smear, what are her chances of getting cervical cancer?

- ☐ High
- ☐ Medium
- ☐ Low
- ☐ No chance
- ☐ Don't know

If a woman is diagnosed with HPV on her cervix, what are her chances of getting cervical (cervix) cancer?

- ☐ High
- ☐ Medium
- ☐ Low
- ☐ No chance
- ☐ Don't know

What percentage of sexually active people will ever get an HPV infection?

- ☐ 5 out of 100
- ☐ 10 out of 100
- ☐ 25 out of 100
- ☐ 50 out of 100
- ☐ 75 out of 100
- ☐ Don't know

What are symptoms of HPV infection on a woman's cervix? Mark all that apply:

- ☐ Pain or burning while urinating (peeing)
- ☐ Lower stomach pain
- ☐ Itching around the vagina
- ☐ Painful sex
- ☐ Bumps or warts
- ☐ Discharge or dripping from the vagina

- ☐ Sores
- ☐ No symptoms
- ☐ Don't know

What are symptoms of genital warts in women or men? Mark all that apply:

- ☐ Pain or burning while urinating (peeing)
- ☐ Lower stomach pain
- ☐ Itching around the penis or vagina
- ☐ Painful sex
- ☐ Bumps or warts
- ☐ Discharge or dripping from the penis or vagina
- ☐ Sores
- ☐ No symptoms
- ☐ Don't know

If someone has an HPV infection, how long does it take for it to go away?

- ☐ 2 weeks
- ☐ 3 months
- ☐ 6 months
- ☐ 1-2 years
- ☐ 5 years
- ☐ Never, once someone has HPV it will not go away
- ☐ Don't know

What is Gardasil? Mark all that apply:

- ☐ Genital wart vaccine
- ☐ Herpes vaccine
- ☐ Cervical cancer vaccine
- ☐ HPV vaccine
- ☐ HIV vaccine
- ☐ Don't know

Who can get vaccinated with Gardasil? Mark all that apply:

- ☐ Young girls (age 12 and under)
- ☐ Young boys (age 12 and under)
- ☐ Teenage girls (age 13-19)
- ☐ Teenage boys (age 13-19)
- ☐ Young women (age 20-35)
- ☐ Young men (age 20-35)
- ☐ Middle-aged women (age 36-54)
- ☐ Middle-aged men (age 36-54)

- ☐ Older women (age 55 and up)
- ☐ Older men (age 55 and up)
- ☐ Don't know

What is Cervarix? Mark all that apply:

- ☐ Genital wart vaccine
- ☐ Herpes vaccine
- ☐ Cervical cancer vaccine
- ☐ HPV vaccine
- ☐ HIV vaccine
- ☐ Don't know

Who can get vaccinated with Cervarix? Mark all that apply:

- ☐ Young girls (age 12 and under)
- ☐ Young boys (age 12 and under)
- ☐ Teenage girls (age 13-19)
- ☐ Teenage boys (age 13-19)
- ☐ Young women (age 20-35)
- ☐ Young men (age 20-35)
- ☐ Middle-aged women (age 36-54)
- ☐ Middle-aged men (age 36-54)
- ☐ Older women (age 55 and up)
- ☐ Older men (age 55 and up)
- ☐ Don't know

HPV and HPV Vaccine Information: We would like to know where you have learned about HPV and HPV vaccines.

Before participating in this study, had you ever heard of human papillomavirus (HPV)?

We want to know where you have learned about HPV. Did you learn about HPV from:

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Gardasil commercials or advertisements?
- ☐ Cervarix commercials or advertisements?
- ☐ www.gardasil.com?
- ☐ www.hpv.com?
- ☐ Other websites?
- ☐ School?
- ☐ Books?
- ☐ News?

- ☐ Gardasil pamphlets?
- ☐ Cervarix pamphlets?
- ☐ Other? Please explain.

Patients want health information they can trust. If you wanted to learn about HPV, how much would you trust each of these sources of information? Please rate your trust on a scale of 1-5, 5 meaning completely trusted and 1 meaning not trusted at all.

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Gardasil commercials or advertisements?
- ☐ Cervarix commercials or advertisements?
- ☐ www.gardasil.com?
- ☐ www.hpv.com?
- ☐ Other websites?
- ☐ School?
- ☐ Books?
- ☐ News?
- ☐ Gardasil pamphlets?
- ☐ Cervarix pamphlets?
- ☐ Other? Please explain.

Before participating in this study, had you ever heard of Gardasil?
Where did you first hear about Gardasil? (i.e., doctor, commercial, website, etc.)
We want to know where you have learned about Gardasil. Have you learned about Gardasil from:

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Gardasil commercials or advertisements?
- ☐ www.gardasil.com?
- ☐ www.hpv.com?
- ☐ Other websites?
- ☐ School?
- ☐ Books?
- ☐ News?
- ☐ Gardasil pamphlets?
- ☐ Other? Please explain.

Women want health information they can trust. If you wanted to learn about Gardasil, how much would you trust each of these sources of information? Please rate your trust on a scale of 1-5, 5

being completely trusted and 1 being not trusted at all. Please leave it blank if you don't know or haven't heard of the source.

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Gardasil commercials or advertisements?
- ☐ www.gardasil.com?
- ☐ www.hpv.com?
- ☐ Other websites?
- ☐ School?
- ☐ Books?
- ☐ News?
- ☐ Gardasil pamphlets?
- ☐ Other? Please explain.

Before participating in this study, had you ever heard of Cervarix?
Where did you first hear about Cervarix? (i.e., doctor, commercial, website, etc.)
We want to know where you have learned about Cervarix. Have you learned about Cervarix from:

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Cervarix commercials or advertisements?
- ☐ Websites?
- ☐ School?
- ☐ Books?
- ☐ News?
- ☐ Cervarix pamphlets?
- ☐ Other? Please explain.

Women want health information they can trust. If you wanted to learn about Cervarix, how much would you trust each of these sources of information? Please rate your trust on a scale of 1-5, 5 being completely trusted and 1 being not trusted at all. Please leave it blank if you don't know or haven't heard of the source.

- ☐ Doctor or nurse?
- ☐ Family members?
- ☐ Friends?
- ☐ Cervarix commercials or advertisements?
- ☐ Websites?
- ☐ School?
- ☐ Books?

□ News?
□ Cervarix pamphlets?
□ Other? Please explain.

Final Questions
Has anyone close to you ever been diagnosed with HPV, genital warts, or HPV-related cancer?
What do you wish young women would know about HPV?
What do you wish young women would know about HPV vaccines?
What do you wish young men would know about HPV?
What do you wish young men would know about HPV vaccines?
Where did you hear about the study? (list websites where call for participants is posted, plus 'friend,' 'family member,' and 'other')

Are you interested in participating in a telephone interview? Interviews will take approximately 30 minutes to 1 hour. Your responses will be confidential. If you would like to be interviewed, please fill in your contact information:
First name, Email, Phone

For more information on human papillomavirus, please click Next.

Following the survey, the following information will be displayed:

Note to Study Participants: This information is for educational purposes only and is not medical advice. This research is not sponsored by any pharmaceutical companies. The researcher does not endorse or recommend against any medical tests, vaccines or treatments. Please do your own research and talk to your doctor about any medical decisions.

- Human papillomavirus (HPV) is very common. Most people will get an HPV infection during their lifetime.
- There are over 100 strains of HPV. About 40 strains can be passed through sex. There are two types: high- and low-risk.
- High-risk HPVs can cause abnormal cells in the cervix (opening of the uterus), vagina, vulva (outside "lips" of the vagina), penis, and anus. If not treated, high-risk HPV may lead to cancer. Cancers of the vulva, vagina, penis, and anus are rare. Men who have sex with men are at higher risk for anal cancer. HIV-positive women and men are at higher risk for HPV-related cancers.
- Low-risk HPVs can cause genital warts or abnormal cells in the cervix, vulva, vagina, penis, and anus that do not cause cancer.
- Most people with HPV don't get cancer or warts.
- HPV is transmitted by skin touching skin. It is mostly spread through vaginal sex (penis in vagina) or anal sex (penis in anus). HPV can also be spread through oral sex (mouth on penis, vagina, or anus), sex toys, and rubbing sex organs together. People of any sexual orientation can give HPV to their partners.

- Condoms protect some but not 100%. The infection can be on skin that is not covered by the condom.
- Most HPV infections show no symptoms. Most people don't know they have HPV.
- Most HPV infections go away on their own. Most infections don't need treatment.
- Someone can have HPV for years before it causes any health problems.
- Partners often have the same strain of HPV infection. It's not likely you can be re-infected with the same strain again. However, you can have more than one strain at a time.
- Pap smears test for HPV abnormal cells in the cervix (opening of the uterus). Regular pap smears reduce the risk of cervical cancer because problems are caught early. Doctors recommend women of all sexual orientations get Pap smears at age 21 or within 3 years of becoming sexually active. If results are normal for 3 years in a row, the test can then be done every 2-3 years.
- Men or women who have receptive anal sex might ask their doctor about anal Pap smears.
- There is no test to check your HPV status. Women only know they have HPV after an abnormal Pap smear. Doctors diagnose genital warts by looking at the area.
- High-risk HPV does not cause infertility or problems with pregnancy. Genital warts may grow during pregnancy but don't usually cause problems giving birth.
- There is no test for men, so they only need to see a doctor if they bumps on or near their penis, testicles or anus.
- Genital warts can be removed. Treatment can stop abnormal cells in the cervix (opening of the uterus), vagina, vulva (outside "lips" of the vagina), penis, and anus from turning into cancer.
- Treatments don't kill the virus, so warts and abnormalities can come back.
- A vaccine may protect against strains of HPV that cause most cancers and warts. Both women and men can get the vaccine. The vaccine is controversial and patients should weigh the risks and benefits of any medical or pharmaceutical choice.

Appendix D - Interview Schedule for Females With Serious HPV Vaccine Side Effects

Vaccination

Why did you decide to get vaccinated with Gardasil or Cervarix?

How do you feel about your decision?

Tell me about the side effects you experienced after Gardasil or Cervarix.
- How certain are you that these health problems are due to Gardasil or Cervarix?
- Does your doctor agree these health problems are due to Gardasil or Cervarix?

Did you feel any different about your body after getting vaccinated? Did you feel any different about your cervix after getting vaccinated?

How did you feel about your HPV risk after getting vaccinated? What about your cervical cancer risk?

What is your opinion on HPV vaccines? What would you tell a friend who wanted to get Gardasil or Cervarix?

HPV Diagnosis

Is your current doctor a man or a woman? At your doctor's office, do you usually see a male nurse or a female nurse?

If diagnosed with HPV/genital warts:

You were diagnosed with HPV/genital warts. Had you ever heard of HPV or genital warts before you diagnosis?
- If so, where? What did you know?
- Did you feel at risk for HPV or genital warts?
  - How would you describe this feeling of risk?

Did your current doctor diagnose you? If not, was that doctor a man or a woman?

How did your doctor describe your diagnosis to you?
- What did your doctor tell you about HPV/genital warts?
- Did your doctor give you any written information or pamphlets when you were diagnosed?

How did you feel about being diagnosed?
- How did you feel about your body after your diagnosis?

If cervical HPV:

Did your diagnosis change how you think or feel about your cervix?
How did you think or feel about your cervix after being diagnosed?

Did your doctor tell you anything about cervical cancer? What did she/he tell you?
After diagnosis, did you feel at risk for cervical cancer?
How much did you feel at risk?

1. No risk, a little, some, a lot

How would you describe this feeling of risk?

After your diagnosis, did you look for information about HPV/genital warts? If so, where?

Did your doctor give you any advice about your sexual partner(s)?

If respondent reports male partners:

Did your doctor tell you about HPV in men?

If respondent reports both male and female partners:

Was your doctor's advice different for male versus female partners?

If respondent had a partner at time of diagnosis:

Did you tell your partner about your diagnosis? Why or why not?
How did you feel about your partner's risk for HPV? For cancer?

If respondent told partner:

Did your partner feel at risk for HPV? For cancer?

If respondent had an abnormal pap but was not diagnosed with HPV:

Did your current doctor diagnose you? If not, was that doctor a man or a woman?

How did your doctor describe your diagnosis to you?

What did your doctor tell you about abnormal pap smears?
Did your doctor give you any written information or pamphlets when you were diagnosed?

How did you feel about being diagnosed?
How did you feel about your body after your diagnosis?

Did your diagnosis change how you think or feel about your cervix?

How did you think or feel about your cervix after being diagnosed?

Did your doctor tell you anything about cervical cancer? What did she/he tell you?
After diagnosis, did you feel at risk for cervical cancer?
How much did you feel at risk?
2. No risk, a little, some, a lot
How would you describe this feeling of risk?

HPV Information Sources and Perspective

Generally, what do you know about HPV?

You said you have learned about HPV from Source 1, Source, 2, Source 3, etc.

Ask detail about each source marked:

What was the doctor or nurse's gender?
Which family members or friends?
Which Gardasil or Cervarix ads? TV, magazines, etc.?
Which websites?
What classes in school?
What books?
What news sources?
Where did you get Gardasil or Cervarix pamphlets?
Other?

Which of these sources was most important in learning about HPV?

How did this source make you feel about your risk for HPV?
How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?
How would you describe these feelings of risk?

Which of these sources was second most important in learning about HPV?

How did this source make you feel about your risk for HPV?
How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?
How would you describe these feelings of risk?

Which of these sources was third most important in learning about HPV?

How did this source make you feel about your risk for HPV?
How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?
How would you describe these feelings of risk?

In your opinion, how big of a health problem is HPV for society? For women? For men?

<u>Gardasil Information Sources and Perspective</u>

Generally, what do you know about Gardasil?

You said you have learned about Gardasil from Source 1, Source, 2, Source 3, etc. What do you remember learning from Source 1, Source 2, Source 3, etc.?

Ask detail about each source marked:

- What was the doctor or nurse's gender?
- Which family members or friends?
- Which Gardasil ads? TV, magazines, etc.?
- Which websites?
- What classes in school?
- What books?
- What news sources?
- Where did you get Gardasil pamphlets?
- Other?

Which of these sources was most important in learning about Gardasil?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was second most important in learning about Gardasil?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

Which of these sources was third most important in learning about Gardasil?

How did this source make you feel about your risk for HPV?

How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?

How would you describe these feelings of risk?

If discussed Gardasil with a doctor/nurse and says this was one of three most important sources, add these questions to those above. If doctor/nurse not one of three most important, ask these questions next:

What did your doctor/nurse tell you about Gardasil?
Did they recommend Gardasil?
In this conversation, did your doctor make you feel at risk for HPV? For cervical cancer?
How would you describe this feeling of risk?

What is your perspective on Gardasil?
What do you see as Gardasil's benefits?
What do you see as Gardasil's drawbacks?
Do you think boys and men should be vaccinated with Gardasil? Why or why not?

<u>Cervarix Information Sources and Perspective</u>
Generally, what do you know about Cervarix?

You said you have learned about Cervarix from Source 1, Source, 2, Source 3, etc. What do you remember learning from Source 1, Source 2, Source 3, etc.?
Ask detail about each source marked:
What was the doctor or nurse's gender?
Which family members or friends?
Which Cervarix ads? TV, magazines, etc.?
Which websites?
What classes in school?
What books?
What news sources?
Where did you get Cervarix pamphlets?
Other?

Which of these sources was most important in learning about Cervarix?
How did this source make you feel about your risk for HPV?
How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?
How would you describe these feelings of risk?

Which of these sources was second most important in learning about Cervarix?
How did this source make you feel about your risk for HPV?
How would you describe these feelings of risk?
How did this source make you feel about your risk for cervical cancer?
How would you describe these feelings of risk?

Which of these sources was third most important in learning about Cervarix?
How did this source make you feel about your risk for HPV?
How would you describe these feelings of risk?

How did this source make you feel about your risk for cervical cancer?
How would you describe these feelings of risk?

What is your perspective on Cervarix?
What do you see as Cervarix's benefits?
What do you see as Cervarix's drawbacks?

If discussed Cervarix with a doctor or healthcare worker:
What did your doctor tell you about Cervarix?
Did they recommend Cervarix?
Did this make you feel at risk for HPV? For cervical cancer?
How would you describe this feeling of risk?

Reflection
What would you like to see in terms of HPV and/or Gardasil education?

What do you wish young women would know about HPV?

What do you wish young women would know about HPV vaccines?

What do you wish young men would know about HPV?

What do you wish young men would know about HPV vaccines?

Is there anything else you think is relevant to this study?

Do you have any questions?

Appendix E – List of YouTube Videos

https://www.youtube.com/watch?v=CHEONE0RKvY
https://www.youtube.com/watch?v=VzEgeCw-EAw
https://www.youtube.com/watch?v=v3oVH4SMvbQ
https://www.youtube.com/watch?v=6UHy-EkK2xo
https://www.youtube.com/watch?v=hD5TnDtGKYw
https://www.youtube.com/watch?v=Jp_4bkrFmVg
https://www.youtube.com/watch?v=XbEsTLX-Fmo&list=PLFD715CBB1FE1FF95

Tables

Table 1**: Potential Autoimmune Disorder Adverse Events Comparing Gardasil to "Placebo"**

Conditions	GARDASIL (N = 10,706)	AAHS Control* or Saline Placebo (N = 9,412)
	n (%)	n (%)
Arthralgia/Arthritis/Arthropathy**	120 (1.1)	98 (1.0)
Autoimmune Thyroiditis	4 (0.0)	1 (0.0)
Celiac Disease	10 (0.1)	6 (0.1)
Diabetes Mellitus Insulin-dependent	2 (0.0)	2 (0.0)
Erythema Nodosum	2 (0.0)	4 (0.0)
Hyperthyroidism***	27 (0.3)	21 (0.2)
Hypothyroidism†	35 (0.3)	38 (0.4)
Inflammatory Bowel Disease‡	7 (0.1)	10 (0.1)
Multiple Sclerosis	2 (0.0)	4 (0.0)
Nephritis¶	2 (0.0)	5 (0.1)
Optic Neuritis	2 (0.0)	0 (0.0)
Pigmentation Disorder§	4 (0.0)	3 (0.0)
Psoriasis#	13 (0.1)	15 (0.2)
Raynaud's Phenomenon	3 (0.0)	4 (0.0)
Rheumatoid Arthritis††	6 (0.1)	2 (0.0)
Scleroderma/Morphea	2 (0.0)	1 (0.0)
Stevens-Johnson Syndrome	1 (0.0)	0 (0.0)
Systemic Lupus Erythematosus	1 (0.0)	3 (0.0)
Uveitis	3 (0.0)	1 (0.0)
All Conditions	245 (2.3)	218 (2.3)

*AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate
**Arthralgia/Arthritis/Arthropathy includes the following terms: Arthralgia, Arthritis, Arthritis reactive, and Arthropathy
***Hyperthyroidism includes the following terms: Basedow's disease, Goiter, Toxic nodular goiter, and Hyperthyroidism
†Hypothyroidism includes the following terms: Hypothyroidism and thyroiditis
‡Inflammatory bowel disease includes the following terms: Colitis ulcerative, Crohn's disease, and Inflammatory bowel
disease
¶Nephritis includes the following terms: Nephritis, Glomerulonephritis minimal lesion, Glomerulonephritis proliferative

§Pigmentation disorder includes the following terms: Pigmentation disorder, Skin depigmentation, and Vitiligo
#Psoriasis includes the following terms: Psoriasis, Pustular psoriasis, and Psoriatic arthropathy
††Rheumatoid arthritis includes juvenile rheumatoid arthritis. One woman counted in the rheumatoid arthritis group
reported rheumatoid arthritis as an adverse experience at Day 130.
N = Number of individuals enrolled
n = Number of individuals with specific new Medical Conditions
NOTE: Although an individual may have had two or more new Medical Conditions, the individual is counted only once
within a category. The same individual may appear in different categories.
****Reproduced from Merck & Co, Inc. Gardasil Package Insert, 2009, p. 10, Table 9. Originally entitled Summary of
Girls and Women 9 Through 26 Years of Age Who Reported an Incident Condition Potentially Indicative of a Systemic
Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL, Regardless of Causality.

Table 2*. Increased Risk of CIN2/3 Among HPV-Positive Participants

		Endpoint	HPV 6/11/16/18 CIN 2/3 or worse
Gardasil™	**N=2717**	N (subgroup)	156
		Number of cases	31
		PY at risk	278.9
		Incidence Rate per 100 person years at risk	11.1
Placebo	**N=2725**	N (subgroup)	137
		Number of cases	19
		PY at risk	247.1
		Incidence Rate per 100 person years at risk	7.7
		Observed Efficacy	-0.446
		95% CI	<0.0,8.5%

*Reproduced from VRBPAC Background Document: Gardasil™ HPV Quadrivalent Vaccine, May 18, 2006 VRBPAC Meeting, p. 13
Originally entitled: Table 17. Study 013: Applicant's analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among
subjects who were PCR positive and seropositive for relevant HPV types at day 1. [From original BLA, study 013 CSR, Table 11-88, p. 636]

Table 3: Adverse Events Experienced by Survey/Interview Participants

	Neurological	Gastrointestinal	Autoimmune	Reproductive	Muscular	Dermatological	Other
1	Seizures Brain fog Encephalitis Personality changes Traumatic brain injury				Muscle pain	Skin rashes	Sleep problems Weight loss
2	Peripheral neuropathy in feet Peripheral vision loss in left eye Syncope with paraplegia	Fatty liver Gastroenteritis Ulcerative colitis Vomiting	Joint pain Peripheral neuropathy	Ovarian failure Amenorrhea	Muscle pain	Fungal rashes Folliculitis	Orthostatic hypotension Blisters in mouth Difficulty breathing Fever
3	Migraines Visual problems Seizures Atypical Guillian-Barre syndrome Numbness in legs Syncope Swelling at base of skull Sensitivity to sound Personality changes	Gastroparesis	Atypical Guillian-Barre syndrome	Changes in menstrual cycle	Difficulty walking	Skin rashes	Weight loss Changes in voice Adrenal exhaustion Aluminum poisoning New food/medicine intolerances Epstein Barr Virus Incontinence
4	Seizures Severe headaches Memory loss Syncope Sensitivity to light and sound				Weakness		Asthma Sleep problems
5	Acute disseminated encephalomyelitis Transferse myelitis Numbness & tingling in legs Headaches	Nausea	Acute disseminated encephalomyelitis Transverse myelitis		Back pain Muscle weakness Inability to walk without support		

6		Ulcerative colitis	Ulcerative colitis				
7	Migraines Numbness throughout body “MS-like symptoms”	Ulcerative colitis Nausea Bloody stool	Ulcerative colitis Joint pain		Muscle tremors		Fever Weight loss Infection

Table 4: Adverse Events Experienced by YouTube Participants

	Neurological	Gastrointestinal	Autoimmune	Reproductive	Muscular	Dermatological	Other
1	Seizures Syncope Personality changes Paralysis Migraines				Muscle pain		Weight loss
2	Numbness in legs Dizziness	Nausea Vomiting			Muscle pain Muscle inflammation	Skin rashes	Difficulty breathing Fatigue
3	Headaches Seizures						Fatigue
4	Dizziness Tingling in legs		Joint pain	Possible mass on uterus Possible ovarian issues			Fatigue Pain in hips, pelvis, & legs Severely compromised immune system Hypothyroid Fibromyalgia Epstein-Barr Virus
5	Dizziness						Fatigue Possible Fibromyalgia

Table 5: Causal Conditions and Expected Impact on Outcomes

Causal Condition		Expected Impact on Outcomes
Q1: Drug & Disease Education		
learndr	Learned about HPV or Gardasil from participant's doctor	Present or Absent
learnfamily	Learned about HPV or Gardasil from participant's mother	Present or Absent
learnfriends	Learned about HPV or Gardasil from friends	Present or Absent
learngardads	Learned about HPV or Gardasil from Gardasil advertisements	Present
learngardpamph	Learned about HPV or Gardasil from Gardasil pamphlets	Present
Q2: Social Influence		
learndr	Learned about HPV or Gardasil from participant's doctor	Present or Absent
learnfam	Learned about HPV or Gardasil from participant's mother	Present or Absent
learnfriends	Learned about HPV or Gardasil from friends	Present or Absent
friendfamcancerhpv	Friend or family member has been diagnosed with HPV, genital warts or HPV-related cancer	Present
friendfamvax	Friend or family member has received the Gardasil vaccine	Present
Q3: Perception and Experience of Risk		
everatrisk	Indicated ever feeling at risk for HPV or cervical cancer	Present
friendfamcancerhpv	Friend or family member has been diagnosed with HPV, genital warts or HPV-related cancer	Present
hpvdiagnosis	HPV, genital warts or HPV-related cancer diagnosis	Present
sideeffectworry	Ever worried or warned by friend or family about Gardasil safety	Absent

Table 6: Truth Table 1

hpvdiag	friendfamcancer	everatrisk	sideeffectworry	Frequency	PositiveOpinion	Raw Consistency
0	1	1	1	1	1	1.000
1	1	0	0	1	1	1.000
1	1	1	0	1	1	1.000
0	1	0	1	2	1	1.000
0	0	0	1	6	1	0.833
1	1	1	1	2	0	0.500
0	0	1	1	4	0	0.500
0	0	0	0	4	0	0.250
0	1	1	0	1	0	0.000

Table 7: Truth Table 2

hpvdiag	friendfamcancer	everatrisk	sideeffectworry	Frequency	Vaccinated	Raw Consistency
0	1	1	0	1	1	1.000
0	1	1	1	1	1	1.000
1	1	0	0	1	1	1.000
1	1	1	0	1	1	1.000
0	1	0	1	2	1	1.000
1	1	1	1	2	1	1.000
0	0	1	1	4	1	1.000
0	0	0	1	6	1	1.000
0	0	0	0	4	0	0.250

Table 8: Truth Table 3

learndr	learnfamily	learnfriend	friendfamcancer	friendfamvax	Frequency	PositiveOpinion	Raw Consistency
1	0	0	0	1	1	1	1.000
1	0	0	1	1	1	1	1.000
1	0	1	0	0	1	1	1.000
1	0	1	0	1	1	1	1.000
1	1	1	0	1	1	1	1.000
1	1	1	1	0	1	1	1.000
1	1	1	1	1	1	1	1.000
1	1	0	1	1	2	1	1.000
1	1	0	0	1	5	0	0.600
1	0	0	0	0	2	0	0.500
1	0	1	1	1	2	0	0.500
1	0	0	1	0	1	0	0.000
0	0	0	0	0	3	0	0.000

Table 9: Truth Table 4

learndr	learnfamily	friendfamvax	learnfriend	friendfamcancer	Frequency	Vaccinated	Raw Consistency
1	0	0	0	1	1	1	1.000
1	0	0	1	0	1	1	1.000
1	0	1	0	0	1	1	1.000
1	0	1	0	1	1	1	1.000
1	0	1	1	0	1	1	1.000
1	1	0	1	1	1	1	1.000
1	1	1	1	0	1	1	1.000
1	1	1	1	1	1	1	1.000
1	0	0	0	0	2	1	1.000
1	0	1	1	1	2	1	1.000
1	1	1	0	1	2	1	1.000
1	1	1	0	0	5	1	1.000
0	0	0	0	0	3	0	0.000

Table 10: Truth Table 5

learndr	learnfamily	learnfriend	learngardpamph	learngardads	Frequency	PositiveOpinion	Raw Consistency
1	1	1	0	1	1	1	1.000
1	0	0	0	1	2	1	1.000
1	0	1	0	1	2	1	1.000
1	1	1	1	1	2	1	1.000
1	1	0	0	1	6	1	0.833
1	0	0	1	1	2	0	0.500
1	0	1	1	1	2	0	0.500
0	0	0	0	0	1	0	0.000
1	0	0	0	0	1	0	0.000
1	1	0	1	1	1	0	0.000
0	0	0	0	1	2	0	0.000

Table 11: Truth Table 6

learndr	learnfamily	learnfriend	learngardpamph	learngardads	Frequency	Vaccinated	Raw Consistency
0	1	0	0	0	1	1	1.000
1	1	1	0	1	1	1	1.000
1	1	1	1	0	1	1	1.000
1	1	0	0	0	2	1	1.000
1	1	0	0	1	2	1	1.000
1	1	0	1	0	2	1	1.000
1	1	0	1	1	2	1	1.000
1	1	1	1	1	2	1	1.000
1	1	1	0	0	6	1	1.000
0	0	0	0	0	1	0	0.000
1	0	0	0	0	2	0	0.000

Table 12: Analysis 1

Outcome: positiveopinion
Causal Conditions: learndr, learnfamily, learnfriend, learngardpamphlet, learngardads
Assumptions: learngardads (present), learngardpamphlet (present)
Prime Implicants: None
Diversity Index: 13/32 (40.6%)

	Raw Coverage	Unique Coverage	Consistency
LEARNGARDADS*LEARNDR	0.947	0.737	1.000
learnfriend*learnfamily*LEARNDR	0.263	0.053	1.000

Solution Coverage: 1.000
Solution Consistency: 1.000

Table 13: Analysis 2

Outcome: vaccinated
Causal Conditions: learndr, learnfamily, learnfriend, learngardpamphlet, learngardads
Assumptions: learngardads (present), learngardpamphlet (present)
Prime Implicants: None
Diversity Index: 11/32 (34.4%)

	Raw Coverage	Unique Coverage	Consistency
LEARNGARDADS*learngardpamphlet*LEARNDR	0.714	0.643	0.909
LEARNGARDADS*LEARNFRIEND*LEARNFAMILY*LEARNDR	0.214	0.143	1.000

Solution Coverage: 0.857
Solution Consistency: 0.923

Table 14: Analysis 3

Outcome: positiveopinion
Causal Conditions: learndr, learnfamily, learnfriend, friendfamcancerhpv, friendvamvax
Assumptions: friendfamcancerhpv (present), friendfamvax (present)
Prime Implicants: LEARNDR*LEARNFAM*LEARNFRIEND*FRIENDFAMVAX
Diversity Index: 13/32 (40.6%)

	Raw Coverage	Unique Coverage	Consistency
friendfamcancerhpv*LEARNFRIEND*learnfamily*LEARNDR	0.143	0.143	1.000
learnfriend*FRIENDFAMVAX*learnfamily*LEARNDR	0.143	0.143	1.000
friendfamcancerhpv*LEARNFRIEND*learnfamily*LEARNDR	0.143	0.143	1.000

Solution Coverage: 0.428
Solution Consistency: 1.000

Table 15: Analysis 4

Outcome: vaccinated
Causal Conditions: learndr, learnfamily, learnfriend, friendfamcancerhpv, friendvamvax
Assumptions: friendfamcancerhpv (present), friendfamvax (present)
Prime Implicants: None
Diversity Index: 13/32 (40.6%)

	Raw Coverage	Unique Coverage	Consistency
FRIENDFAMVAX*LEARNDR	0.737	0.421	1.000
learnfamily*LEARNDR	0.474	0.211	1.000
FRIENDFAMCANCERHPV*LEARNFRIEND*LEARNDR	0.211	0.053	1.000

Solution Coverage: 1.000
Solution Consistency: 1.000

Table 16: Analysis 5

Outcome: positiveopinion
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectworry
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectworry (absent)
Prime Implicants: None
Diversity Index: 9/16 (56.3%)

	Raw Coverage	Unique Coverage	Consistency
everatrisk*SIDEEFFECTWORRY	0.500	0.357	0.875
HPVDIAGNOSIS*FRIENDFAMCANCERHPV*sideeffectworry	0.143	0.142	1.000
hpvdiagnosis*FRIENDFAMCANCERHPV*SIDEEFFECTWORRYY	0.214	0.071	1.000

Solution Coverage: 0.714
Solution Consistency: 0.909

Table 17: Analysis 6

Outcome: vaccinated
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectworry
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectworry (absent)
Prime Implicants: None
Diversity Index: 9/16 (56.3%)

	Raw Coverage	Unique Coverage	Consistency
SIDEEFFECTWORRY	0.789	0.631	1.000
HPVDIAGNOSIS*FRIENDFAMCANCERHPV	0.210	0.052	1.000
FRIENDFAMCANCERHPV*EVERATRISK	0.263	0.052	1.000

Solution Coverage: 0.947
Solution Consistency: 1.000

Table 18: Analysis 7

Outcome: positiveopinion
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectconcern
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectconcern (absent)
Prime Implicants: ~EVERATRISK*FRIENDFAMCANCERHPV
Diversity Index: 9/16 (56.3%)

	Raw Coverage	Unique Coverage	Consistency
~EVERATRISK*~SIDEEFFECTCONCERN	0.500	0.357	0.778
FRIENDFAMCANCERHPV*~EVERATRISK	0.214	0.714	1.000
HPVDIAG*FRIENDFAMCANCER*~SIDEEFFECTCONCERN	0.143	0.714	1.000

Solution Coverage: 0.643
Solution Consistency: 0.818

Table 19: Analysis 8

Outcome: vaccinated
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectconcern
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectconcern (absent)
Prime Implicants: None
Diversity Index: 10/16 (62.5%)

	Raw Coverage	Unique Coverage	Consistency
~SIDEEFFECTCONCERN	0.737	0.316	0.933
FRIENDFAMCANCERHPV	0.421	0.053	1.000
EVERATRISK	0.474	0.053	1.000

Solution Coverage: 0.947
Solution Consistency: 0.947

Table 20: Analysis 9

Outcome: positiveopinion
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectwarn
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectwarn (absent)
Prime Implicants: SIDEEFFECTWARN*FRIENDFAMCANCERHPV,
~SIDEEFFECTWARN*EVERATRISK*~FRIENDFAMCANCERHPV
Diversity Index: 9/16 (56.3%)

	Raw Coverage	Unique Coverage	Consistency
~HPVDIAG*SIDEEFFECTWARN	0.357	0.357	0.933
HPVDIAG*FRIENDFAMCANCERHPV*~SIDEEFFECTWARN	0.143	0.143	1.000
~HPVDIAG*FRIENDFAMCANCERHPV*~EVERATRISK	0.143	0.143	1.000

Solution Coverage: 0.643
Solution Consistency: 1.000

Table 21: Analysis 10

Outcome: vaccinated
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectwarn
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectwarn (absent)
Prime Implicants: ~SIDEEFFECTWARN*EVERATRISK*~HPVDIAG
Diversity Index: 9/16 (56.3%)

	Raw Coverage	Unique Coverage	Consistency
FRIENDFAMCANCERHPV	0.421	0.158	1.000
EVERATRISK	0.474	0.158	1.000
SIDEEFFECTWARN	0.368	0.211	1.000

Solution Coverage: 0.842
Solution Consistency: 1.000

Table 22: Analysis 11

Outcome: positiveopinion
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectconcern, sideeffectwarn
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectconcern (absent) sideeffectwarn (absent)
Prime Implicants: ~SIDEEFFECTWARN*HPVDIAG, SIDEEFFECTWARN*~FRIENDFAMCANCERHPV
Diversity Index: 14/32 (43.8%)

	Raw Coverage	Unique Coverage	Consistency
~SIDEEFFECTCONCERN*SIDEEFFECTWARN	0.357	0.071	0.778
~HPVDIAG*SIDEEFFECTWARN	0.357	0.071	1.000
HPVDIAG*FRIENDFAMCANCERHPV*~SIDEEFFECTWARN	0.143	0.071	1.000
FRIENDFAMCANCERHPV*~EVERATRISK*~SIDEEFFECTWARN	0.214	0.143	1.000

Solution Coverage: 0.714
Solution Consistency: 1.000

Table 23: Analysis 12

Outcome: vaccinated
Causal Conditions: hpvdiagnosis, friendfamcancerhpv, everatrisk, sideeffectconcern, sideeffectwarn
Assumptions: hpvdiagnosis (present), friendfamcancerhpv (present), everatrisk (present), sideeffectconcern (absent), sideeffectwarn (absent)
Prime Implicants: None
Diversity Index: 14/32 (43.8%)

	Raw Coverage	Unique Coverage	Consistency
~SIDEEFFECTCONCERN	0.500	0.357	0.933
FRIENDFAMCANCERHPV	0.214	0.714	1.000
EVERATRISK	0.143	0.714	1.000
SIDEEFFECTWARN	0.368	0.053	1.000

Solution Coverage: 1.0
Solution Consistency: 0.95

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