

AN INTERDISCIPLINARY ARGUMENT TO LOWER THE AGE OF CONSENT FOR
THE HUMAN PAPILLOMAVIRUS VACCINE

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Dedication

This thesis is dedicated to my parents, Dan and Karen, and my sisters, Kaitlin and Molly.

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INTRODUCTION

“Our children are basically guinea pigs in this grotesque experiment because so much is not yet know [sic] about the effects of this new vaccine.”¹

“[W]e just don’t trust it. Knowing that Merck, you know, the makers of Vioxx, developed it doesn’t help.”²

“There is no history for Gardasil. It hasn’t been around long enough for that. Are doctors and Big Pharma infallible? I don’t think so, and I don’t think my doctor’s word is gospel.”³

“If you have a daughter . . . DO NOT allow yor [sic] child to have this vaccine, it is dangerous and could cause death, paralysis, suffocation, seizures, lupis [sic], and Gillian Barre syndrom [sic] which mimicks [sic] MS!!!”⁴

“While an HPV vaccine may be a smart health choice for some, my choice to vaccinate my hypothetical child or not does not have the same impact on YOUR hypothetical child’s safety as it does with illnesses like polio, measles [sic], diphtheria [sic], and other mandatory vaccinating diseases.”⁵

¹ cags2606, Comment to *Why Aren’t More Girls Getting the HPV Vaccine?*, RH REALITY CHECK (May 9, 2012, 4:00 AM), <http://rhrealitycheck.org/article/2012/05/09/why-arent-more-girls-getting-hpv-vaccine/#comment-794749645>.

² anonymous99, Comment to *Why Aren’t More Girls Getting the HPV Vaccine?*, RH REALITY CHECK (May 9, 2012, 4:00 AM), <http://rhrealitycheck.org/article/2012/05/09/why-arent-more-girls-getting-hpv-vaccine/#comment-794749650>. Vioxx was a painkiller manufactured by Merck and initially approved by the FDA. Vioxx was later withdrawn from the market after it was found to greatly increase the risk of heart problems and even death. Estimates suggest Vioxx use was linked to thousands of heart attacks and deaths. See Snigdha Prakash & Vikki Valentine, *Timeline: The Rise and Fall of Vioxx*, NAT’L PUB. RADIO (Nov. 10, 2007, 2:40 PM), <http://www.npr.org/templates/story/story.php?storyId=5470430>.

³ bess, Comment to *Why Aren’t More Girls Getting the HPV Vaccine?*, RH REALITY CHECK (May 9, 2012, 4:00 AM), <http://rhrealitycheck.org/article/2012/05/09/why-arent-more-girls-getting-hpv-vaccine/#comment-794749666>.

⁴ Nancy Jones, Comment to Amanda Froelich, *It’s Official: 139 Girls Have Died from HPV Vaccinations*, TRUE ACTIVIST (Oct. 13, 2013, 3:13 PM), <http://www.trueactivist.com/its-official-139-girls-have-died-from-hpv-vaccinations/>.

⁵ maiac, Comment to *Why Aren’t More Girls Getting the HPV Vaccine?*, RH REALITY CHECK (May 9, 2012, 4:00 AM), <http://rhrealitycheck.org/article/2012/05/09/why-arent-more-girls-getting-hpv-vaccine/#comment-794749670>. This statement is somewhat misguided. Although HPV is not transmitted through casual contact like other diseases frequently vaccinated against such as the flu, measles, mumps, and rubella, an individual’s decision whether or not to get the

“[A] vaccine that has been around since 2006 has NOT stood the test of time in terms of long term effects. There is no damn way I am letting a pharmaceutical company tell me that THEIR studies show that it is ‘safe’ when they stand to make \$600 off of me Ever heard of the fox and the chicken house? They think I am stupid and have all of you little minions telling me how foolish I am for refusing a ‘life saving vaccination’ because of my ‘ignorance’ and ‘fear.’”⁶

“I don’t want my daughter to act irresponsibly or suffer unknown side effects.”⁷

“She told me that her little daughter took [the HPV] vaccine . . . and she suffered from mental retardation thereafter. . . . There is no second chance for these little girls if there is any dangerous consequences to their bodies.”⁸

“Our students shouldn’t be forced to [receive the HPV vaccine]. It’s not an airborne disease and abstinence works every time.”⁹

HPV vaccine *does* affect others, as suggested by recent studies on herd immunity and the vaccine. See, e.g., Jessica A. Kahn et al., *Vaccine-Type Human Papillomavirus and Evidence of Herd Protection After Vaccine Introduction*, 130 PEDIATRICS e249 (2012) [hereinafter Kahn et al., *Vaccine-Type HPV*]; Sepehr N. Tabrizi et al., *Assessment of Herd Immunity and Cross-Protection After Human Papillomavirus Vaccination Programme in Australia: A Repeat Cross-Sectional Study*, 14 LANCET INFECTIOUS DISEASES 958 (2014).

⁶ Tracey Seth, Comment to *Why Some Parents are Refusing HPV Vaccine for their Children*, SHOT OF PREVENTION (Aug. 21, 2013, 10:31 PM), <http://shotofprevention.com/2013/08/20/why-some-parents-are-refusing-hpv-vaccine-for-their-children/>.

⁷ Donna T. Chen et al., *The HPV Vaccine and Parental Consent*, 14 AM. MED. ASS’N J. ETHICS 5, 5 (2012).

⁸ Carrie Gann, *Michele Bachmann’s HPV Vaccine Safety and ‘Retardation’ Comments Misleading, Doctors Say*, ABC NEWS, Sept. 14, 2011, <http://abcnews.go.com/Health/Wellness/michele-bachmanns-hpv-vaccine-safety-retardation-comments-misleading/story?id=14516625> (quoting former Representative Michele Bachmann (R-Minn.)).

⁹ This quote, by South Carolina Senator Shane Martin, expressed Martin’s opposition to a South Carolina Senate bill that allowed, but did not require, the state to offer free HPV vaccines to young people entering seventh grade. The bill did not *mandate* the vaccine for students entering seventh grade, it merely sought to increase the vaccine’s accessibility and affordability. Martha Kempner, *South Carolina Senate Committee Approves HPV Vaccine Bill, Amid Opposition*, RH REALITY CHECK (May 19, 2014, 10:07 AM), <http://rhrealitycheck.org/article/2014/05/19/south-carolina-senate-committee-approves-hpv-vaccine-bill-amid-opposition/>.

“I wanted to get [the HPV vaccine] but my mom refused because she thinks I’m not sexually active. . . . I’m pretty sure I will have sex when I get in college and I think I won’t be able to pay for the vaccine I just want to have a safe sex life.”¹⁰

“I bet if we put out an Ebola virus vaccine tomorrow, half of this country would take it, even though it hasn’t killed anyone who hasn’t traveled [to the affected countries]. Yet you can’t get parents to give their children an HPV vaccine to prevent [sic] a virus that kills 4,000 citizens a year.”¹¹

“[Political and public opposition to the vaccine] speaks volumes about how the anti sex anti choice brigade feels about women. That unapproved sex should be punished with a pregnancy and even death. they are willing to put their daughters healths [sic] and lives at risk because they’re so terrified of female sexuality. . . . To deliberately put your child’s [sic] health at risk because you think your daughter’s chastity [sic] is more important than her potential health is [] disgusting.”¹²

“With early vaccination and regular screening, we can prevent cervical cancer. . . . Whether you are Republican or Democrat, conservative or liberal, the science behind these vaccines is indisputable.”¹³

“The policy paradox left unsaid is that United States laws allow minors to independently gain access to treatment for sexually transmitted diseases, but only California has passed laws to obtain the HPV vaccine without parental consent. This is more than a matter of public policy; it is about the rights of youths to independently consent to HPV vaccination. . . . [I]t is

¹⁰ *How to Get My Mom to Let me Get a HPV Vaccination?*, YAHOO! ANSWERS: PREGNANCY & PARENTING—ADOLESCENT, <https://answers.yahoo.com/question/index?qid=20130525191006AAwubci> (last visited Feb. 18, 2015).

¹¹ Liz Szabo, *Voices: Even Germaphobes Don’t Need to Fear Ebola*, USA TODAY (Oct. 3, 2014, 2:31 PM), <http://www.usatoday.com/story/news/nation/2014/10/02/ebola-risks-in-perspective/16589979/> (quoting Dr. Paul Offit, Chief of Infectious Diseases at Children’s Hospital of Philadelphia).

¹² Pinkladyapple, Comment to Kempner, *supra* note 9.

¹³ Szabo, *supra* note 11 (quoting Dr. Mark Einstein, director of gynecologic oncology at Montefiore Medical Center in New York City).

about their rights to quality health and health care, optimal survival, and a voice and participation in health decisions.”¹⁴

“Human papillomavirus — or HPV — is the most common sexually-transmitted disease in the U.S., with the CDC reporting 79 million current infections and 14 million new infections each year. I account for one of those numbers. Every day, I live with the knowledge that I could someday develop cervical cancer, and I could have prevented this risk by accepting a recommended vaccine that I was too conservative to take. . . . Parents, please vaccinate your teens. I’m living proof that you can’t afford to ignore HPV, regardless of your opinions and fears about sexuality.”¹⁵

The previous quotations illustrate the controversy and debate surrounding the Human Papillomavirus (HPV) vaccine. Nine years after its initial approval by the United States Food and Drug Administration (FDA) for females in 2006, the debate rages on.¹⁶ The vaccine is now also approved for use in males ages nine- through twenty-six to prevent genital warts.¹⁷ The vaccine can be given starting at nine years of age and the Advisory Committee on Immunization Practices (ACIP) recommends it for girls and boys at eleven or twelve years of age to increase the likelihood the three-dose series is

¹⁴ Rita Nathawad & Jeffrey Goldhagen, Letter to the Editor, *The Discomfort Over HPV Vaccine*, N.Y. TIMES, Aug. 30, 2014, http://www.nytimes.com/2014/08/30/opinion/the-discomfort-over-hpv-vaccine.html?_r=0.

¹⁵ Mary McCoy, *Every Girl Needs the HPV Vaccine, So Why are So Many Skipping It?*, SHEKNOWS.COM (July 25, 2014), <http://www.sheknows.com/parenting/articles/1045037/this-woman-is-proof-that-every-girl-needs-the-hpv-vaccine>.

¹⁶ Eileen F. Dunne et al., *CDC Grand Rounds: Reducing the Burden of HPV-Associated Cancer and Disease*, 63 MORBIDITY & MORTALITY WKLY. REP. 69, 69 (2014) [hereinafter Dunne et al., *CDC Grand Rounds*], available at <http://www.cdc.gov/mmwr/pdf/wk/mm6304.pdf>; Lauri E. Markowitz et al., *Reduction in Human Papillomavirus (HPV) Prevalence Among Young Women Following HPV Vaccine Introduction in the United States, National Health and Nutrition Examination Surveys, 2003–2010*, 208 J. INFECTIOUS DISEASES 385, 385 (2013) [hereinafter Markowitz et al., *Reduction in HPV Prevalence Among Young Women Following HPV Vaccine Introduction in United States*].

¹⁷ News Release, FDA, FDA Approves New Indication for Gardasil to Prevent Genital Warts in Men and Boys (Oct. 16, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm187003.htm>.

complete before sexual initiation, which improves the vaccine's effectiveness.¹⁸ Despite increasing evidence of the vaccine's safety and effectiveness,¹⁹ some parents remain reluctant to vaccinate their children and some health care providers (HCPs) fail to recommend the vaccine, particularly for young male patients.²⁰ There are many possible reasons why HPV vaccination rates remain relatively low, including HCP failure to recommend and/or discuss the vaccine, the vaccine's cost, lack of patient knowledge and understanding of the disease and vaccine, and patient failure to complete the three-dose series.²¹ Because the vaccine targets young adolescents, parental consent is generally

¹⁸ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 70; Eileen F. Dunne et al., *Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males—Advisory Committee on Immunization Practices (ACIP), 2011*, MORBIDITY & MORALITY WKLY. REP. 1705 (2011) [hereinafter Dunne et al., *Recommendations on the Use of Quadrivalent HPV Vaccine in Males*], available at <http://www.cdc.gov/mmwr/pdf/wk/mm6050.pdf>.

¹⁹ See Jessica Fishman et al., *Parent and Adolescent Knowledge of HPV and Subsequent Vaccination*, 134 PEDIATRICS e1049 (2014) (finding that knowledge about the vaccine was neither associated with nor predicative of vaccination).

²⁰ See Paul M. Darden et al., *Reasons for Not Vaccinating Adolescents: National Immunization Survey of Teens, 2008–2010*, 131 PEDIATRICS 645 (2013) (finding that (1) even when physicians *do* recommend the vaccine, parents increasingly refused to consent to the HPV vaccine for their daughters and (2) concerns about the vaccine's safety grew each year during the study); Kelly L. Donahue, *Acceptability of the Human Papillomavirus Vaccine and Reasons for Non-Vaccination Among Parents of Adolescent Sons*, 32 VACCINE 3883 (2014) (finding that the most common reason for non-vaccination of adolescent boys was because the HCP failed to recommend or discuss it); Teri L. Malo et al., *Physicians' Human Papillomavirus Vaccine Recommendations in the Context of Permissive Guidelines for Male Patients: A National Study*, 23 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2126 (2014) (concluding that less than 15% of physicians surveyed “always” recommended HPV vaccine to male patients).

²¹ Dawn M. Holman et al., *Barriers to Human Papillomavirus Vaccination Among US Adolescents: A Systematic Review of the Literature*, 168 J. AM. MED. ASS'N PEDIATRICS 76 (2014). Although a series of three shots is still required, there is some evidence to suggest that one or two doses may be enough. More research is needed, however, before fewer doses are recommended in practice. See Manboobeh Safaeian et al., *Durable Antibody Responses Following One Dose of the Bivalent Human Papillomavirus L1 Virus-Like Particle Vaccine in the Costa Rica Vaccine Trial*, 6 CANCER PREVENTION RES. 1242 (2013); Alexandra Sifferlin, *Less is More: One, Instead of Three Doses of HPV Vaccine May Protect Against Cervical Cancer*, TIME (Nov. 4, 2013), <http://healthland.time.com/2013/11/04/less-is-more-one-instead-of-three-doses-of-hpv-vaccine-may-protect-against-cervical-cancer/>.

required and can be an additional barrier to vaccination.²² There are numerous reasons parents may refuse to consent, including attitudes and beliefs about the vaccine's safety²³ and concerns about its influence on adolescent sexual behavior.²⁴

This thesis examines parental refusal and/or deferral to vaccinate until a later age as a barrier to improving HPV vaccination rates among adolescents. It takes an interdisciplinary approach to analyzing and addressing this issue and emphasizes both public policy and individual rights concerns. From a public policy perspective, this thesis supports the notion that states should enact laws and regulations that encourage vaccination to promote the common good. From an individual rights perspective, it argues that states should enact laws that allow minors to exercise their autonomy and choose their own futures by providing them with the right to consent to the HPV vaccine despite parental refusal.

Part I provides background information on HPV and HPV-related diseases, the vaccine's development and approval, and vaccination rates. It then outlines parental rights and minor consent laws related to health care decisions. Part II discusses opposition to the HPV vaccine and lowering the age of consent, including a brief history of the origins of the anti-vaccination movement. Part III responds to Part II, providing medical, ethical, and policy-based arguments for lowering the age of consent. Part IV concludes that lowering the statutory age of consent is an appropriate and potentially effective approach to overcome the negative effect of parental refusal on HPV vaccination rates among adolescent males and females. Lowering the age of consent can

²² Holman et al., *supra* note 21, at 79.

²³ Darden et al., *supra* note 20, at 649.

²⁴ Holman et al., *supra* note 21, at 78.

increase vaccine availability and use and is consistent with many states' current policies related to STI treatment and diagnosis. This thesis argues that the age of consent for the HPV vaccine should be lowered to twelve years of age to allow young adolescents with non-consenting parents to receive this important and potentially life-saving vaccine.²⁵ It concludes by proposing statutory language states can consider when amending existing laws or drafting new laws to lower the age of consent for the HPV vaccine and other similar vaccines.

I. HUMAN PAPILOMAVIRUS, CANCER, AND THE VACCINE'S DEVELOPMENT

Part I provides background information about HPV and the vaccine. Part A discusses HPV's prevalence, risk factors, and consequences. Part B describes the vaccine's development, safety, efficacy, and current use. Part C then provides the legal background of parental rights and minor consent laws, describing situations in which minors are frequently allowed to consent to certain medical services despite parental refusal or non-consent.²⁶

A. HUMAN PAPILOMAVIRUS: PREVALENCE, RISK, AND CONSEQUENCES

Human papillomavirus is the most common sexually transmitted infection (STI) in the United States.²⁷ There are more than forty HPV types that can infect the genital

²⁵ This thesis limits the proposal to lowering the statutory age of consent. It is not proposing a vaccine mandate *requiring* all males and females to receive the vaccine by a certain age. Although the lower age of consent could be used in conjunction with a mandate, that is beyond the scope of this thesis.

²⁶ "Non-consent" refers to situations in which the parent is not involved in or aware of the decision, such as when a minor goes to her doctor without her parent's knowledge to receive the vaccine.

²⁷ *What is HPV?*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hpv/whatishpv.html> (last updated Feb. 5, 2013).

areas and over one hundred types that can infect the mouth and throat.²⁸ Most individuals with HPV do not know they are infected,²⁹ yet the majority of sexually active individuals will acquire HPV during their lifetime.³⁰ Recent data indicate that seventy-nine million individuals are currently infected with HPV and fourteen million are newly infected each year in the United States.³¹ Although HPV communicability is difficult to assess, experts assume it is high because of the large number of new infections each year.³² Risk factors are primarily related to sexual behavior, including number of sex partners and a sex partner's sexual history.³³ Young age (under twenty-five), age at sexual initiation, inconsistent condom use, number of pregnancies, smoking, an uncircumcised male partner, and oral contraceptive use are also considered risk factors.³⁴

HPV types are classified as “high-risk” (oncogenic) or “low-risk” (non-oncogenic).³⁵ High-risk HPV causes many types of cancer including cancers of the cervix, vagina, vulva, penis, and anus.³⁶ Low-risk HPV causes anogenital warts and recurrent papillomatosis, a rare condition in which warts grow in the throat and airway.³⁷ Although most HPV infections are clinically insignificant with few or no symptoms, persistent infection can lead to disease or cancer.³⁸ Recent studies indicate that 66% of

²⁸ *Id.*

²⁹ *Id.*

³⁰ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

³¹ *Id.*

³² CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 141 (William Atkinson et al. eds., 12th ed. 2011) [hereinafter CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES].

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 139.

³⁶ *Id.*

³⁷ *Id.*; Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

³⁸ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

cervical cancers, 55% of vaginal cancers, 79% of anal cancers, and 62% of oropharyngeal cancers are attributable to HPV types 16 or 18, two high-risk HPV strains.³⁹ From 2006 to 2010, approximately 33,200 HPV-associated cancers were diagnosed in the United States—20,600 among females and 12,600 among males.⁴⁰ The two most common types of cervical cancer worldwide are caused by HPV.⁴¹ Importantly, HPV is not one of many viruses that cause cervical cancer—it is the *only* virus that causes it.⁴² The HPV vaccine, therefore, is considered a “lifesaving breakthrough.”⁴³

Racial, ethnic, and gender disparities exist among HPV-associated cancers. Hispanic, black, and American Indian/Alaskan Native women have higher rates of cervical cancer than white women.⁴⁴ From 1999 to 2011, black women were more likely to die from cervical cancer than any other racial or ethnic group, followed by Hispanic, white, Asian/Pacific Islander, and American Indian/Alaska Native women.⁴⁵ HPV-associated vaginal cancers are slightly more common among blacks and vulvar cancers are more frequent among whites.⁴⁶ There are many possible reasons for these racial and ethnic disparities, including demographics (e.g., socioeconomic status), insurance status, screening practices, tobacco use, or other factors related to HPV infection or

³⁹ *Id.*

⁴⁰ *HPV-Associated Cancer Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/cancer/hpv/statistics/> (last updated Sept. 2, 2014).

⁴¹ CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 142.

⁴² PAUL A. OFFIT, DEADLY CHOICES: HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL 73 (2011) [hereinafter OFFIT, DEADLY CHOICES].

⁴³ *Id.*

⁴⁴ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

⁴⁵ *Cervical Cancer Rates by Race & Ethnicity—Death Rates by Race/Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/cancer/cervical/statistics/race.htm> (last updated Aug. 27, 2014).

⁴⁶ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

persistence.⁴⁷ HPV-associated oropharyngeal cancers are increasing among both men and women, but at faster rates among men.⁴⁸ HPV-associated anal cancers have also increased among both sexes and across all racial groups.⁴⁹

The connection between HPV and cervical cancer receives most of the scholarly and public attention, particularly in discussions and debates about the HPV vaccine. In 2011, approximately 4,092 women died from cervical cancer in the United States.⁵⁰ Cervical cancer used to be the leading cause of cancer death for women in the United States but its incidence and death rates have declined over the past four decades, largely a result of more women receiving regular Pap smears, which can detect cervical precancers and allow early intervention and preventive treatment.⁵¹ Increasing vaccination rates could further decrease rates of HPV and HPV-related cancers, preventing both precancers and cancers, allowing complete *prevention* rather than early detection.

⁴⁷ Xiocheng Wu et al., *Human Papillomavirus-Associated Cancers—United States, 2004–2008*, 61 MORBIDITY & MORTALITY WKLY. REP. 258, 260–61 (2012); see also Stuart Cowburn et al., *The Association Between Insurance Status and Cervical Cancer Screening in Community Health Centers: Exploring the Potential of Electronic Health Records for Population-Level Surveillance*, 10 PREVENTING CHRONIC DISEASE (Oct. 2013), http://www.cdc.gov/pcd/issues/2013/pdf/13_0034.pdf; Harold P. Freeman & Barbara K. Wingrove, *Excess Cervical Cancer Mortality: A Marker for Low Access to Health Care in Poor Communities*, NAT'L CANCER INST. CTR. TO REDUCE CANCER HEALTH DISPARITIES 5–17 (2005), <http://www.cancer.gov/aboutnci/organization/crchd/about-health-disparities/resources/excess-cervical-cancer-mortality.pdf> (outlining several risk factors for cervical cancer).

⁴⁸ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

⁴⁹ *Id.*

⁵⁰ *Cervical Cancer Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/cancer/cervical/statistics/#2> (last updated Sept. 2, 2014).

⁵¹ *Id.*

Historically, discussions about HPV focused mostly on females, but there is increasing medical and public awareness⁵² of HPV's impact on males and the potential benefits of HPV vaccination for females *and* males.⁵³ Long before HPV was identified as the causal agent for cervical cancer, patterns of sexual behavior and male involvement in HPV transmission were known to influence HPV rates.⁵⁴ Because some type of sexual intercourse (oral, anal, or vaginal) is “virtually a necessary step” for transmitting and acquiring HPV, men are frequently involved in HPV's “epidemiological chain” of infection.⁵⁵ Men act as both “carriers” and “vectors” of HPV and contribute to a partner's risk of acquiring the virus and developing an HPV-related cancer.⁵⁶ As a result, a woman's risk of acquiring HPV may “depend less on her own sexual behavior than on that of her” male partner.⁵⁷ A woman who believes she is in a monogamous relationship, for example, who has only had sex with one particular male partner, may nevertheless

⁵² See, e.g., Maria Cheng, *Michael Douglas: Oral Sex Can Cause Throat Cancer*, KOMO NEWS (June 3, 2013, 12:18 PM), <http://www.komonews.com/news/entertainment/Michael-Douglas-blames-oral-sex-for-throat-cancer-209928971.html>. Although Douglas's cancer was not caused by oral sex, his diagnosis stimulated discussion about the many causes of the cancer, including HPV transmitted via oral sex. *Id.*; see also Spring Chenoa Cooper et al., *Listen Up, Guys: You Should Get the HPV Vaccine, Too*, WASH. POST (Sept. 24, 2014), <http://www.washingtonpost.com/posteverything/wp/2014/09/24/listen-up-men-you-should-get-the-hpv-vaccine-too/> (stressing the importance of men getting the HPV vaccine and noting that “most people can get HPV-related cancers too”).

⁵³ See, e.g., Harrel W. Chesson et al., *The Cost-Effectiveness of Male HPV in the United States*, 29 VACCINE 8443 (2011) [hereinafter Chesson et al., *The Cost-Effectiveness of Male HPV in the United States*] (noting that vaccinating adolescent boys could be cost-effective, especially if female vaccination rates remain low); Elamin H. Elbasha & Erik J. Dasbach, *Impact of Vaccinating Boys and Men Against HPV in the United States*, 28 VACCINE 6858, 6866 (2010) (concluding that including boys and men in HPV vaccination programs could further reduce HPV-related morbidity and mortality, resulting in significant cost savings).

⁵⁴ Xavier Castellsague et al., *The Male Role in Cervical Cancer*, 43 SALUD PUBLICA DE MEXICO S345, S346 (2003).

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ D.G. Skegg et al., *Importance of the Male Factor in Cancer of the Cervix*, 320 LANCET 581, 581 (1982).

acquire the virus and later develop an HPV-related cancer if her male partner contracted HPV from a previous sexual partner or is currently engaging in sex with other infected individuals.⁵⁸

Although individuals should ideally know whether their partner is infected with an STI and/or whether their partner is involved in a “concurrent sexual partnership” (defined as those in which “one or both partners have other sexual partners while continuing sexual activity with the original partner”),⁵⁹ this is not always the case. In a study of ninety-six couples, Lydia Drumright and colleagues found that only twenty-six percent of individuals whose partners had concurrent partners were aware of this, an important fact to know because concurrency is associated with an increased risk of STIs.⁶⁰ Adolescents are particularly likely to be involved in concurrent relationships, ranging from twelve percent to more than sixty percent in some populations.⁶¹ For

⁵⁸ See, e.g., J.D. Buckley et al., *Case Control Study of the Husbands of Women with Dysplasia or Carcinoma of the Cervix Uteri*, 318 LANCET 1010, 1010, 1013 (1981) (finding, among a small sample, that the number of sexual partners reported by a woman’s husband was a significant risk factor for cervical epithelial abnormalities).

⁵⁹ Lydia N. Drumright et al., *Do People Really Know Their Sex Partners?: Concurrency, Knowledge of Partner Behavior, and Sexually Transmitted Infections Within Partnerships*, 31 SEXUALLY TRANSMITTED DISEASES 437, 437 (2004).

⁶⁰ *Id.*; Kathleen Ford et al., *American Adolescents: Sexual Mixing Patterns, Bridge Partners, and Concurrency*, 29 SEXUALLY TRANSMITTED DISEASES 13, 14 (2001) (“Concurrent partnerships increase the opportunity for an infection to spread quickly in a network of sexual partners by allowing infections during a given period to be transmitted to and from each partner who participates in the network.”).

⁶¹ See Ford et al., *supra* note 60, at 17 tbl. 4 (reporting that 61% of black females and 64% of Latino females engaged in concurrent relationships); Stephanie S. Kelley et al., *The Role of Sequential and Concurrent Sexual Relationships in the Risk of Sexually Transmitted Diseases Among Adolescents*, 32 J. ADOLESCENT HEALTH 296, 299, 302 (2003) (finding that among sexually active teens with more than one partner in the past 18 months, 40% were overlapping or concurrent in time and those in concurrent relationships were more likely to report an STD than single-relationship teens); Melanie D. Rosenberg et al., *Concurrent Sex Partners and Risk for Sexually Transmitted Diseases Among Adolescents*, 26 SEXUALLY TRANSMITTED DISEASES 208, 208 (1999) (finding that among adolescents who reported having at least one main partner in the

example, in a large survey of adolescents between thirteen and seventeen years old, Kathleen Ford and colleagues found that fifty-four percent reported having concurrent partners.⁶² Although this percentage is higher than that found in most other studies, its large sample size (9,303 sexually active survey respondents)⁶³ increases the strength of its findings and supports previous studies that have found relatively high rates of concurrency among adolescents.⁶⁴

Not knowing about a partner's concurrent relationships in combination with a lack of knowledge about a partner's STI status further increases STI risk. In a study of 217 couples enrolled in a risk intervention trial from 1997 to 2002, 10% of women and 12% of men were unaware their partner had recently received an STI diagnosis.⁶⁵

Another study of 363 females between 14 and 19 found that 22% of those with new sex partners within the past month did not know whether their partner had any STIs.⁶⁶ Other qualitative research indicates "that when people feel they 'just know' their partner, they judge the partner to be safe," even if the partner has never been tested.⁶⁷ Relatively high

previous six months, thirty-one percent had at least one concurrent partner during a main relationship, and a greater number of concurrent partners was associated with STD diagnosis/exposure); Freya L. Sonenstein et al., *Levels of Sexual Activity Among Adolescent Males in the United States*, 23 FAM. PLANNING PERSP. 162, 166 (1991) (reporting that 20% of sexually active males ages 15–19 were involved in more than one relationship simultaneously during the previous 12 months).

⁶² Ford et al., *supra* note 60, at 17.

⁶³ *Id.* at 15.

⁶⁴ See sources cited *supra* note 61.

⁶⁵ Susan S. Witte et al., *Lack of Awareness of Partner STD Risk Among Heterosexual Couples*, 42 PERSP. ON SEXUAL & REPROD. HEALTH 49, 52 (2010).

⁶⁶ Linda M. Niccolai et al., *New Sex Partner Acquisition and Sexually Transmitted Disease Risk Among Adolescent Females*, 34 J. ADOLESCENT HEALTH 216, 221 (2004).

⁶⁷ C.L. Masaro, *Perceptions of Sexual Partner Safety*, 35 SEXUALLY TRANSMITTED DISEASES 566, 569 (2008); see also David Skidmore & Emma Hayter, *Risk and Sex: Ego-Centricity and Sexual Behavior in Young Adults*, 2 HEALTH, RISK & SOC'Y 24, 31 (2000) (finding that females

rates of concurrency among adolescents and fairly low awareness about whether one's partner is engaged in a concurrent relationship illustrate the importance of safe-sex and preventive behaviors such as condom use and the HPV vaccine.

Because HPV infection in males is frequently asymptomatic, there are potentially large numbers of infected males who unknowingly act as HPV vectors, transmitting the virus to their sexual partners (male or female) who may develop more serious symptoms or potentially fatal cancers.⁶⁸

Some argue that as more females receive the HPV vaccine, the benefit and cost-effectiveness of vaccinating males decreases because of herd immunity. Herd immunity refers to the indirect protection of individuals who have not been vaccinated “when a critical portion of a community is immunized against a contagious disease.”⁶⁹ When herd immunity occurs, “most members of the community are protected against that disease because there is little opportunity for an outbreak.”⁷⁰ Marc Brisson and colleagues argue that “[i]f vaccinating girls significantly reduces the burden of HPV-related diseases in males through herd immunity, vaccinating boys will produce limited additional reductions in morbidity/mortality and thus will not be cost-effective.”⁷¹ This is a valid

were “quite happy to accept” their male partner’s account about previous partners, unprotected sex, and STD exposure “after a very short period of acquaintance”).

⁶⁸ Susie B. Baldwin et al., *Human Papillomavirus Infection in Men Attending a Sexually Transmitted Disease Clinic*, 187 J. INFECTIOUS DISEASES 1064, 1064 (2003).

⁶⁹ U.S. Dep’t of Health & Human Servs., *Community Immunity (“Herd Immunity”)*, VACCINES.GOV, <http://www.vaccines.gov/basics/protection/> (last updated Nov. 27, 2013) [hereinafter HHS, *Community Immunity (“Herd Immunity”)*].

⁷⁰ *Id.*

⁷¹ Marc Brisson et al., *Incremental Impact of Adding Boys to Current Human Papillomavirus Vaccination Programs: Role of Herd Immunity*, 372 J. INFECTIOUS DISEASES 372, 372 (2011).

argument to consider, but does not justify currently or even eventually ending male vaccination.⁷²

This thesis is not primarily concerned with justifying male vaccination, but offers a few responses to arguments against vaccinating males, even if the number of vaccinated females increases. First, although there is some evidence of herd immunity resulting from the HPV vaccine,⁷³ current rates of females completing three full doses (37.6% of females ages 13–17),⁷⁴ is unlikely to establish wide-spread herd immunity.⁷⁵ For female-only vaccination to be cost-effective, various published models suggest female coverage must reach at least eighty percent.⁷⁶ Second, it ignores the fact that men who have sex with men (MSM) receive little or no benefit from herd immunity created by female vaccination. HPV is now linked to *many* cancers beyond cervical cancer, therefore relying on female-created herd immunity would leave MSM at greater risk of cancers of the anus, tonsils and tongue, penis, larynx, head, and neck.⁷⁷

⁷² Furthermore, the cost-effectiveness of the vaccine for both males and females may change in the future, particularly if the vaccine's price declines. Jane J. Kim, *Weighing the Cost and Benefits of HPV Vaccine of Young Men*, 364 NEW ENG. J. MED. 393, 395 (2011).

⁷³ Kahn et al., *Vaccine-Type HPV*, *supra* note 5, at e252 (finding a decrease in vaccine-type HPV among vaccinated and unvaccinated 13–26 year old women).

⁷⁴ *Estimated Vaccination Coverage with Selected Vaccines Among Adolescents Aged 13–17 Years, by State and Selected Area—National Immunization Survey-Teen, United States, 2013*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vaccines/imz-managers/coverage/nis/teen/tables/13/tab01_iap_2013.pdf (last visited Feb. 18, 2014).

⁷⁵ Margaret Stanley, *Vaccinate Boys Too*, 488 NATURE S10, S10 (2012) (noting that “few countries have achieved the required rate of female HPV vaccination” to establish herd immunity).

⁷⁶ See Marc Brisson et al., *Economic Evaluation of Human Papillomavirus Vaccination in Developed Countries*, 12 PUB. HEALTH GENOMICS 343, 343 (2009); Mark Jit et al., *Economic Evaluation of Human Papillomavirus Vaccination in the United Kingdom*, 337 BRIT. MED. J. 331, 333 (2008).

⁷⁷ Margaret Stanley, *Vaccinate Boys Too*, 488 NATURE S10, S10 (2012).

Targeting vaccination of MSM rather than all males could address this issue, but would be difficult to implement in reality. Because the optimal age for the HPV vaccine is early adolescence—prior to sexual initiation—an MSM-targeted program would require questioning young adolescent boys about their sexual orientation long before many have established or even considered their sexual orientation.⁷⁸ This also assumes that sexual orientation will eventually be *firmly* established, despite evidence that it is fluid for many individuals.⁷⁹ It further assumes that young heterosexual boys do not sexually experiment with other boys despite still identifying as heterosexual.⁸⁰ And the alternative—targeting men in their late teens or early twenties when they are more likely to “know” their sexual orientation—will lower the vaccine’s effectiveness because many will already be sexually active and potentially infected.⁸¹

Third, it ignores the fact that young males (and females), regardless of their sexual orientation, could be molested, sexually abused, or sexually assaulted, with no

⁷⁸ *Id.*; see also Jane J. Kim, *Targeted Human Papillomavirus Vaccination of Men Who Have Sex With Men in the USA: A Cost-Effectiveness Modelling Analysis*, 10 LANCET INFECTIOUS DISEASES 845, (2010) (positing that the benefits and cost-effectiveness of the vaccine for MSM can justify vaccination of all males at young ages since “targeting” MSM as a population at young ages is likely “infeasible”).

⁷⁹ Linda D. Garnets, *Sexual Orientations in Perspective*, 8 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 115, 117 (2002); Mary Jane Rotheram-Borus & M. Isabel Fernandez, *Sexual Orientation and Developmental Challenges Experienced by Gay and Lesbian Youths*, 25 SUICIDE & LIFE-THREATENING BEHAV. 26, 28 (1995) (stating that coming out occurs on a “continuum” and its dimensions are “fluid”).

⁸⁰ See, e.g., Janice McCabe et al., *Patterns and Correlates of Same-Sex of Same-Sex Sexual Activity Among U.S. Teenagers and Young Adults*, 43 PERSP. ON SEXUAL & REPROD. HEALTH 142, 149 (2011) (extrapolating their findings to estimate that more than 552,000 young men and almost 1.5 million young women aged 15–21 have engaged in consensual same-sex activity but that the majority of them do not self-identify as homosexual or bisexual or “even acknowledge having sexual attraction to people of the same gender”); Gary Remafedi et al., *Demography of Sexual Orientation in Adolescence*, 89 PEDIATRICS 714, 718 (1992) (finding that only 27.1% of students in grades 7–12 with at least one homosexual experience actually identified as homosexual or bisexual).

⁸¹ Stanley, *supra* note 77, at S10.

control over the STI status of their attacker.⁸² Fourth, vaccinating both males and females is a more ethical policy. As argued by Hull and Caplan, “[a]ll moral agents, regardless of gender, have a duty to assume responsibility for the consequences of their behavior, sexual or otherwise. . . . Men bear a moral duty to take simple and safe steps to reduce the burden of disease in their partners.”⁸³

Gender-neutral vaccination policies promote a fairer distribution of the burdens related to sexual health and reproductive decision-making, which women already bear disproportionately. Writing on the ethics of HPV vaccination, De Melo-Martin stated that gender-neutral vaccination policies “can emphasize the need for both men and women to share responsibility equally for sexual and reproductive matters, perhaps having more impact on the sociology of sexually transmitted diseases than vaccines alone.”⁸⁴

Promoting male and female vaccination will help dispel the commonly-held belief that HPV is primarily a female issue, which is incorrect because HPV is now known to

⁸² Researchers estimate that 1 in 6 men have an abusive sexual experience before age 18, which is considered a low estimate due to under-reporting. Shanta R. Dube et al., *Long-Term Consequences of Childhood Sexual Abuse by Gender of Victim*, 28 AM. J. PREVENTIVE MED. 430, 433 (2005). Precise rates of child sexual abuse are difficult to determine because it is often under-reported, and experts agree that the incidence is far higher than the numbers reported to authorities. Some statistics include: 1 in 5 girls and 1 in 20 boys are victims of child sexual abuse; in a self-report study, 20% of adult females and 5–10% of adult males recall a childhood sexual assault or sexual abuse incident; over the course of their lifetime, 28% of U.S. youth 14–17 had been sexually victimized. Offenders are overwhelmingly male. NAT’L CTR. FOR VICTIMS OF CRIME, CHILD SEXUAL ABUSE STATISTICS, <http://www.victimsofcrime.org/media/reporting-on-child-sexual-abuse/child-sexual-abuse-statistics> (last visited Feb. 18, 2015); NAT’L CTR. FOR VICTIMS OF CRIME, STATISTICS ON PERPETRATORS OF CHILD SEXUAL ABUSE, <http://www.victimsofcrime.org/media/reporting-on-child-sexual-abuse/statistics-on-perpetrators-of-csa> (last visited Feb. 18, 2015).

⁸³ Sarah C. Hull & Arthur L. Caplan, *The Case for Vaccinating Boys Against Human Papillomavirus*, 12 PUB. HEALTH GENOMICS 362, 364 (2009).

⁸⁴ Immaculada de Melo-Martin, *The Promise of the Human Papillomavirus Vaccine Does Not Confer Immunity Against Ethical Reflection*, ONCOLOGIST, 393, 395 (2006).

increase the risk of oral, anal, penile, and head and neck cancers.⁸⁵ Because this thesis supports male vaccination, it proposes lowering the age of consent for both males and females.

B. THE VACCINE’S DEVELOPMENT, SAFETY, EFFICACY, AND CURRENT USE

This Part discusses the HPV vaccine’s initial research and development, safety, efficacy, and uptake.⁸⁶

1. Development and Licensure of Gardasil and Cervarix

Three HPV vaccines, a bivalent, a quadrivalent, and a new nonavalent, are approved and licensed by the FDA.⁸⁷ The bivalent vaccine is directed against HPV-16 and HPV-18, two high-risk HPV types that cause cervical and other HPV-related cancers.⁸⁸ The bivalent vaccine is manufactured by GlaxoSmithKline Biologicals and is sold under the name “Cervarix.”⁸⁹ Cervarix is licensed for use in females nine to twenty-five years of age.⁹⁰ The quadrivalent vaccine is directed against HPV-16 and HPV-18 as

⁸⁵ Meg Watson et al., *Using Population-Based Cancer Registry Data to Assess the Burden of Human Papillomavirus-Associated Cancers in the United States: Overview of Method*, 113 *CANCER* 2841, 2841 (2008) (“It is believed that HPV also is associated with approximately 90% of anal cancers; 40% of penile cancers, vaginal, and vulvar cancers; 25% of oral cavity cancers; and 35% of oropharyngeal cancers.”).

⁸⁶ Vaccine “uptake” is a function of initiation (getting the first vaccine dose) and completion (getting all three doses). PRESIDENT’S CANCER PANEL, ACCELERATING HPV VACCINE UPTAKE: URGENCY FOR ACTION TO PREVENT CANCER, U.S. DEP’T HEALTH & HUMAN SERVS. 7 (2014), available at http://deainfo.nci.nih.gov/advisory/pcp/annualReports/HPV/PDF/PCP_Annual_Report_2012-2013.pdf.

⁸⁷ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

⁸⁸ *Id.* Preventing HPV-16 and HPV-18 would prevent approximately 70% of cervical cancer cases. OFFIT, DEADLY CHOICES, *supra* note 42, at 73.

⁸⁹ *Approved Products: Cervarix*, FDA, <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186957.htm> (last updated July 24, 2014).

⁹⁰ *Id.*

well as HPV-6 and HPV-11, two low-risk HPV types that cause anogenital warts.⁹¹ The quadrivalent vaccine is manufactured by Merck & Co. and sold under the name “Gardasil.”⁹² Gardasil is licensed for use in females and males ages nine through twenty-six.⁹³ Merck recently received FDA approval for a new nonavalent HPV vaccine that protects against nine HPV types, seven of which are considered high risk.⁹⁴ The nonavalent vaccine was over ninety percent effective in a Phase III trial⁹⁵ and has the potential to prevent approximately ninety percent of cervical, vulvar, vaginal, and anal cancers.⁹⁶ It is approved for use in females ages nine to twenty-six and males ages nine to fifteen.⁹⁷

The HPV vaccine is a “recombinant vaccine,” created through a process used since 1986 to develop the Hepatitis B vaccine.⁹⁸ For each strain of the virus, “a single

⁹¹ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 69.

⁹² *Approved Products: Gardasil*, FDA, <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM094042> (last updated Mar. 19, 2014).

⁹³ *Id.*; *Diseases and the Vaccines That Prevent Them: HPV*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office.pdf> (updated June 2014); *HPV Vaccine is Recommended for Boys*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/features/hpvvaccineboys/> (last updated July 18, 2013).

⁹⁴ News Release, FDA, FDA Approves Gardasil 9 for Prevention of Certain Cancers Caused by Five Additional Types of HPV (Dec. 10, 2014), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm426485.htm> [hereinafter News Release, FDA Approves Gardasil 9]; *see also* Elmar A. Joura et al., *Attribution of 12 High-Risk Human Papillomavirus Genotypes to Infection and Cervical Disease*, 23 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 1997 (2014).

⁹⁵ Joura et al., *supra* note 94; News Release, Merck, Merck’s Investigational 9-Valent HPV Vaccine, V503, Prevented 97 Percent of Cervical, Vaginal, and Vulvar Pre-Cancers Caused by Five Additional HPV Types, in Phase III Study (Nov. 4, 2013), *available at* <http://www.mercknewsroom.com/news-release/research-and-development-news/mercks-investigational-9-valent-hpv-vaccine-v503-prevente>.

⁹⁶ News Release, FDA Approves Gardasil 9, *supra* note 94.

⁹⁷ *Id.*

⁹⁸ CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 123–24; OFFIT, DEADLY CHOICES, *supra* note 42, at 73, 120–21.

viral protein is isolated. When these proteins are expressed, virus-like particles (VLPs) are created. These VLPs contain no genetic material from the viruses and cannot cause illness, but prompt an immune response that provides future protection against HPV.”⁹⁹

Gardasil was introduced into the United States’ routine immunization schedule in late 2006 for eleven- and twelve-year-old females, with “catch-up” vaccination recommended by ACIP for females between thirteen and twenty-six.¹⁰⁰ Routine vaccination with the quadrivalent vaccine is now recommended for both males and females eleven- to twelve-years of age and can be started as young as nine.¹⁰¹ “Catch-up” vaccination is recommended for males between thirteen and twenty-one.¹⁰² A “catch-up” vaccine is for those never vaccinated or those who did not complete the three-dose series of the vaccine.¹⁰³ The HPV vaccine is also recommended for MSM.¹⁰⁴

The FDA approved a “Fast Track” approval for Gardasil.¹⁰⁵ To receive a fast track designation, a drug must target a “serious or life-threatening disease” and it must

⁹⁹ The History of Vaccines, *Different Types of Vaccines*, COLL. OF PHYSICIANS OF PHILA., <http://www.historyofvaccines.org/content/articles/different-types-vaccines> (last updated July 31, 2014).

¹⁰⁰ Markowitz et al., *Reduction in HPV Prevalence Among Young Women Following HPV Vaccine Introduction in United States*, *supra* note 16, at 385.

¹⁰¹ *Vaccine Information Statement: HPV Vaccine Gardasil: What You Need to Know*, CTRS. FOR DISEASE CONTROL & PREVENTION 1 (May 17, 2013), <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil.pdf> [hereinafter *Vaccine Information Statement: Gardasil*].

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Vaccines & Related Biological Prod. Advisory Comm., *Background Document: Gardasil HPV Quadrivalent Vaccine 2* (May 18, 2006), available at <http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4222B3.pdf>; see also Lucija Tomljenovic & Christopher A. Shaw, *Too Fast or Not Too Fast: The FDA’s Approval of Merck’s HPV Vaccine Gardasil*, 40 J. L., MED. & ETHICS 673, 674 (2012).

fill an “unmet need.”¹⁰⁶ If there are available therapies, a fast track drug must show some advantage over the available therapy, such as:

- (1) superior effectiveness, effect on serious outcomes or improved effect on serious outcomes;
- (2) avoiding serious side effects of an available therapy;
- (3) decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment; or
- (4) ability to address emerging or anticipated public health need.¹⁰⁷

A drug that receives fast track designation is eligible for various benefits such as:

- (1) more meetings with the FDA to discuss the drug’s development plan to ensure appropriate data are collected to support approval;
- (2) more frequent communication from the FDA about the design of proposed clinical trials, use of biomarkers, and other important factors in receiving approval;
- (3) eligibility for “Accelerated Approval and Priority Review;” and
- (4) “Rolling Review,” which allows a drug company to submit completed sections of a Biologic License Application for FDA review rather than waiting until every section is completed.¹⁰⁸

If the drug receives fast track designation, the FDA recommends “early and frequent communication between the FDA and a drug company . . . throughout the entire

¹⁰⁶ 21 U.S.C. § 356(b)(1)(2014); Tomljenovic & Shaw, *supra* note 105, at 674.

¹⁰⁷ *Fast Track*, FDA, <http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm> (last updated Sept. 15, 2014).

¹⁰⁸ *Id.*

drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.”¹⁰⁹ In its news release announcing Gardasil’s approval, Dr. Jesse Goodman, Director of FDA’s Center for Biologics Evaluation and Research, stated that “[i]t’s rapid approval underscores FDA’s commitment to help make safe and effective vaccines available.”¹¹⁰ Dr. Andrew C. von Eschenbach, Acting Commissioner of Food and Drugs, further stated that the FDA’s review “help[s] facilitate the development of very novel vaccines to address unmet medical needs. . . . [And] which address significant public health needs.”¹¹¹ Cervarix was denied fast track designation in 2007.¹¹²

The safety of Gardasil and Cervarix were studied in clinical trials each involving approximately 30,000 females before they were licensed.¹¹³ The majority of adverse events were not serious and generally included pain, redness, or tenderness at the injection site, fatigue, headache, dizziness, nausea, and muscle/joint aches.¹¹⁴ These are

¹⁰⁹ *Id.*

¹¹⁰ News Release, FDA, FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm> [hereinafter News Release, FDA, FDA Licenses New Vaccine].

¹¹¹ *Id.*

¹¹² Jane Wardell, *FDA Declines to Fast-Track Glaxo Vaccine*, USA TODAY (May 31, 2007, 2:07 PM), http://usatoday30.usatoday.com/money/economy/2007-05-31-2653082668_x.htm.

¹¹³ *Frequently Asked Questions About HPV Vaccine Safety*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vaccinesafety/Vaccines/HPV/hpv_faqs.html (last updated Sept. 15, 2014) [hereinafter *Frequently Asked Questions About HPV Vaccine Safety*].

¹¹⁴ B.A. Pahud & C.J. Harrison, *Known Vaccine-Associated Adverse Events*, in *VACCINOPHOBIA AND VACCINE CONTROVERSIES OF THE 21ST CENTURY* 51, 76 (Archana Chatterjee ed., 2013); News Release, FDA, FDA Approves New Vaccine for Prevention of Cervical Cancer (Oct. 16, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm187048.htm>; News Release, FDA, FDA Licenses New Vaccine, *supra* note 110.

common mild side effects of almost all immunizations.¹¹⁵ Gardasil and Cervarix continue to use post-licensure studies and monitoring to ensure the vaccines' continued safety and to provide a mechanism for the drug manufacturers, the FDA, and the Centers for Disease Control and Prevention (CDC) to learn of any unexpected adverse events.¹¹⁶

2. Monitoring Vaccine Safety

Like all vaccines, Gardasil and Cervarix continue to be monitored after approval and licensure. After a vaccine is licensed, the CDC and the FDA primarily rely on three systems to monitor and evaluate a vaccine's safety¹¹⁷:

- (1) **The Vaccine Adverse Event Reporting System (VAERS):** allows individuals to report adverse health events following a vaccination. VAERS helps the CDC and FDA detect new, unexpected, or increased trends in adverse events.
- (2) **The Vaccine Safety Datalink (VSD):** collaboration between the CDC and several healthcare organizations which use de-identified health records to monitor and evaluate adverse events following vaccinations.
- (3) **The Clinical Immunization Safety Assessment (CISA) Project:** collaboration between the CDC and medical research centers to conduct research to understand how vaccines may have caused adverse events.

In response to concerns from consumers, parents, and HCPs about Gardasil's safety, the FDA and the CDC reviewed available information and safety monitoring data

¹¹⁵ See *Possible Side Effects from Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm> (last updated Aug. 19, 2014).

¹¹⁶ *Human Papillomavirus (HPV) Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccinesafety/vaccines/HPV/index.html> (last updated Sept. 25, 2014).

¹¹⁷ *Id.*

and concluded that Gardasil remained “safe and effective, and its benefits continue to outweigh its risks.”¹¹⁸

From June 2006 to March 2014, approximately sixty-seven million doses of the HPV vaccine were distributed.¹¹⁹ VAERS received approximately 25,000 adverse event reports occurring in girls and women who received the HPV vaccine.¹²⁰ This is an adverse event rate of .03% and of the events reported, 92% were classified as “non-serious.”¹²¹ The most frequently reported adverse symptoms included (1) injection-site reactions; (2) dizziness; (3) fainting; (4) nausea; and (5) headache.¹²²

In 2011, a VSD-conducted study evaluated the occurrence of specific adverse events following more than 600,000 doses of Gardasil and compared these adverse events to another population of adolescents who received vaccines other than the HPV vaccine.¹²³ The adverse events reported after the HPV vaccine were no more common than those reported by a comparison group receiving other vaccines such as the Tdap,¹²⁴ Td,¹²⁵ meningococcal, or varicella (chicken pox) vaccine.¹²⁶ According to the CDC, no

¹¹⁸ *Gardasil Vaccine Safety: Information from FDA and CDC on the Safety of Gardasil Vaccine*, FDA (Aug. 20, 2009), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm179549.htm> (last updated July 15, 2014).

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ Julianne Gee et al., *Monitoring the Safety of Quadrivalent Human Papillomavirus Vaccine: Findings from the Vaccine Safety Datalink*, 29 *VACCINE* 8279, 8280 (2011).

¹²⁴ “Tdap” is the tetanus-diphtheria-acellular pertussis vaccine. *Tdap Vaccine for Preteens and Teens* (June 2014), CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/who/teens/vaccines/tdap.pdf>.

¹²⁵ “Td” is a vaccine for tetanus and diphtheria. *Td Vaccine: What You Need to Know*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 4, 2014), <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/td.pdf>.

¹²⁶ Gee et al., *supra* note 123, at 8280.

new or unusual patterns of adverse events occurred from June 2006 to March 2014 to cause concern about the HPV vaccine's safety.¹²⁷ Although no vaccine is 100% safe and all have potential side effects (just like *any* medical treatment), the evidence collected by the monitoring agencies suggests the vaccine is as safe, if not safer, than other recommended vaccines.¹²⁸

Reliable and medically-sound information about the vaccine's safety is important to counter claims that the vaccine is responsible for serious side effects and multiple deaths.¹²⁹ Contrary to sensationalistic reports about deaths and injuries from the HPV

¹²⁷ Shannon Stokley et al., *Human Papillomavirus Vaccination Coverage Among Adolescents, 2007–2013, and Postlicensure Vaccine Safety Monitoring, 2006–2014—United States*, 63 MORBIDITY & MORTALITY WKLY. REP. 620, 623 (2014) (“National safety monitoring data continue to indicate that the HPV vaccine is safe.”).

¹²⁸ See *Possible Side-Effects from Vaccines*, VACCINES.GOV, http://www.vaccines.gov/basics/safety/side_effects/index.html# (last updated Oct. 4, 2014) (stating that Gardasil and Cervarix are both “very safe”); see also *Human Papillomavirus (HPV) Vaccine (Detailed Information)*, CTRS. FOR DISEASE CONTROL & PREVENTION http://www.cdc.gov/vaccinesafety/Vaccines/HPV/hpv_detailed.html (last updated Jan. 26, 2015) (“HPV vaccines have a good safety record.”).

¹²⁹ The recent story of a twelve-year-old Wisconsin girl is illustrative. After receiving a dose of the HPV vaccine on July 30, 2014, Meredith Prohaska “complained of feeling sleepy” and slept for much of the day. Later that day, her mother found her face down on the floor. She had vomited, her lips were purple, and she was not breathing. She was pronounced dead at the hospital. Meredith’s parents believe the vaccine caused her death but after an autopsy the medical examiner concluded that the HPV vaccine neither caused nor contributed to her death. Her death was caused by “diphenhydramine intoxication”—ingestion of a lethal level of an antihistamine used in several over-the-counter cold and allergy products. The medical examiner did not rule whether the intoxication was accidental or intentional, but the report vindicated the vaccine from any fault. Nevertheless, stories like this can be misunderstood by the public and presented by vaccine opponents as casting doubt on the vaccine’s safety. See Karen Herzog, *Medical Examiner: Girl’s Death Not Caused by HPV Vaccination*, MILWAUKEE-WIS. J. SENTINEL (Oct. 22, 2014), www.jsonline.com/news/health/medical-examiner-girls-death-not-caused-by-routine-vaccination-b99376029z1-280058462.html; Jessica Jerreat, *‘Did the HPV Vaccine Kill My Daughter’: Mother Demands Answers After Healthy and Active Daughter, 12, Collapses and Dies After Getting Vaccine*, DAILY MAIL (Aug. 9, 2014, 8:29 AM), <http://www.dailymail.co.uk/news/article-2720333/Did-HPV-vaccine-kill-daughter-Mother-demands-answers-healthy-active-daughter-12-collapses-dies-getting-vaccine.html>; Hillary Mintz & Christina Palladino, *Medical Examiner Rules Waukesha Girl Did Not Die of HPV Vaccine*,

vaccine, the risk of dying from cervical cancer is much greater than a vaccine-related death. 4,092 women in the United States died from cervical cancer in 2011¹³⁰ whereas there have been *no confirmed deaths* caused by the HPV vaccine since its introduction.¹³¹ To achieve its full potential, the majority of a vaccine's target population must

[B]elieve in the value and benefits associated with an immunization recommendation, be confident in the safety of the recommendation and the recommended vaccine (including that the benefits of getting vaccinated outweigh the risks), be confident that the vaccines work, and trust the health and medical professionals who formulated the recommendation.¹³²

The evidence suggests there *is* reason to believe the HPV vaccine is valuable and beneficial, yet at least some parents (who must be considered part of the “target population” under current laws requiring parental consent) do not, in fact, believe this. Nevertheless, in the vast majority of cases, the vaccine's typically-minor side effects are far preferable to contracting HPV and developing HPV-related cancer.

3. Vaccine Efficacy

One obstacle to assessing the vaccine's efficacy is that many cancers targeted by the HPV vaccine occur years after initial infection.¹³³ Therefore, “it might be decades

WISN12 (Oct. 22, 2014, 10:23 PM), <http://www.wisn.com/news/me-waukesha-girl-did-not-die-of-hpv-vaccine/29274950>.

¹³⁰ *Cervical Cancer Statistics*, *supra* note 50.

¹³¹ *Frequently Asked Questions About HPV Vaccine Safety*, *supra* note 113.

¹³² Glen J. Nowak et al., *Insights from Public Health: A Framework for Understanding and Fostering Vaccine Acceptance*, in *VACCINOPHOBIA AND VACCINE CONTROVERSIES OF THE 21ST CENTURY* 459, 460 (Archana Chatterjee ed., 2013) (emphasis added).

¹³³ Lauri E. Markowitz et al., *Human Papillomavirus: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 63 *MORBIDITY & MORTALITY WKLY. REP.: RECOMMENDATIONS & REPS.* NO. 5, Aug. 29, 2014, at 1, 8 (2014) [hereinafter Markowitz et al., *HPV: Recommendations of ACIP*] (“[S]tudies using invasive cervical cancer as an endpoint are not feasible because . . . [t]he time from acquisition of infection to the development of cancer can exceed 20 years.”). One study, for example, found that in a sample of 432 females ages 20–

before an impact of vaccination is observed on these outcomes.”¹³⁴ Other HPV-associated outcomes, however, which occur closer to the time of initial infection, can be measured as surrogate markers for cancers. For example, the basis for licensing Gardasil and Cervarix for females was incident HPV16- and 18-related “cervical intraepithelial neoplasia” (CIN) 2/3 or “adenocarcinoma in situ” (AIS or CIN2+), which served as surrogate markers for cervical cancer.¹³⁵ “Vulvar intraepithelial neoplasia” (VIN2/3), “vaginal intraepithelial neoplasia” (VaIN 2/3) and “anal intraepithelial neoplasia” were commonly used as endpoints and surrogate markers in trials evaluating the vaccine’s efficacy in preventing vaginal, vulvar, and anal cancers.¹³⁶

Initial data on the vaccine’s efficacy is promising. When given as a three-dose series over a period of six months, the vaccine has a high efficacy for preventing vaccine-type cervical precancers.¹³⁷ Within four years of the vaccine’s introduction, vaccine-type

24, 43.4% had “high risk” HPV. Susan Hariri et al., *Prevalence of Genital Human Papillomavirus Among Females in the United States, the National Health and Nutrition Examination Survey, 2003–2006*, 204 J. INFECTIOUS DISEASES 566, 568–69 (2011). The median age of cervical cancer diagnosis, however, is 49. Surveillance, Epidemiology, and End Results Program (SEER), *SEER Stat Fact Sheets: Cervix Uteri Cancer*, NAT’L CANCER INST., <http://seer.cancer.gov/statfacts/html/cervix.html> (last visited Feb. 18, 2015).

¹³⁴Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 1; *see also* Charlotte J. Huang, *Human Papillomavirus Vaccination—Reasons for Caution*, 359 N. ENGL. J. MED. 861, 861 (2008) (“The bad news is that the overall effect of the vaccines on cervical cancer remains unknown.”); *HPV Vaccination*, ALLIANCE FOR NATURAL HEALTH, <http://anh-europe.org/campaigns/vaccine-choice/hpv-vaccination> (last visited Feb. 18, 2015) (“We have no way of knowing what the effect of the vaccine will be on risk of developing cervical cancer, because it can take decades to appear.”).

¹³⁵ Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 8.

¹³⁶ *Id.*

¹³⁷ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 70; *see also* FUTURE II Study Group, *Quadrivalent Vaccine Against the Human Papillomavirus to Prevent High-Grade Cervical Lesions*, 356 N. ENGL. J. MED. 1915 (2007); Susanne K. Kjaer et al., *A Pooled Analysis of Continued Prophylactic Efficacy of Quadrivalent Human Papillomavirus (Types 6/11/16/18) Vaccine against High-grade Cervical and External Genital Lesions*, 2 CANCER PREVENTION RES. 868 (2009); J. Paavonen et al., *Efficacy of Human Papillomavirus (HPV)-16/18 AS04-Adjuvanted*

HPV prevalence decreased among fourteen- to nineteen-year-old females, despite relatively low vaccine uptake.¹³⁸ Information on the vaccine's efficacy in males is less developed because of its more recent approval for use in adolescent males, but initial studies are promising. In a Phase III efficacy trial involving over 4,000 males between sixteen and twenty-six, the quadrivalent vaccine was almost 90% effective in preventing vaccine-type genital warts.¹³⁹

Vaccine efficacy against cervical intraepithelial neoplasia grade 3 or greater (CIN3+), the immediate precursor to invasive cervical cancer, provides the most stringent evidence of the vaccine's potential to prevent cancer.¹⁴⁰ A study evaluating Cervarix found a 100% vaccine efficacy against CIN3+ associated with HPV-16/18.¹⁴¹ Studies on Gardasil's quadrivalent vaccine show similar results, with one study finding the vaccine 100% effective in preventing vaginal, vulvar, perineal, and perianal intraepithelial lesions or warts associated with vaccine-type HPV.¹⁴² In a study of Danish women born from 1989 to 1999, even receiving just one dose of the vaccine provided some protection, with

Vaccine Against Cervical Infection and Precancer Caused by Oncogenic HPV Types (PATRICIA): Final Analysis of a Double-Blind, Randomised Study in Young Women, 374 LANCET 301 (2009).

¹³⁸ Markowitz et al., *Reduction in HPV Prevalence Among Young Women Following HPV Vaccine Introduction in United States*, *supra* note 16, at 389–90 (finding that among 14–19 year old females, the vaccine-type HPV prevalence decreased from 11.5% to 5.1%); *see also* Krystle A. Lang Kuhs et al., *Reduced Prevalence of Vulvar HPV16/18 Infection Among Women Who Received the HPV 16/18 Bivalent Vaccine: A Nested Analysis Within the Costa Rica Vaccine Trial*, 210 J. INFECTIOUS DISEASES 1890 (2014).

¹³⁹ Dunne et al., *Recommendations on the Use of Quadrivalent HPV Vaccine in Males*, *supra* note 18, at 1705.

¹⁴⁰ Matti Lehtinen et al., *Overall Efficacy of HPV-16/18 AS04-Adjuvanted Vaccine Against Grade 3 or Greater Cervical Intraepithelial Neoplasia: 4-Year End-of-Study Analysis of the Randomised, Double-Blind PATRICIA Trial*, 13 LANCET ONCOLOGY 89, 90 (2012).

¹⁴¹ *Id.* at 89.

¹⁴² Suzanne M. Garland et al., *Quadrivalent Vaccine against Human Papillomavirus to Prevent Anogenital Diseases*, 356 N. ENGL. J. MED. 1928, 1932 (2007).

risks for CIN 2/3 and CIN3 reduced by up to 80% among women who received at least one dose of the quadrivalent vaccine.¹⁴³

As additional efficacy studies are performed, the vaccine's ability to decrease precancer cervical abnormalities is continuously confirmed¹⁴⁴ and new developments are increasing the number of HPV types prevented by the vaccine. On December 10, 2014, the FDA approved Merck's "Gardasil 9," a 9-valent ("nonavalent") vaccine targeting nine HPV types, five more than Gardasil.¹⁴⁵ It has the potential to prevent approximately ninety percent of all cervical, vulvar, vaginal, and anal cancers,¹⁴⁶ a marked improvement from Gardasil's seventy percent effectiveness.¹⁴⁷

Even for individuals who never develop precancers or cancer, the vaccine effectively prevents vaccine-type HPV prevalence and genital warts. Within four years of the vaccine's introduction, vaccine-type HPV prevalence decreased among fourteen- to nineteen-year-old females in the United States, despite relatively low vaccine uptake.¹⁴⁸

¹⁴³ Birgitte Baldur-Felskov et al., *Early Impact of Human Papillomavirus Vaccination on Cervical Neoplasia—Nationwide Follow-up of Young Danish Women*, 106 J. NAT'L CANCER INST., no. 3, Mar. 12, 2014, at 1, 4.

¹⁴⁴ See, e.g., Allan Hildesheim et al., *Efficacy of the HPV-16/18 Vaccine: Final According to Protocol Results from the Blinded Phase of the Randomized Costa Rica HPV-16/18 Vaccine Trial*, 32 VACCINE 5087 (2014); Nubia Munoz et al., *Safety, Immunogenicity, and Efficacy of Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine in Women Aged 24–45 Years: A Randomised, Double-Blind Trial*, 373 LANCET 1949 (2009); S. Rachel Skinner et al., *Efficacy, Safety, and Immunogenicity of the Human Papillomavirus 16/18 AS04-Adjuvanted Vaccine in Women Older than 25 Years: 4-Year Interim Follow-Up of the Phase 3, Double-Blind, Randomised Controlled VIVIANE Study*, 384 LANCET 2213 (2014).

¹⁴⁵ News Release, FDA Approves Gardasil 9, *supra* note 94.

¹⁴⁶ *Id.*

¹⁴⁷ Elmar A. Joura et al., *supra* note 94; Mandy Oaklander, *The New HPV Vaccine Could be 90% Effective*, TIME (Oct. 1, 2014), <http://time.com/3450739/new-hpv-vaccine-more-effective/>.

¹⁴⁸ Markowitz et al., *Reduction in HPV Prevalence Among Young Women Following HPV Vaccine Introduction in United States*, *supra* note 16, at 389–90 (finding that among 14–19 year old females, the vaccine-type HPV prevalence decreased from 11.5% to 5.1%); see also Kuhs et al., *supra* note 138.

A Scottish study monitoring the vaccine's impact after a national HPV immunization program began in 2008 found that completing three doses of the bivalent vaccine was associated with a significant reduction in the prevalence of HPV-16/18 from 29.8% to 13.6%.¹⁴⁹ It also found potential cross-protection against non-vaccine HPV types 31, 33, and 45.¹⁵⁰ These findings are consistent with studies from other countries and among various sample sizes and types.¹⁵¹ Studies focusing on the vaccine's efficacy in males also show reductions in external genital lesions associated with vaccine-type HPV.¹⁵² Males will also benefit from the reductions found in precancers related to anal cancer¹⁵³

¹⁴⁹ K. Kavanaugh et al., *Introduction and Sustained High Coverage of the HPV Bivalent Vaccine Leads to a Reduction in Prevalence of HPV 16/18 and Closely Related HPV Types*, 110 BRIT. J. CANCER 2804, 2806–07 (2014).

¹⁵⁰ *Id.* at 2807; see also Cosette M. Wheeler et al., *The Impact of Quadrivalent Human Papillomavirus (HPV; Types 6, 11, 16, and 18) L1 Virus-Like Particle Vaccine on Infection and Disease Due to Oncogenic Nonvaccine HPV Types in Sexually Active Women Aged 16–26 Years*, 199 J. INFECTIOUS DISEASES 936, 938 (2009) (finding a 17.7% reduction of non-vaccine type HPV 31/33/45/52/58).

¹⁵¹ See, e.g., Yvonne Delere et al., *Human Papillomavirus Prevalence and Probable First Effects of Vaccination in 20 to 25 Year-Old Women in Germany: A Population-Based Cross Sectional Study Via Home-Based Self-Sampling*, 14 BMC INFECTIOUS DISEASES, 2014, at 1 (finding a significantly lower prevalence of HPV 16/18 in vaccinated women (13.9%) than in unvaccinated women (22.5%)); Anna Soderlund-Strand et al., *Change in Population Prevalences of Human Papillomavirus after Initiation of Vaccination: The High-Throughput HPV Monitoring Study*, 23 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2757 (2014) (finding a major reduction of HPV 6, 16, and 18 prevalence in a study conducted after Sweden implemented an organized, publicly-funded HPV vaccination program for 10- to 18-year olds).

¹⁵² Anna R. Giuliano et al., *Efficacy of Quadrivalent HPV Vaccine Against HPV Infection and Disease in Males*, 364 N. ENGL. J. MED. 401, 409 (2011) (finding a 90.4% reduction in the incidence of external genital lesions related to HPV 6, 11, 16, or 18 among males who were HPV-negative at the beginning of the study who received all three vaccinations within one year). Phase III efficacy studies of 4,065 males 16–26 years of age submitted to the FDA found an 89.4% efficacy rate for preventing genital warts related to HPV types 6, 11, 16, or 18 among males receiving all three vaccine doses. *FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP)*, 59 MORBIDITY & MORALITY WKLY. REP. 630, 630 (2010).

¹⁵³ Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 8; Joel M. Palefsky et al., *HPV Vaccine Against Anal HPV Infection and Anal Intraepithelial Neoplasia*, 365 N. ENGL. J. MED. 1576 (2011) (concluding, in a study of heterosexual men and MSM, that the quadrivalent HPV vaccine was effective against anal intraepithelial neoplasia associated with vaccine-type

and potentially penile cancer.¹⁵⁴ The vaccine's efficacy in reducing oral HPV, which is now known to play a role in a subset of head and neck cancers,¹⁵⁵ may also reduce incidence rates of these cancers in both men and women.¹⁵⁶

4. HPV Vaccination Rates

Since the vaccine was first licensed in 2006, HPV vaccine coverage among American adolescent females increased but remains low compared to other recommended adolescent vaccines.¹⁵⁷ This section briefly discusses the most recent data on HPV vaccination rates among adolescent males and females.

The 2013 National Immunization Survey-Teen (NIS-Teen) found that although there were modest increases in vaccine coverage among adolescents ages 13 to 17 for vaccines routinely recommended by ACIP for pre-teens and teens such as the tetanus,

HPVs, grade 2 or 4 intraepithelia neoplasia related to infected with vaccine-type HPV, and risks of persistent anal infection with vaccine-type HPVs).

¹⁵⁴ More studies are needed on the vaccine's efficacy in reducing penile cancer. But because HPV has been implicated in penile cancer, there is reason to believe the vaccine may reduce penile cancer rates. Amber Flaherty et al., *Implications for Human Papillomavirus in Penile Cancer*, 32 UROLOGIC ONCOLOGY: SEMINARS & ORIG. INVESTIGATIONS 53.e1 (2014).

¹⁵⁵ Gypsyamber D'Souza & Amanda Dempsey, *The Role of HPV in Head and Neck Cancer and Review of the HPV Vaccine*, 53 PREVENTIVE MED. S7 (2011); Hisham Mehanna et al., *Prevalence of Human Papillomavirus in Oropharyngeal and Nonoropharyngeal Head and Neck Cancer—Systemic Review and Meta-Analysis of Trends by Time and Region*, 35 HEAD & NECK 747 (2013).

¹⁵⁶ D'Souza & Dempsey, *supra* note 155, at S10; Rolando Herrero et al., *Reduced Prevalence of Oral Human Papillomavirus (HPV) 4 Years after Bivalent HPV Vaccination in a Randomized Clinical Trial in Costa Rica*, 8 PLOS ONE e68329 (2014) (finding a 93% vaccine efficacy of the bivalent vaccine in preventing oral HPV, suggesting the vaccine may help prevent common HPV-associated oropharyngeal cancers), available at <http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0068329&representation=PDF>; Mehanna et al., *supra* note 155, at 747 (arguing that “HPV-OPC is potentially preventable” by the HPV vaccine).

¹⁵⁷ Holman et al., *supra* note 21, at 77; Henry J. Kaiser Fam. Found., *The HPV Vaccine: Access and Use in the U.S.* 4 (Sept. 2014), <http://files.kff.org/attachment/the-hpv-vaccine-access-and-use-in-the-u-s-fact-sheet> [hereinafter KFF, *The HPV Vaccine*]; Stokley et al., *supra* note 127, at 622.

diphtheria, and pertussis vaccine (“Tdap”), vaccination coverage estimates for HPV remained low in 2013.¹⁵⁸ Among 13- to 17-year-old females, 57.3% had received at least one dose of the HPV vaccine at the time of the survey and 37.6% had completed all three doses.¹⁵⁹ Among males, 34.6% had received at least one dose and only 13.9% had received three doses.¹⁶⁰ As a comparison, eighty-six percent of adolescents in this age group received the ACIP-recommended Tdap vaccine.¹⁶¹

The HPV vaccine can be safely administered at the same time as other recommended vaccines and ACIP advises that all recommended vaccines be given in a single visit.¹⁶² The NIS-Teen survey found, however, that many adolescents do not receive the HPV vaccine when they received other recommended vaccines.¹⁶³ These missed opportunities have a significant impact on vaccination rates. For example, for the cohort of girls born in 2000, 46.8% received at least one dose of the vaccine by the time they turned thirteen.¹⁶⁴ Had the vaccine been administered at health care visits when they received another vaccine, 91.3% of this cohort would have received at least one dose of

¹⁵⁸ Stokley et al., *supra* note 127, at 622. The other ACIP-recommended vaccines for this age group include 1 dose of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine and two doses of meningococcal conjugate (MenACWY vaccine). Laurie D. Elam-Evans et al., *National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years—United States, 2013*, 63 MORBIDITY & MORTALITY WKLY. REP. 625, 625 (2014).

¹⁵⁹ *Estimated Vaccination Coverage with Selected Vaccines Among Adolescents Aged 13–17 Years, by State and Selected Area—National Immunization Survey-Teen, United States, 2013*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vaccines/imz-managers/coverage/nis/teen/tables/13/tab01_iap_2013.pdf (last visited Oct. 18, 2014).

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Stokley et al., *supra* note 127, at 620.

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 621.

the vaccine.¹⁶⁵ Missed opportunities can arise for a variety of reasons, including incorrect assumptions about the vaccine's effect on sexual behavior and lack of HCP recommendation.¹⁶⁶

Parental consent requirements are another barrier to increasing HPV vaccine uptake. Most state laws and policies currently require parental consent for adolescent vaccinations. Part C discusses the legal background of parental consent and minors consent generally and in the specific context of health care decision-making.

C. THE LEGAL LANDSCAPE OF PARENTAL RIGHTS AND MINOR CONSENT

Parental rights and minors' rights arise from common law and statutory law. Although parental rights are often viewed as protecting a parent's right from *governmental* interference, laws strengthening minors' rights are also in tension with parental rights when they allow minors to make decisions without parental involvement. In the context of health care decision-making, state law generally controls whether parental consent is required.¹⁶⁷

This Part discusses the source and scope of parental rights and minors' rights, both generally and in the specific context of health care decisions. Part 1 provides background information on the history and current state of the law on parental consent to

¹⁶⁵ *Id.*

¹⁶⁶ Rebecca B. Perkins et al., *Missed Opportunities for HPV Vaccination in Adolescent Girls: A Qualitative Study*, 134 PEDIATRICS e657, e672 (2014); Susan T. Vadaparampil et al., *Missed Clinical Opportunities: Provider Recommendation for HPV Vaccination for 11–12 Year Old Girls is Limited*, 29 VACCINE 8634, 8640 (2011) (finding that the proportion of physicians who reported they always recommend the HPV vaccine to females 11–26 years of age ranged from 25.8% to 74.5%).

¹⁶⁷ Abigail English et al., *Legal Basis of Consent for Health Care and Vaccination for Adolescents*, 121 PEDIATRICS S85 (2008).

a child's medical care. Part 2 describes minor consent laws and when the law allows minors to consent without parental consent and/or notification.

1. Parental Rights and Parental Consent to Minors' Health Care

a. *History and Background Law*

Throughout much of history, childhood was a “grim experience” for many children.¹⁶⁸ Children were not considered persons under the law and were often treated as property.¹⁶⁹ Children's status slowly changed and by the nineteenth century they were generally considered a “special class requiring protection and nurturance.”¹⁷⁰ This evolution in thought gave rise to a “child-saving era” focused on children's health and welfare¹⁷¹ but it was not until the latter half of the twentieth century that children's status as persons under the law emerged.¹⁷² The Supreme Court has recognized that “a child, merely on account of his minority, is not beyond the protection of the Constitution.”¹⁷³

Despite this evolution in children's rights and status as “persons,” the law and society still treat children differently in many ways, often justifiably. Although the Supreme Court has increasingly recognized children as persons afforded protection under the United States Constitution, it does not give them the *full* protections provided to

¹⁶⁸ NANCY E. WALKER ET AL., CHILDREN'S RIGHTS IN THE UNITED STATES: IN SEARCH OF A NATIONAL POLICY 20 (1999) (“[Children] were bought, sold, cared for, and abandoned in much the same way as a pair of shoes. . . . commonly [] neglected, abandoned, abused (sexually and otherwise), sold into slavery, mutilated and even killed with impunity.”) (internal quotations and citations omitted).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 21.

¹⁷¹ *Id.*

¹⁷² In *Tinker v. Des Moines Independent Community School District*, the Supreme Court stated that “[s]tudents, *in school as well as out of school*, are ‘persons’ under our Constitution. They are possessed of fundamental rights which the State must respect.” 393 U.S. 503, 511 (1969) (emphasis added).

¹⁷³ *Belotti v. Baird*, 443 U.S. 622, 634 (1979); *see also In re Gault*, 387 U.S. 1, 13 (1967) (holding that “neither the Fourteenth Amendment nor the Bill of Rights is for adults alone”).

adults. The Court recognizes three reasons why children’s constitutional rights are not equivalent to those of adults: (1) the peculiar vulnerability of children; (2) children’s inability to make critical decisions in an informed, mature manner; and (3) the importance of the parental role in child rearing.¹⁷⁴ As a result, parents retain significant control over their children’s lives and if a child does not have parents, or his parents are “unfit,” the State can step in as “*parens patriae*.”¹⁷⁵

Because of children’s unique characteristics rendering them “incapable” of making certain decisions, the rights of parents to make decisions concerning their minor children’s welfare and upbringing have a long history rooted in the common law and constitutional doctrine.¹⁷⁶ The United States Constitution does not explicitly provide parental rights but the Supreme Court has recognized an implicit fundamental constitutional right for parents to raise their children as they see fit.¹⁷⁷ In a long line of cases,¹⁷⁸ the Court indicates these rights derive from the Fifth and Fourteenth Amendments, which prohibit governmental interference with individual liberty. *Meyer v. Nebraska* is the foundational case for this proposition, in which the Court held that a parent’s power “to control the education of their own” is protected by the Fourteenth

¹⁷⁴ *Belotti*, 443 U.S. at 634.

¹⁷⁵ See *Schall v. Martin*, 467 U.S. 253, 265 (1984) (“Children, by definition, are not assumed to have the capacity to take care of themselves. They are assumed to be subject to the control of their parents, and if parental control falters, the State must play its part as *parens patriae*.”).

¹⁷⁶ See Ann MacLean Massie, *Withdrawal of Treatment for Minors in a Persistent Vegetative State: Parents Should Decide*, 35 ARIZ. L. REV. 174, 186 (1993).

¹⁷⁷ See, e.g., *Troxel v. Granville*, 530 U.S. 57 (2000); *Bellotti*, 443 U.S. 622; *Wisconsin v. Yoder*, 406 U.S. 205 (1972); *Prince v. Massachusetts*, 321 U.S. 158 (1944); *Pierce v. Soc’y of the Sisters*, 268 U.S. 510 (1925); *Meyer v. Nebraska*, 262 U.S. 390 (1923).

¹⁷⁸ See cases cited *id.*

Amendment,¹⁷⁹ which declares that “[n]o state . . . shall deprive any person of life, liberty, or property without due process of law.”¹⁸⁰ The Court reasoned that the Fourteenth Amendment “denotes not merely freedom from bodily restraint but also the right of the individual to . . . establish a home and bring up children.”¹⁸¹ The Court has consistently reaffirmed parent’s fundamental rights, such as in *Troxel v. Granville*, in which the Court stated that “the interest of parents in the care, custody, and control of their children [] is perhaps the oldest of the fundamental liberty interests recognized by this Court.”¹⁸²

Early Supreme Court cases addressing parental rights frequently involved educational¹⁸³ and religious¹⁸⁴ decisions. These cases, however, set the foundation for recognizing a parent’s right to make health care decisions for his or her children.¹⁸⁵ Courts presume that parents act in their children’s best interests when making decisions on their behalf. In *Parham v. J.R.*, for example, the Court upheld a Georgia law allowing parents or guardians to voluntarily admit their minor children to mental hospitals.¹⁸⁶ Minors being treated in Georgia state mental hospitals challenged the law under the

¹⁷⁹ *Meyer*, 262 U.S. at 401.

¹⁸⁰ U.S. CONST. amend XIV, § 1.

¹⁸¹ *Meyer*, 262 U.S. at 401.

¹⁸² *Troxel*, 530 U.S. at 66.

¹⁸³ *See, e.g.*, *Pierce v. Soc’y of the Sisters*, 268 U.S. 510, 534–35 (1925) (arguing that parents have the liberty “to direct the upbringing and education of children under their control”); *Meyer*, 262 U.S. at 401 (recognizing parents’ right “to control the education of their own”).

¹⁸⁴ *See, e.g.*, *Prince v. Massachusetts*, 321 U.S. 158, 165 (1944) (upholding a child labor law restricting children’s ability to hand out and sell religious literature but acknowledging that parents have a right to provide their children with “religious training”).

¹⁸⁵ *Custody of a Minor*, 379 N.E.2d 1053, 1062 (Mass. 1978) (“[I]n the area of medical treatment for minors, courts have shown great reluctance to overturn parental objections to medical treatment where the child’s condition is not life-threatening In some cases, this has been true even where the proposed medical treatment would offer great benefit to the child.”).

¹⁸⁶ 442 U.S. 584 (1979).

Fourteenth Amendment, claiming it did not adequately protect their due process rights and their liberty interest against unnecessary confinement for medical treatment.¹⁸⁷ The Court concluded the statute did not violate the minors' rights because "natural bonds of affection lead parents to act in the best interests of their children" and parents "possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult decisions."¹⁸⁸ According to the Court, "[m]ost children, even in adolescence, simply are not able to make sound judgments concerning many decisions, including their need for medical care or treatment."¹⁸⁹ The Court also stated that a child's disagreement with his parent's decision does not automatically transfer the power of consent to the child, state, or other agency.¹⁹⁰ As a result of these Supreme Court decisions, parents generally have wide discretion in making decisions on behalf of their children, including health care decisions.¹⁹¹

Although parental rights are strong, they are not absolute and the presumption that parents act in their children's best interests can be overcome. The fact that parents sometimes act *against* their children's best interests "creates a basis for caution."¹⁹² The state has the power to intervene if a parent's decisions jeopardize the child's physical or

¹⁸⁷ *Id.* at 600, 607.

¹⁸⁸ *Id.* at 602.

¹⁸⁹ *Id.* at 603.

¹⁹⁰ *Id.*

¹⁹¹ Douglas S. Diekema, *Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention*, 25 THEORETICAL MED. 243, 244 (2004).

¹⁹² *Parham*, 442 U.S. at 602 ("As with so many other legal presumptions, experience and reality may rebut what the law accepts as a starting point; the incidence of child neglect and abuse cases attest to this."); *see also* *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (holding that the rights of parenthood are not "beyond limitation").

mental health.¹⁹³ The best interest standard has become the threshold for determining whether a parent’s decision warrants state intervention.¹⁹⁴ As early as 1880, a state removed children from a parent’s care because the parent failed to seek medical treatment for his children.¹⁹⁵ Charles Heinemann had five children, three of whom died along with his wife. Instead of seeking a medical doctor, Heinemann provided his own treatment.¹⁹⁶ The Supreme Court of Pennsylvania appointed a guardian for the two surviving children based on Heinemann’s “shameful[]” neglect of his three deceased children.¹⁹⁷

The United States Supreme Court has also upheld state intervention in parental decisions regarding their children’s medical care. In *Jehovah’s Witnesses in the State of Washington v. King County Hospital Unit No. 1*, the Court affirmed the Washington District Court’s decision to uphold a state law empowering superior court judges to declare children dependent for purposes of authorizing blood transfusions against expressed parental objections.¹⁹⁸ In reaching its decision, the court cited *Prince v. Massachusetts*, which held that “neither rights of religion nor rights of parenthood are beyond limitation.”¹⁹⁹ The fact the parents objected to blood transfusions for their children on religious grounds did not shield their decision from state intervention. Importantly, the court reiterated that although “parents may be free to become martyrs themselves. . . . [i]t does not follow they are free . . . to make martyrs of their

¹⁹³ *Parham*, 442 U.S. at 603; see also *Custody of a Minor*, 379 N.E.2d 1053, 1066 (Mass. 1978).

¹⁹⁴ Diekema, *supra* note 191, at 246; Loretta M. Kopelman, *Best-Interests Standard as Threshold, Ideal, and Standard of Reasonableness*, 22 J. MED. & PHIL. 271 (1997) (defending the best interests standard).

¹⁹⁵ Appeal of Heinemann, 96 Pa. 112 (Pa. 1880).

¹⁹⁶ *Id.* at 115.

¹⁹⁷ *Id.*

¹⁹⁸ 278 F. Supp. 488 (W.D. Wash. 1967), *aff’d* 390 U.S. 598 (1968).

¹⁹⁹ *Id.* at 504 (citing *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944)).

children.”²⁰⁰ Furthermore, “[t]he right to practice religion freely does not include liberty to expose . . . the child to . . . ill health or death.”²⁰¹ In other cases, courts have found parents guilty of involuntary manslaughter,²⁰² reckless homicide,²⁰³ child neglect,²⁰⁴ and child endangerment²⁰⁵ for the consequences of failing to seek medical care for their children.

The exact situations when a court will allow limits on parental rights, however, are far from clear. The case law is inconsistent, with some courts allowing parents to make health care decisions that may contribute to the child’s ill health or even death. In 2002, for example, an Ohio court upheld a mother and father’s right to choose “alternative” treatments (such as nutritional supplements and dietary changes) over standard chemotherapy to treat their son Noah’s cancer, even though chemotherapy had a high success rate for treating his particular type of cancer.²⁰⁶ Noah’s cancer returned four months after he stopped chemotherapy.²⁰⁷ Despite his parents’ eventual agreement to re-

²⁰⁰ *Id.* (citing *Prince*, 321 U.S. at 170).

²⁰¹ *Id.* (citing *Prince*, 321 U.S. at 166).

²⁰² *Commonwealth v. Barnhart*, 497 A.2d 616, 626 (Pa. Super. Ct. 1985) (affirming parents’ convictions for involuntary manslaughter and endangering the welfare of a child after their son died from an untreated tumor because the parents did not believe in modern medicine).

²⁰³ *Bergmann v. State*, 486 N.E.2d 653 (Ind. Ct. App. 1985) (upholding parents’ convictions for reckless homicide and neglect of a dependent for the death of their ill nine-month old daughter who they treated with “prayers, fasting and invocations of scripture”).

²⁰⁴ *Id.*

²⁰⁵ *People v. Rippberger*, 283 Cal. Rptr. 111 (Cal. Ct. App. 1991) (upholding parents’ conviction for child endangerment for withholding medical treatment from their daughter based on their Christian Science beliefs, who died from meningitis); *Barnhart*, 497 A.2d. 616.

²⁰⁶ Jeffrey D. Hord, *Do Parents Have the Right to Refuse Standard Treatment for their Child with Favorable-Prognosis Cancer?—Ethical and Legal Concerns*, 24 J. CLINICAL ONCOLOGY 5454, 5454 (2006).

²⁰⁷ Associated Press, *Boy at Centre of Chemo Controversy Dies*, NBC NEWS (May 22, 2007, 11:27 AM), http://www.nbcnews.com/id/18801460/ns/health-cancer/t/boy-center-chemo-controversy-dies/#.VEZ-BfnF_uQ.

start chemotherapy, Noah died in 2007.²⁰⁸ His parents still question whether he would still be alive if he had received the initially-recommended chemotherapy treatments.²⁰⁹

Courts appear most likely to intervene when the minors involved are young and not considered mature enough to express with own wishes. Courts are somewhat less inclined to intervene if an older minor agrees with his parents' decision and if the minor appears competent to make such a decision.²¹⁰ Such decisions comport with the AAP's position that although physicians should usually obtain parental consent, patient involvement and *assent* (which implies the minor agrees with the parent's decision) is extremely important and minors should not be excluded from decision-making "without persuasive reason."²¹¹ It is also supported by the Hastings Center's guidelines, which suggest that a minor's preferences become more "ethically significant" with increasing

²⁰⁸ Elizabeth Cohen, *What are Parents' Rights Regarding a Child's Medical Treatment?*, CNN (May 28, 2009, 9:38 AM), <http://www.cnn.com/2009/HEALTH/05/28/treatment.parental.rights/>.

²⁰⁹ *Id.*

²¹⁰ *See, e.g., In re E.G.*, 549 N.E.2d 322 (Ill. 1989) (finding a mother not guilty of neglect for agreeing with her seventeen-year-old daughter's decision to refuse life-sustaining treatment). Courts will sometimes even consider younger children's desires, such as those of a ten-year-old girl who "begged her parents to stop [] chemotherapy." A judge agreed and blocked an Ohio hospital from forcing her to resume chemotherapy after her parents decided to stop the treatment. John Seewer, *Sarah Hershberger, Ohio Amish Girl, Can't Be Forced to Resume Cancer Treatments*, HUFFINGTON POST (Sept. 5, 2013, 11:37 AM), http://www.huffingtonpost.ca/2013/09/05/sarah-hershberger-ohio-amish-girl_n_3873941.html. *But see* Samantha Masunaga, *Connecticut Teen Fighting State Justices' Ruling on Forced Chemotherapy*, L.A. TIMES (Jan. 10, 2015, 8:53 PM), <http://www.latimes.com/nation/la-na-teen-chemo-20150111-story.html>. This article discusses the January 2015 ruling of the Connecticut Supreme Court, which held that the rights of 17-year-old Cassandra C. were not violated by the state forcing her to undergo chemotherapy she did not want. Unlike some cases (and unlike cases involving parental *refusal* for vaccines), however, Cassandra actually had her mother's support to refuse the treatment. Cassandra was diagnosed with high-risk Hodgkin's disease in September 2014 and doctors testified that without treatment, she would die, whereas with treatment she had an 80–85% chance of survival and recovery. *Id.*

²¹¹ Am. Acad. Pediatrics Comm. on Bioethics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314, 314 (1995).

age.²¹² By the age of fourteen, the Hastings Center states that “the decision-making capacity of adolescents should be respected” and they should have the opportunity to make their own informed choices and/or participate with their parents/guardians in decisions about their health care.²¹³

b. Vaccinations and Parental Consent

Many vaccines are recommended at an age when there is little, if any, question about the child’s *inability* to consent or assent. The three-dose Hepatitis B vaccine, for example, is recommended to be completed by eighteen months of age.²¹⁴ Numerous other vaccines are recommended by the time the child is six, including vaccines for *Haemophilus influenzae* type B (Hib); Measles, Mumps, and Rubella (MMR); Polio; Varicella (chicken pox); and Hepatitis A.²¹⁵ Like other forms of health care, parents must consent to immunizations, even if the vaccine is required for children to attend public schools or day care.²¹⁶ No federal vaccination law exists but all fifty states require certain vaccines for children entering public schools. States frequently require some or all of the following vaccines: MMR; Tdap; and polio.²¹⁷ However, parents are often allowed to

²¹² THE HASTINGS CENTER GUIDELINES FOR DECISIONS ON LIFE-SUSTAINING TREATMENT 84 (Nancy Berlinger et al. eds., 2d ed. 2013). The Hastings Center is “an independent, nonpartisan, and nonprofit bioethics research institute” that addresses “fundamental ethical issues in the areas of health, medicine, and the environment as they affect individuals, communities, and societies.” *About Us: Our Mission*, HASTINGS CTR., <http://www.thehastingscenter.org/About/Default.aspx?id=5009> (last visited Mar. 30, 2015).

²¹³ THE HASTINGS CENTER GUIDELINES FOR DECISIONS ON LIFE-SUSTAINING TREATMENT, *supra* note 212, at 85.

²¹⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, RECOMMENDED IMMUNIZATION SCHEDULE FOR PERSONS AGED 0 THROUGH 18 YEARS—UNITED STATES 2014 (Jan. 1, 2014), <http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-schedule-bw.pdf>.

²¹⁵ *Id.*

²¹⁶ *State Vaccination Requirements*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html> (last updated Sept. 30, 2011).

²¹⁷ *Id.*

seek exemptions from these requirements. The reasons for exemptions vary by state and include medical, religious, and philosophical/personal belief exemptions.²¹⁸ The “philosophical exemptions” are broad and may allow exemptions based on moral, philosophical, or other personal beliefs.²¹⁹

For vaccines that are recommended but not state-mandated,²²⁰ parents have absolute power to determine whether their children receive a particular vaccine because there are no additional procedural “hoops” to jump through to receive an exemption. In fact, one way lawmakers have tried to decrease the number of exemptions from mandated vaccines is by making the procedure to request and receive an exemption more time-consuming and burdensome, such as requiring annual exemption renewals and physician signatures.²²¹

²¹⁸ *School Vaccination Requirements, Exemptions and Web Links*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www2a.cdc.gov/nip/schoolsurv/schImmRqmtReport.asp> (last updated July 21, 2011).

²¹⁹ *States with Religious and Philosophical Exemptions from School Immunization Requirements* (Mar. 3, 2015), NAT’L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>.

²²⁰ Which vaccines are or are not mandated for public school attendance varies somewhat by state. The HPV vaccine, for example, is only required in Virginia and D.C. for girls entering sixth grade public schools. KFF, *The HPV Vaccine*, *supra* note 157, at 4. The seasonal flu vaccine is another commonly recommended but not required vaccine. *School Starts Soon—Is Your Child Fully Vaccinated?*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Aug. 11, 2014), <http://www.cdc.gov/Features/CatchUpImmunizations/>; *State Information*, IMMUNIZATION ACTION COAL. (last updated Feb. 24, 2015), <http://www.immunize.org/laws/> (indicating which vaccines are required for public school attendance).

²²¹ See Editorial, *Unvaccinated Kids Make Everyone Sick*, BLOOMBERGVIEW (Mar. 6, 2014, 6:50AM), <http://www.bloombergtview.com/articles/2014-03-06/unvaccinated-kids-make-everyone-sick> (arguing for laws that will make it more difficult for parents to obtain philosophical exemptions); Tara Haelle, *US States Make Opting Out of Vaccinations Harder*, NATURE (Oct. 5, 2012), <http://www.nature.com/news/us-states-make-opting-out-of-vaccinations-harder-1.11548> (“To increase vaccination rates, law-makers want to make it harder to get an exemption than it is to get a vaccination.”).

As of September 2014, only Virginia and the District of Columbia (D.C.) mandate the HPV vaccine for girls entering sixth grade.²²² Many states have proposed legislative mandates with little success. Texas, for example, was the first state to enact a mandate by executive order from Governor Perry.²²³ After much controversy and public debate, the Texas legislature passed House Bill 1098 to override the executive order and Governor Perry did not attempt to veto the bill.²²⁴ Like other mandates, parents can opt out of the Virginia and D.C. requirements. The D.C. mandate, for example, allows parents to opt out for medical, religious, or “*any* reason.”²²⁵ The Virginia law has similar provisions making it easy to opt-out. The Virginia mandate states:

Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent’s or guardian’s *sole discretion*, may elect for the . . . child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved by the [State Board of Health Regulations for the Immunization of School Children].²²⁶

Legislative mandates are a common approach to addressing low uptake rates for important vaccines. Mandates, however, especially for the HPV vaccine, are controversial and almost always include broad exemptions.²²⁷ As a result, mandates are

²²² KFF, *The HPV Vaccine*, *supra* note 157, at 4.

²²³ *HPV Vaccine Policies*, NAT’L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/hpv-vaccine-state-legislation-and-statutes.aspx> (last visited Feb. 18, 2015); Wade Goodwin, *In Texas, Perry’s Vaccine Mandate Provoked Anger*, NAT’L PUB. RADIO (Sept., 16, 2011, 3:22 PM), <http://www.npr.org/2011/09/16/140530716/in-texas-perrys-vaccine-mandate-provoked-anger>.

²²⁴ *HPV Vaccine Policies*, *supra* note 223.

²²⁵ D.C. CODE § 7-1651.04 (West 2014).

²²⁶ VA. CODE ANN. § 32.1-46(D)(3) (West 2014).

²²⁷ See Jason L. Schwartz, *Unintended Consequences: The Primacy of Public Trust in Vaccination*, 107 MICH. L. REV. FIRST IMPRESSIONS 100 (2009) (noting the increasing

generally inadequate when parents can obtain exemptions for practically any or no reason at all.²²⁸ Allowing minors to make informed decisions and consent to the HPV vaccine may be a useful component to other measures attempting to increase HPV vaccination rates. The next Part discusses minor consent laws in the context of health care decisions and provides a foundation for laws lowering the age of consent for the HPV vaccine.

2. Minors' Consent to Health Care

Under the common law, competent adults have complete autonomy over their own bodies, including the right to consent to or refuse medical care. As stated by Supreme Court Justice Horace Gray in 1891, “[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”²²⁹ In 1914, Justice Benjamin Cardozo elaborated on this right in the medical context, stating that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”²³⁰ This complete autonomy over one’s body, however, does not generally extend to minors.

availability of personal belief exemptions from state vaccination requirements and the concern that these exemptions will impact vaccine rates).

²²⁸ VA. CODE ANN. § 32.1-46(D)(3). In a study examining the impact of philosophical exemptions between 1991 and 2004, the number of unvaccinated children in states with philosophical exemptions more than doubled. Saad B. Omer et al., *Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence*, 296 J. AM. MED. ASS’N 1757, 1760 (2006) [hereinafter Omer et al., *Nonmedical Exemptions*]. A follow-up study concluded that philosophical exemptions have continued to increase and the rate of increase has accelerated. Saad B. Omer et al., *Vaccination Policies and Rates of Exemption from Immunization, 2005–2011*, 367 N. ENGL. J. MED. 1170, 1171 (2012).

²²⁹ *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

²³⁰ *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *abrogated by Bing v. Thunig*, 143 N.E. 2d 3 (N.Y. 1957).

Minors are generally considered incompetent to make legally-binding health care decisions, and parents or guardians are empowered to make decisions on their behalf.²³¹ In the majority of states, a “minor” is any person under eighteen and absent an applicable exception, an HCP may only provide treatment to a minor with the parent’s (or other lawfully authorized party’s) consent.²³²

As previously discussed, parental decisions on behalf of their minor children are generally subject to the best interest standard and the state may intervene if such decisions are not in a child’s best interest.²³³ In addition to a state’s ability to intervene, minors themselves are legally empowered to make certain decisions without parental consent. Despite the long legal and social history of treating minors as incompetent, times have changed and adolescents are no longer “regarded as property of their parents [or] regarded as merely the recipients of paternalistic decisions made on their behalf by physicians and parents in health care settings.”²³⁴ Adolescents are increasingly recognized as having the capacity to make their own health care decisions.²³⁵ State laws recognizing minors’ rights to consent to certain types of medical treatment seek to balance parental rights and obligations with minors’ autonomy and rights to privacy when accessing certain health care. Attempts to achieve this balance, however, have resulted in “a confusing set of seemingly arbitrary and sometimes conflicting provisions.”²³⁶

²³¹ WALKER ET AL., *supra* note 168, at 141–42.

²³² David M. Vukadinovich, *Minors’ Rights to Consent to Treatment: Navigating the Complexity of State Laws*, 37 J. HEALTH L. 667, 670 (2004).

²³³ Diekema, *supra* note 191, at 246.

²³⁴ Robert F. Weir & Charles Peters, *Affirming the Decisions Adolescents Make About Life and Death*, 27 HASTINGS CTR. REP., Nov./Dec. 1997, at 29, 29.

²³⁵ *Id.*

²³⁶ *Id.* at 668.

There are numerous exceptions to the presumption of parental consent that allow minors to consent to their own medical treatment. The first exception arises in emergency situations when delaying treatment to obtain parental consent could jeopardize the minor's health.²³⁷ This exception developed in case law and statutory law. Statutes providing the emergency exception to parental consent typically take one of three forms: (1) allowing treatment without parental consent; (2) relieving provider liability for those who treat without consent; and (3) allowing minors to consent to emergency care.²³⁸ A second exception allows "emancipated minors" to make personal health decisions.²³⁹ A minor may be considered "emancipated" based on a variety of factors such as marriage, parenthood, military service, parental consent, judicial order, or financial independence.²⁴⁰ "Mature minors" are a third class recognized as having the capacity to make personal health decisions because they are considered "sufficiently mature to make their own decisions about recommended medical treatment and, when necessary, to go against their parents' views regarding the treatment."²⁴¹ The "mature minor" doctrine is generally rooted in common law²⁴² and a few states have codified the doctrine.²⁴³

²³⁷ See ROGER J.R. LEVESQUE, ADOLESCENTS, SEX, AND THE LAW: PREPARING ADOLESCENTS FOR RESPONSIBLE CITIZENSHIP 78 (2000).

²³⁸ *Id.* For a list of states with such statutes, see *id.* at 95 nn. 192–94.

²³⁹ *Id.* at 78.

²⁴⁰ Weir & Peters, *supra* note 234, at 33. For example, under New York's "Family Health Care Decisions Act," an "emancipated minor" is a minor who is a parent or who is sixteen or older and lives independently from his or her parents. N.Y. PUB. HEALTH LAW § 2994-a(8)(West 2014). Under the Act, emancipated minors can make decisions about life-sustaining treatment. N.Y. PUB. HEALTH LAW § 2994-e (West 2014).

²⁴¹ Weir & Peters, *supra* note 234, at 33.

²⁴² See, e.g., *Younts v. St. Francis Hosp. & Sch. of Nursing*, 469 P.2d 330, 338 (Kan. 1970) (holding that parental consent is not required when a minor is "mature enough to understand the nature and consequences and to knowingly consent to" a beneficial procedure); *Cardwell v. Bechtol*, 724 S.W.2d 739, 746 (Tenn. 1987) (recognizing the mature minor exception that allows a minor to consent to treatment "when the child is close to majority or maturity and knowingly

A fourth exception and one of particular relevance for lowering the age of consent for the HPV vaccine originates from statutes carving out specific services and treatments that minors may consent to without parental involvement. These statutes often address services related to pregnancy and abortion,²⁴⁴ treatment for infectious/communicable disease such as STIs,²⁴⁵ alcohol and drug abuse treatment,²⁴⁶ and mental health services.²⁴⁷ Some of these statutes impose a minimum age, such as twelve²⁴⁸ or fourteen,²⁴⁹ for minors to consent to certain services without parental consent. A few states have adopted a lower age of majority specifically for medical treatment of *any*

gives an informed consent to the treatment”); *Belcher v. Charleston Area Med. Ctr.*, 422 S.E.2d 827, 838 (W. Va. 1992) (recognizing the mature minor doctrine which allows a minor to consent to medical treatment if they “appreciate the nature, risks, and consequences of the medical procedure to be performed, or the treatment to be administered or withheld”).

²⁴³ *See, e.g.*, ALASKA STAT. § 25.20.025(2) (West 2014) (granting minors the right to consent to medical treatment if a parent cannot be contacted or, if contacted, the parent is unwilling to provide consent); ARK. CODE § 20-9-602(7) (West 2014) (allowing unemancipated minors to consent to medical treatment if they are “of sufficient intelligence to understand and appreciate the consequences of the proposed” treatment); IDAHO CODE ANN. § 39-4503 (West 2014) (providing that “*any* person who comprehends the need for, the nature of, and the significant risks inherent in any contemplated . . . treatment or procedure is competent to consent thereto on his or her own behalf”) (emphasis added); NEV. REV. STAT. § 129.030(2) (West 2014) (allowing minors to consent to medical treatment if they “understand[] the nature and purpose of the proposed examination or treatment and its probable outcome, and voluntarily request it”).

²⁴⁴ *See* Guttmacher Inst., *An Overview of Minors’ Consent Law*, ST. POLICIES IN BRIEF (Oct. 1, 2014) http://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf [hereinafter Guttmacher Inst., *An Overview of Minors’ Consent Law*] (providing a chart listing a minor’s rights to consent to services such as contraception, STI treatment, prenatal care, and abortion).

²⁴⁵ Vukadinovich, *supra* note 232, at 685 n. 80 (listing some of the state statutes providing minors the right to consent to treatment of certain infectious and/or STDs).

²⁴⁶ *See* LEVESQUE, *supra* note 238, at 79–80 (discussing laws providing exceptions to parental consent requirements for particular services); Vukadinovich, *supra* note 232, at 684 n.72 (listing state laws allowing certain minors to consent to medical treatment and counseling services related to drug or alcohol related problems).

²⁴⁷ Vukadinovich, *supra* note 232, at 682 n. 57 (listing state laws allowing certain minors to consent to mental health services).

²⁴⁸ *See, e.g.* ALA. CODE § 22-11A-19 (West 2014); CAL. FAM. CODE § 6926 (West 2014); DEL. CODE ANN. § 710 (West 2014); 410 ILL. COMP. STAT. 210/§ 4 (West 2014); VT. STAT. ANN. tit. 18, § 4226 (West 2014).

²⁴⁹ IDAHO CODE ANN. § 39-3801 (West 2014); N.H. REV. STAT § 141-C:18 (II) (West 2014); N.D. CODE ANN. § 14-10-17 (West 2013); REV. CODE WASH. ANN. § 70.24.110 (West 2014).

kind. For example, South Carolina law provides that “any minor who has reached the age of sixteen years may consent to any health services”²⁵⁰ and Oregon law provides that “a minor 15 years of age or older may give consent, without the consent of a parent or guardian of the minor to” medical care by a licensed physician, physician assistant, or nurse practitioner.²⁵¹

All fifty states and D.C. allow minors to consent for health care related STIs and do not require parental consent or notification except in limited situations.²⁵² As noted, some of these statutes provide a minimum age for such consent (e.g., twelve through fifteen) whereas others allow a minor of any age to give such consent. Most of the statutes limit the minor’s ability to consent to STI *diagnosis* and *treatment* and therefore typically do not extend to vaccines which are considered preventative.²⁵³ Although some

²⁵⁰ S.C. LAWS ANN. § 63-5-350 (West 2014).

²⁵¹ ORE. REV. STAT. ANN § 109.640 (West 2014); *see also* KAN. STAT. ANN. § 38-123b (West 2014) (“[A]ny minor sixteen (16) years of age or over . . . may give consent to the performance and furnishing of hospital, medical, or surgical treatment.”).

²⁵² Guttmacher Inst., *An Overview of Minors’ Consent Law*, *supra* note 244; Kimberly A. Workowski & Stuart Berman, *Sexually Transmitted Diseases Treatment Guidelines, 2010*, 59 MORBIDITY & MORALITY WKLY. REP. 10 (2010), *available at* <http://www.cdc.gov/std/treatment/2010/std-treatment-2010-rr5912.pdf>.

²⁵³ ALA. CODE § 22-11A-19 (West 2014); ALASKA STAT. § 25.20.025 (West 2014); ARIZ. REV. STAT. § 44-132.01 (West 2014); ARK. CODE ANN. § 20-16-508 (West 2014); COLO. REV. STAT. § 25-4-402 (West 2014); CONN. GEN. STAT. § 19a-216 (West 2014); DEL. CODE ANN. tit. 16 § 710 (West 2014); FLA. STAT. ANN. § 384.30 (West 2014); GA. CODE ANN. § 31-17-7 (West 2014); HAW. REV. STAT. § 577A-2 (West 2014); IDAHO CODE ANN. § 39-3801 (West 2014); 410 LL. COM. STAT. § 210/4 (West 2014); IND. CODE ANN. § 16-36-1-3 (West 2014); KY. REV. STAT. § 214.185 (West 2014); LA. STAT. ANN. § 40:1065.1 (West 2014); ME. REV. STAT. tit. 32, § 3292 (West 2014); MD. CODE ANN. HEALTH-GEN. § 20-102; MASS. GEN. LAW ANN. 112 § 12F (West 2014); MICH. COMP. LAWS ANN. § 333.5127 (West 2014); MINN. STAT. ANN. § 144.343 (West 2014); MISS. CODE ANN. § 41-41-13 (West 2014); MO. REV. STAT. § 431.061(1)(4)(b) (West 2014); NEB. REV. STAT. § 71-504 (West 2014); NEV. REV. STAT § 129.060 (West 2014); N.J. STAT. ANN. § 9:17A-4 (West 2014); N.M. STAT. ANN. § 24-1-9 (West 2014); N.Y. PUB. HEALTH LAW § 2305 (West 2014); N.D. CODE ANN. § 14-10-17 (West 2014); OHIO REV. CODE ANN. § 3709.241 (West 2014); ORE. REV. STAT. ANN. § 109.610 (West 2014); 35 PENN. STAT. § 10103 (West 2014); R.I. GEN. LAWS § 23-11-11 (West 2014); TENN. CODE § 68-10-104 (West 2014);

argue that “diagnosis and treatment” should include preventative measures, others disagree.²⁵⁴ This uncertainty makes many HCPs wary of providing the vaccine in absence of parental consent for fear of potential legal liability.

A California statute allowing minors twelve years and older to “consent to medical care related to the prevention of a sexually transmitted disease” is interpreted to include the right to consent to vaccinations.²⁵⁵ California Assemblyman Tim Donnelly proposed a bill to amend the law in 2013 to include a provision stating “this section *does not* authorize a minor to receive a vaccine without the consent of the parent or guardian of the minor.”²⁵⁶ The amendment did not pass.²⁵⁷ Missouri recently amended its law to allow minors to consent to “any surgical, medical, or other treatment or procedures, including immunizations” for venereal disease.²⁵⁸

TEX. FAM. CODE ANN. § 32.003 (West 2014); UTAH CODE ANN. § 26-6-18 (West 2014); VT. STAT. ANN. tit. 18, § 4226 (West 2014); VA. CODE ANN. § 54.1-2969 (West 2014); WASH. REV. CODE ANN. § 70.24.110 (West 2014); W.VA. CODE ANN. § 16-4-10 (West 2014); WISC. STAT. ANN. § 252.11 (1m) (West 2014); WYO. STAT. ANN. § 35-4-131 (West 2014).

²⁵⁴ Angela Roddey Holder, *From Chattel to Consenter: Adolescents and Informed Consent*, 83 YALE J. BIOL. & MED. 35, 36–37 (2010) (arguing that when the law is unclear whether “diagnosis and treatment” includes preventive services such as vaccines, “good medical practice” indicates that vaccines should be given even without parental consent); Memorandum from Donna Lieberman & Galen Sherwin, N.Y. Civ. Liberties Union, to Interested Parties (June 6, 2008) (discussing the New York Civil Liberties Union’s belief that New York law permits minors to provide informed consent for the HPV vaccine without parental involvement). *But see* Donna T. Chen et al., *The HPV Vaccine and Parental Consent*, 14 VIRTUAL MENTOR 5 (2012) (arguing that a Virginia statute allowing minors to consent to “services that test or treat sexually transmitted or other reportable diseases . . . do not explicitly cover *prevention* of sexually transmitted diseases” likely does not extend to the HPV vaccine).

²⁵⁵ CAL. FAM. CODE § 6926 (West 2014).

²⁵⁶ CAL. A.B. No. 599, 2013–14 Reg. Sess. (Cal. 2013) (failed to pass) (emphasis added).

²⁵⁷ *Id.*; Patrice La Vigne, *New State Vaccine Bills Threaten Vaccine Choices*, NAT’L VACCINE INFO. CTR. (Apr. 22, 2013, 11:54 AM), <http://www.nvic.org/NVIC-Vaccine-News/April-2013/New-State-Vaccine-Bills-Threaten-Vaccine-Choices.aspx> (arguing that the amendment should have been passed because the current statute is “a violation of parental informed consent”).

²⁵⁸ MO. STAT. § 431.061 (West 2014).

Some state statutes include language about *prevention* of venereal diseases and thus could arguably apply to vaccinations. Iowa’s statute, for example, states that “[a] minor shall have the legal capacity to act and give consent to provision of medical care or services . . . for the prevention, diagnosis, or treatment of a sexually transmitted disease or infection.”²⁵⁹ The previous version of this law only allowed minors to consent to diagnosis and treatment of STIs,²⁶⁰ thus the addition of the word “prevention” suggests a deliberate change that would arguably allow minors to consent to vaccinations to prevent STIs.²⁶¹ However, some (but not all) of these statutes include language that may limit a minor’s ability to consent to preventive treatment to situations in which the minor was potentially *exposed* to the virus.²⁶² Such a limitation would preclude a pre-sexually active minor from consenting to the HPV vaccine because they have not been “potentially exposed” to HPV. The statutory language makes it unclear whether minors have the authority to consent to the HPV vaccine, particularly if the minor has never been exposed (or potentially exposed) to the virus (e.g., they are not yet sexually active).²⁶³ Illinois’

²⁵⁹ IOWA CODE § 139A.35 (West 2014).

²⁶⁰ IOWA CODE § 139A.35 (amended 2008).

²⁶¹ *Reminder: New Laws Effective July 1*, IOWA MED. SOC’Y (June 13, 2008), <http://www.lamblawoffice.com/documents/IAUpdate.pdf>.

²⁶² D.C. MUN. REG. tit. 22-B, § 600 (West 2014) (not limited to post-exposure prevention); IOWA CODE ANN. § 139A.35 (West 2014) (not limited to post-exposure prevention); KAN. STAT. ANN. § 65-2892 (West 2014) (potentially limited to post-exposure prophylactic treatment); MO. STAT. § 431.061 (West 2014) (not limited to post-exposure prophylactic treatment); MONT. ST. § 41-1-402 (West 2014) (potentially limited to post-exposure prevention); NEB. REV. STAT. § 71-504 (West 2014) (potentially limited to post-exposure prevention); N.C. GEN. STAT. ANN. § 90-21.5 (West 2014) (not limited to post-exposure prevention); (West 2014); OKLA. STAT. ANN. tit. 63, § 2602 (2014) (potentially limited to post-exposure prevention); S.D. COD. LAWS § 34-23-16 (2014) (potentially limited to post-exposure prophylactic treatment).

²⁶³ *See* NEB. REV. STAT. § 71-504 (West 2014) (allowing minors to consent to prophylactic treatment for exposure to STDS “whenever such person is suspected of having [an STD] or contact with anyone having [an STD]”); OKLA. STAT. ANN. tit. 63, § 2602 (West 2014)

statute, for example, provides that “a minor 12 years of age or older who may have come into contact with any sexually transmitted disease . . . may give consent to the furnishing of medical care or counseling related to the diagnosis or treatment of the disease.”²⁶⁴

Although this statutory language does not provide a right to consent to preventative treatment or vaccinations, Illinois’ Administrative Code states that “a minor 12 years of age or older who may have *come into contact* with any STI may give consent to the furnishing of medical care or counseling related to the diagnosis or treatment of, *or vaccination against*, an STI.”²⁶⁵ However, because the regulation’s language appears to restrict the minor’s ability to consent to situations in which the minor has (or may have) been exposed to the venereal disease, this provision may not provide a minor with the right to consent to the HPV vaccine if the minor is not yet sexually active and has not “come into contact with” HPV.

A primary rationale for laws allowing minors to obtain STI treatment without parental consent is to encourage adolescents to seek STI treatment by guaranteeing confidentiality.²⁶⁶ An adolescent’s concerns about confidentiality are a common barrier to the delivery of adolescent health care, particularly sexual and reproductive health services.²⁶⁷ These laws also promote public health by encouraging minors to obtain care

(providing a minor’s right to consent to “prevention, diagnosis, and treatment” if they have been “*afflicted* with any reportable communicable disease”) (emphasis added).

²⁶⁴ 410 ILL. COMP. STAT. § 210/4 (West 2014).

²⁶⁵ ILL. ADMIN. CODE § 693.130 (West 2014).

²⁶⁶ Vukadinovich, *supra* note 232, at 686.

²⁶⁷ Comm. Adolescent Health Care, *Committee Opinion No. 598: Initial Reproductive Health Visit*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS 2 (May 2014); M. Diane McKee et al., *Predictors of Timely Initiation of Gynecologic Care Among Urban Adolescent Girls*, 39 J. OF ADOLESCENT HEALTH 183, 184, 189 (2006) (citing numerous studies suggesting that

for diseases that may pose a threat to others.²⁶⁸ As a result, these laws promote the best interests of the minor and society as a whole. They reduce the impact and potential long-term consequences of STIs for adolescents and reduce STI prevalence in society.

Although many adolescents will involve their parents in such situations, “an adolescent with a sexually-transmitted disease . . . may forego treatment rather than risk a parent’s embarrassment, disapproval, or violence. Many teens live in dysfunctional family environments, and parental involvement laws cannot transform these families into stable homes.”²⁶⁹ Yet HCPs may feel precluded from providing confidential care without parental consent because the lack of legal clarity on these issues may create fears of legal and professional liability.²⁷⁰

Providing adolescents with access to confidential health care is one reason to lower the age of consent for the HPV vaccine. Yet even if parental notification were required (and therefore not providing confidentiality), there are many additional reasons

confidentiality concerns are a well-documented barrier influencing adolescents’ decisions to seek reproductive health care); Vukadinovich, *supra* note 232, at 686.

²⁶⁸ Vukadinovich, *supra* note 232, at 686.

²⁶⁹ John Loxteman, *Adolescent Access to Confidential Health Services*, ADVOCATES FOR YOUTH (July 1997), <http://www.advocatesforyouth.org/publications/publications-a-z/516-adolescent-access-to-confidential-health-services>; *see also* Rachel K. Jones & Heather Boonstra, *Confidential Reproductive Health Services for Minors: The Potential Impact of Mandated Involvement for Contraception*, 36 PERSP. ON SEXUAL & REPROD. HEALTH 182, 182 (2004) (noting that the American Medical Association, the American Congress of Obstetricians and Gynecologists, and the Society for Adolescent Medicine have all “issued statements asserting that confidential reproductive health services should be available to minors”); Rachel K. Jones et al., *Adolescents’ Reports of Parental Knowledge of Adolescents’ Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception*, 293 J. AM. MED. ASS’N 340, 342 (2005) (listing reasons why minors may not inform their parents about their use of sexual health services, such as not wanting their parents to know they are sexually active and fear of disapproval or disappointment).

²⁷⁰ Providing care without informed consent (or the parent’s informed consent, in the case of minors), can result in liability for battery, medical malpractice, and unprofessional conduct, any of which could also result in a suspended license. *See* sources cited *infra* notes 535–539 and accompanying text.

to support lowering the age of consent for the vaccine. These reasons will be fleshed out in Part III. Part II first discusses opposition to the HPV vaccine and lowering the age of consent.

II. OPPOSITION TO THE HPV VACCINE AND LOWERING THE AGE OF CONSENT

Any law limiting parental rights will undoubtedly engender opposition. Lowering the age of consent for the HPV vaccine not only limits a parent's role in her adolescent's health care decisions, it also implicates two controversial topics: vaccination and adolescent sexual health and behavior. Some will continue to oppose the vaccine completely, regardless of who can consent, based on (frequently incorrect) beliefs about the vaccine's safety, effectiveness, and impact on adolescent sexual behavior.

This Part discusses some of the primary reasons individuals may give for opposing a lower age of consent. Part A provides a brief history of anti-vaccine sentiments and controversies that have fueled the recent backlash against vaccines, including the HPV vaccine. Part B focuses on concerns specifically related to the HPV vaccine and lowering the age of consent.

A. BRIEF HISTORY OF THE ANTI-VACCINATION MOVEMENT

Concerns about vaccine safety are not new, beginning shortly after the smallpox vaccine's introduction and continuing "unabated ever since."²⁷¹ Indeed, anti-vaccine

²⁷¹ Robert M. Wolfe & Lisa K. Sharp, *Anti-Vaccinationists Past and Present*, 325 BRIT. MED. J. 430, 430 (2002).

sentiments seem to have increased in recent years, and there are “few public health issues where views are as extremely polarized as those concerning vaccination policies.”²⁷²

A major catalyst for the recent vaccine backlash was a now-retracted study published in *The Lancet* in 1998.²⁷³ The article, written by Dr. Andrew Wakefield and his colleagues, suggested a link between the MMR vaccine and autism, turning “tens of thousands of parents around the world” against the MMR vaccine.²⁷⁴ Wakefield’s small study of only twelve children—carefully selected by Wakefield and funded in part by lawyers for parents suing vaccine manufacturers—received much attention after it was picked up by popular media and fueled by speeches and public appearances of Dr. Wakefield, politicians, and celebrities.²⁷⁵ Parents seeking answers and a cause for their children’s illness were vulnerable to Wakefield’s explanation and “seized upon the apparent link” between routine childhood vaccines and autism.²⁷⁶

After countless studies contested Dr. Wakefield’s findings, *The Lancet* retracted the study, stating that several elements of the paper were “incorrect.”²⁷⁷ The paper has

²⁷² Tomljenovic & Shaw, *supra* note 105.

²⁷³ Andrew J. Wakefield et al., *Illeal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637 (1998). The Article was retracted in February 2010. Editors of the Lancet, *Retraction—Illeal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 375 LANCET 445 (2010).

²⁷⁴ Laura Eggertson, *Lancet Retracts 12-Year-Old Article Linking Autism to MMR Vaccines*, 182 CAN. MED. ASS’N J. E199, E199 (2010).

²⁷⁵ *Id.*; Scott Gottlieb, *Why Debate Over Vaccines and Autism Will Continue*, FORBES (Feb. 4, 2015, 4:34AM), <http://www.forbes.com/sites/scottgottlieb/2015/02/04/why-debate-over-vaccines-and-autism-will-continue/> (discussing how some political leaders helped “sow[] suspicions” and media outlets “gave voice to junky scientific theories propagated by purported ‘experts’ like Jenny McCarthy”).

²⁷⁶ Eggerston, *supra* note 274, at E199.

²⁷⁷ Editors of the Lancet, *supra* note 273; Eggerston, *supra* note 274, at E199.

been described as “an elaborate fraud.”²⁷⁸ Subsequently, Britain’s General Medical Council applied its most severe sanction against Dr. Wakefield, banning him from practicing medicine in Britain.²⁷⁹ After conducting the longest investigation in its history, the Council found Wakefield guilty of more than thirty charges, finding several instances of unprofessional conduct, including conducting unnecessary medical procedures on children and unethical research subject recruitment.²⁸⁰ The Council concluded he had shown a “callous disregard” for the children in his study and had “brought the medical profession into disrepute.”²⁸¹

Despite the study’s retraction, widespread condemnation of Wakefield, and substantial evidence that there is no link between vaccines and autism, “the damage was done.”²⁸² Fears about vaccines have caused many parents to delay, space out, or completely refuse vaccines, including those required for public school attendance.²⁸³

Each year, ACIP publishes immunization “schedules” for various age groups summarizing when ACIP-recommended vaccines should be administered.²⁸⁴ A recent

²⁷⁸ Fiona Godlee et al., *Wakefield’s Article Linking MMR Vaccine and Autism Was Fraudulent*, 342 BRIT. MED. J. (2011); see also Brian Deer, *Exposed: Andrew Wakefield and the MMR-Autism Fraud*, BRIANDEER.COM, <http://briandeer.com/mmr/lancet-summary.htm> (last visited Mar. 18, 2015) (discussing Brian Deer’s investigation into Wakefield’s study).

²⁷⁹ John F. Burns, *British Council Bars Doctor Who Linked Vaccine with Autism*, N.Y. TIMES, May 24, 2010, http://www.nytimes.com/2010/05/25/health/policy/25autism.html?_r=0.

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² Paul A. Offit, *The Anti-Vaccination Epidemic*, WALL ST. J. (Sept. 24, 2014, 6:40 PM), <http://www.wsj.com/articles/paul-a-offit-the-anti-vaccination-epidemic-1411598408>.

²⁸³ *Id.*; see also Philip J. Smith et al., *Parental Delay of Refusal of Vaccine Doses, Childhood Vaccination Coverage at 24 Months of Age, and the Health Belief Model*, 126 PUB. HEALTH REP. 135, 144 (2011) (finding that many parents report concerns about autism as a reason for refusing vaccines).

²⁸⁴ *Birth–18 Years & “Catch-Up” Immunization Schedules: United States, 2015*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Feb. 23, 2015), <http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>.

study reported that the 2009 routine childhood immunization schedule will prevent approximately 42,000 early deaths and 20 million cases of disease among the 2009 birth cohort.²⁸⁵ It will produce a net savings of \$13.5 billion in direct costs and \$68.8 billion in total societal costs.²⁸⁶ Despite these benefits, a growing number of parents seek to deviate from the recommended schedule.²⁸⁷ A 2010 survey of a nationally-representative sample of parents of children six months to six years of age found that 13% of parents reported following an alternative vaccination schedule.²⁸⁸ Eighty-two percent of parents following an alternative schedule believed delaying and/or spacing out vaccines was associated with fewer side effects.²⁸⁹ Following an alternative schedule can lead to “underimmunization,” which significantly increases the risk of acquiring and transmitting vaccine-preventable diseases.²⁹⁰ Despite these negative consequences, a recent study found that increasing numbers of physicians agree to alternative schedules. Thirty-seven percent of physicians surveyed said they often/always agreed and thirty-seven percent said they sometimes agreed.²⁹¹ Physicians reported spending a significant amount of time discussing vaccinations, including the benefits of following the recommended schedule,

²⁸⁵ Fangjun Zhou et al., *Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009*, 133 PEDIATRICS 577, 581–82 (2014).

²⁸⁶ *Id.*

²⁸⁷ Amanda F. Dempsey et al., *Alternative Vaccination Schedule Preferences Among Parents of Young Children*, 128 PEDIATRICS 848, 849 (2011).

²⁸⁸ *Id.* at 850.

²⁸⁹ *Id.* at 852 tbl. 5.

²⁹⁰ Allison Kempe et al., *Physician Response to Parental Requests to Spread out the Recommended Vaccine Schedule*, 135 PEDIATRICS 666, 667 (2015).

²⁹¹ *Id.* at 669–70.

but often agreed to an alternative schedule, believing it would build trust with families and prevent them from leaving their practice.²⁹²

Other parents completely refuse recommended vaccines. In numerous states, parents can cite “personal beliefs” to receive exemptions from mandatory vaccines.²⁹³ In the years following the Wakefield study, the number of parents seeking and receiving exemptions increased. A 2006 study published in the *Journal of the American Medical Association*, for example, reported that in states allowing personal belief exemptions, the mean exemption rate increased an average of 6% per year between 1991 and 2004.²⁹⁴

Vaccine refusal and delays are linked to increasing rates of vaccine-preventable illnesses,²⁹⁵ including the recent measles outbreak in Disneyland in California.²⁹⁶ As of

²⁹² *Id.* at 671. In fact, the AAP recommends that doctors try to keep vaccine-refusing patients instead of refusing to treat them, because losing them would also mean losing “the opportunity to educate, cajole, or persuade them” to eventually consent to vaccination. See Catherine Saint Louis, *Most Doctors Give In to Requests by Parents to Alter Vaccine Schedules*, N.Y. TIMES, Mar. 2, 2015, A12.

²⁹³ According to the National Conference of State Legislatures, at least 20 states allow parents to refuse vaccinations for personal or philosophical reasons. Kristine Goodwin et al., *Calling the Shots*, ST. LEGISLATURE MAG., Feb. 1, 2015, <http://www.ncsl.org/bookstore/state-legislatures-magazine/trends-february-2015.aspx>; Nat’l Conf. St. Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements*, *supra* note 219.

²⁹⁴ Omer et al., *Nonmedical Exemption*, *supra* note 228, at 1760 (2006).

²⁹⁵ *Id.*; see also Ruth Lynfield & Robert S. Dunn, *The Complexity of the Resurgence of Childhood Vaccine-Preventable Diseases in the United States*, 2 CURR. PEDIATRIC REP. 195, 198 (2014) (discussing the increase in measles cases in the United States and their link to parental refusal); Saad B. Omer et al., *Geographic Clustering of Nonmedical Exemptions to School Immunization Requirements and Associations with Geographic Clustering of Pertussis*, 168 AM. J. EPIDEMIOLOGY 1389, 1394 (2008) (finding an increase between exemption rates and pertussis cases); David E. Sugerman, *Measles Outbreak in a Highly Vaccinated Population, San Diego, 2008: Role of the Intentionally Undervaccinated*, 125 PEDIATRICS 747 (2010) (concluding that measles outbreaks can occur among clusters of intentionally unvaccinated and under-vaccinated individuals, undermining measles elimination).

²⁹⁶ Jennifer Zipprich et al., *Measles Outbreak—California, December 2014–February 2015*, 64 MORBIDITY & MORTALITY WKLY. REP., Feb. 20, 2015, at 153, 153.

March 13, 2015, there were 133 confirmed measles cases among California residents.²⁹⁷

Only three of these cases had a different genotype than the outbreak strain, indicating that almost all of the cases were linked to the Disneyland outbreak.²⁹⁸ Among those with documented vaccine status, fifty-seven were unvaccinated and only twenty were vaccinated.²⁹⁹ The remainder had unknown or undocumented vaccine status. In a previous report from February, of forty-nine unvaccinated and infected individuals, twenty-eight (67%) were intentionally unvaccinated because of personal beliefs and one was on an “alternative” vaccination plan.³⁰⁰ Most believe, and the evidence suggests, that the low vaccine rates and vaccine refusals helped fuel, and potentially caused, the Disneyland outbreak.³⁰¹

²⁹⁷ *California Measles Surveillance Update*, CAL. DEP’T PUB. HEALTH (March 13, 2015), http://www.cdph.ca.gov/programs/immunize/Documents/Measles_update_3_-_13_-_2015_public.pdf.

²⁹⁸ *Id.*

²⁹⁹ *Id.*

³⁰⁰ Zipprich et al., *supra* note 296.

³⁰¹ Maimuna S. Majumder et al., *Substandard Vaccination Compliance and the 2015 Measles Outbreak*, J. AM. MED. ASS’N (Mar. 1, 2015). Some media outlets and medical professionals have squarely placed the blame for the outbreak on parents who refuse to vaccinate their children. *See, e.g.*, Karen Kaplan, *Vaccine Refusal Helped Fuel Disneyland Measles Outbreak, Study Says*, L.A. TIMES (Mar. 16, 2016, 5:30 PM), <http://www.latimes.com/science/sciencenow/la-sci-sn-disneyland-measles-under-vaccination-20150316-story.html#page=1> (stating that the measles outbreak has “spread to seven states and two other countries thanks to parents who declined to vaccinate their children”); SERMO Measles Poll, SERMO (Feb. 2, 2015), http://www.sermo.com/assets/pdf/SERMO_Measles_infographic.pdf (reporting the results of a survey of 3,099 doctors, which found that 92% believed the current measles outbreak was attributable to parents refusing to vaccinate their children). *But see* Elena Conis, *We Can’t Just Blame Anti-Vaxxers for the Measles Outbreak. Parents Skip Vaccines for Many Reasons*, WASH. POST (Feb. 2, 2015), <http://www.washingtonpost.com/news/to-your-health/wp/2015/02/02/we-cant-just-blame-anti-vaxxers-for-the-measles-outbreak-parents-skip-vaccines-for-many-reasons/>; Brian Tashman, *Sandy Rios: Blame Immigrants for Measles Outbreak, Not Parents Who Don’t Vaccinate their Kids*, RIGHT WING WATCH (Feb. 4, 2015, 2:55 PM), <http://www.rightwingwatch.org/content/sandy-rios-blame-immigrants-measles-outbreak-not-parents-who-dont-vaccinate-their-kids> (quoting Sandy Rios, governmental affairs director for the American Family Association, who argued that immigrants are to blame for the measles outbreak, not parents who refuse vaccines).

Media and the Internet have fueled the controversies and debates, making the anti-vaccination movement more visible than ever.³⁰² The media and Internet's role in the anti-vaccination movement are particularly important because research shows there are three major sources used by parents seeking information about vaccines: HCPs, the media, and the Internet.³⁰³ Many studies indicate that the pediatrician is a parent's primary source for vaccine information, but these and other studies indicate that the media and Internet are also leading sources for vaccine information.³⁰⁴ This is problematic because non-HCP sources hold

No formal requirement to understand the science behind vaccines or the data that support their safety, nor do they carry a professional obligation to protect the health status of their audience. Inherently, this creates a problematic situation where one of the leading resources families use[] to gather information on the safety and utility of immunizations is flawed in its usefulness to serve as a reliable source of information.³⁰⁵

Given their significant role in other vaccine controversies, there is little doubt the media and Internet will be active in debates about lowering the age of consent—whether

³⁰² *Id.*; see also Jason Behrmann, *The Anti-Vaccination Movement and Resistance to Allergen-Immunotherapy: A Guide for Clinical Allergists*, 6 ALLERGY, ASTHMA, & CLINICAL IMMUNOLOGY 1, 5 (2010) (noting the widespread use of the internet by the “growing and highly visible anti-vaccine movement”); Robert M. Wolfe & Lisa K. Sharp, *Vaccination or Immunization?—The Impact of Search Terms on the Internet*, 10 J. HEALTH COMM’N 539, 539 (2005) (“Vaccine safety has become a hot topic, appearing in popular television shows, newspapers and magazines, on the Internet, and even hearings in Congress.”).

³⁰³ Paola Dees & David M. Berman, *The Media's Role in Vaccine Misinformation*, in VACCINOPHOBIA AND VACCINE CONTROVERSIES OF THE 21ST CENTURY 383, 383 (Archana Chatterjee ed., 2013).

³⁰⁴ *Id.* at 383; see also Bruce G. Gellin et al., *Do Parents Understand Immunizations?: A National Telephone Survey*, 106 PEDIATRICS, 1097, 1099 (2000) (finding that parents cited newspapers or magazines as the second most common source of information about immunizations); Allison Jane Hackett, *Risk, Its Perception, and the Media: The MMR Controversy*, 81 CMTY. PRACTITIONER, July 2008, at 22 (discussing how the media are a primary source of information for many individuals).

³⁰⁵ Dees & Berman, *supra* note 303, at 383.

for good or for ill. The media have been a constant outlet for vaccine opponents who want to provide others with reasons to oppose the vaccine and any attempt to increase its use.³⁰⁶

In light of the growth of anti-vaccine sentiments, it is no surprise the HPV vaccine has been subject to similar debate and controversy. Since its initial approval, it has received much attention from medical, political, and public spheres. The views fall on both ends of the spectrum—ranging from support for mandatory vaccination of all adolescents to those who oppose the vaccine entirely. The vaccine is controversial and opposed for a variety of reasons. These concerns and those specifically related to lowering the age of consent are discussed in the following sections.

B. HPV VACCINE-SPECIFIC CONCERNS AND REASONS FOR OPPOSING A LOWER AGE OF CONSENT

This Part reviews some of the concerns about the HPV vaccine and reasons for opposing a lower age of consent. Part 1 discusses concerns about the HPV vaccine’s safety. Part 2 describes concerns about the vaccine’s influence on sexual mores and sexual behavior. Part 3 discusses the vaccine’s cost as a barrier to vaccination. Part 4

³⁰⁶ Seth Masket, *The Anti-Vaxxers Aren’t Liberal or Conservative . . . Yet*, WASH. MONTHLY BLOG (Feb. 4, 2015, 6:48 AM), http://www.washingtonmonthly.com/ten-miles-square/2015/02/the_antivaxxers_arent_liberal054014.php (suggesting that if enough people, particularly authority figures such as political leaders or cultural figures “publicly question the importance of immunizations, and if such messages go unchallenged or even embraced by commentators on Fox and other . . . media outlets, that message could soon be adopted by . . . parents). Use of the media to spread and promote anti-vaccine views, however, seems to be decreasing in “effectiveness.” This is illustrated by much of the media’s recent treatment of “anti-vaxxers” in the wake of the measles outbreak in Disneyland in California and its spread to other states. See Alison Hudson, *Will Disneyland Change the Vaccination Debate?*, SKEPTOID (Feb. 3, 2015), <http://skeptoid.com/blog/2015/02/03/will-disneyland-change-the-vaccination-debate/> (noting that recently, the “tide is clearly on the side of those advocating for science and sound health”).

discusses cost, payment, and confidentiality concerns specific to lowering the age of consent. Part 5 considers concerns about adolescent ability to understand potential safety risks when consenting to the vaccine. Part 6 examines the role of parents and the importance of parental involvement to promote “parent-child unity.” Part 7 discusses concerns that widespread use of the vaccine will decrease use of cancer screenings and other preventive care. Finally, Part 8 describes issues related to adequate follow-up care and how to ensure completion of the three doses.

1. Safety Concerns

For a relatively new vaccine, the data indicate that both Gardasil and Cervarix are safe. Despite this evidence, some remain skeptical of the vaccine’s safety and the controversy surrounding the vaccine continues.³⁰⁷ There has been significant political and public debate about the vaccine’s safety and concerns that it came to the market too quickly.³⁰⁸ Some express concerns about possible side effects that may become apparent only after the vaccine is used in greater numbers and for longer periods of time.³⁰⁹ Others question how long the vaccine’s protection lasts—will a girl vaccinated at twelve still be protected in five years when she is more likely to actually be sexually active and at risk

³⁰⁷ See, e.g., Tomljenovic & Shaw, *supra* note 105, at 673 (“Ever since its *Fast Track* approval by the [FDA] in 2006, Merck’s [HPV] vaccine Gardasil has been sparking controversy.”); Michelle Castillo, *Side Effect Fears Stop Parents from Getting HPV Vaccine for Daughters*, CBS NEWS (Mar. 18, 2013, 12:05 PM), <http://www.cbsnews.com/news/side-effect-fears-stop-parents-from-getting-hpv-vaccine-for-daughters/> (“[Parents] seemed to be skeptical of its safety.”); Ed Silverman, *Merck & Its HPV Vaccine: Sales & Skepticism Are Both Up*, FORBES (Mar. 27, 2013, 11:00 AM), <http://www.forbes.com/sites/edsilverman/2013/03/27/merck-its-hpv-vaccine-sales-skepticism-are-both-up/> (discussing a study that found more parents are refusing the HPV vaccine for their daughters than in the vaccine’s earlier years).

³⁰⁸ Elisabeth Rosenthal, *Drug Makers’ Push Leads to Cancer Vaccines’ Rise*, N.Y. TIMES, Aug. 20, 2008, <http://www.nytimes.com/2008/08/20/health/policy/20vaccine.html?pagewanted=all>.

³⁰⁹ *Id.*

of infection?³¹⁰ Will a booster shot be necessary?³¹¹ A booster is not currently recommended, but if data from the vaccine's continual monitoring indicate the vaccine loses its effectiveness after a period of time, ACIP will then determine whether a booster is necessary.³¹²

Like other vaccine controversies,³¹³ the HPV vaccine has not escaped the political limelight. During the 2011 presidential race, Gardasil became a key topic among Republican candidates “when Congresswoman Michelle Bachmann criticized Texas Governor Rick Perry over his prior executive order to make the vaccine mandatory.”³¹⁴ Bachmann continued to publicly criticize and question the vaccine, telling NBC's *Today Show* that a woman told Bachmann that her daughter “suffered from mental retardation” after receiving the vaccine.³¹⁵ Bachmann also stated that the vaccine “ravages” the body and suggested that Governor Perry sacrificed children's health for money from drug companies.³¹⁶ After a “barrage of criticism” from medical professionals and others, however, she backtracked slightly, admitting she had “no idea” whether the vaccine

³¹⁰ *Id.*

³¹¹ *Id.*

³¹² *HPV Vaccine—Questions & Answers*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm> (last updated Aug. 6, 2014).

³¹³ See generally OFFIT, DEADLY CHOICES, *supra* note 42 (discussing the growing anti-vaccine movement in the United States).

³¹⁴ Tomljenovic & Shaw, *supra* note 105, at 673.

³¹⁵ Gann, *supra* note 8.

³¹⁶ This was in reference to Perry's former chief of staff, Mike Toomey, who lobbied for Merck and gave \$16,000 to Perry's gubernatorial campaigns. Josh Hafner, *To One Iowa Mother, Bachmann Decries “the Ravages” of HPV Vaccine*, 2012 IOWA CAUCUSES (Nov. 14, 2011, 9:43 PM), <http://caucuses.desmoinesregister.com/2011/11/14/to-one-iowa-mother-bachmann-decries-the-ravages-of-hpv-vaccine/>.

actually causes mental retardation, stating that she was neither a scientist nor a physician, but merely “reporting what this woman told [her] at the debate.”³¹⁷

Other media reports focused on girls “collapsing” or even dying after receiving the vaccine.³¹⁸ But what many of these sensationalized reports fail to mention is that fainting is a potential side effect of *any* vaccine and data on the HPV vaccine indicate that although fainting “may be relatively common after adolescent vaccination,” there is no increased risk of fainting after the HPV vaccine compared to the risk of fainting after other adolescent vaccines.³¹⁹ In response to public concerns about adolescents fainting after the HPV vaccine, the FDA and CDC took steps to remind HCPs that patients should be monitored for fifteen minutes after receiving *any* vaccine.³²⁰ The FDA also requested that the manufacturers change the vaccine label’s precautions section.³²¹

Between June 2006 and March 2014, VAERS received ninety-six reports of death after people received Gardasil.³²² Of those deaths, only forty-seven could be verified

³¹⁷ Chris McGreal & Ian Sample, *Michele Bachmann HPV Row Prompts Fears for Vaccine Programme in US*, GUARDIAN (Sept. 14, 2011, 6:54 PM), <http://www.theguardian.com/world/2011/sep/14/michele-bachmann-hpv-vaccine>.

³¹⁸ See, e.g., Associated Press, *Some Girls Fainting After Receiving HPV Vaccine*, NBC NEWS (Jan. 3, 2008, 5:35 PM), http://www.nbcnews.com/id/22492557/ns/health-childrens_health/t/some-girls-fainting-after-receiving-hpv-vaccine/#.VDRAXvldXuQ; Christina England, *HPV Vaccines Can Kill and they Do!*, VACTRUTH.COM (Aug. 10, 2013), <http://vactruth.com/2013/08/10/hpv-vaccines-can-kill/> (arguing that “based on the evidence, [the HPV] vaccine[] should [] carry a government-issued health warning, stating *HPV Vaccines Can Kill!*”) (emphasis in original).

³¹⁹ Gee et al., *supra* note 123, at 8283; Pahud & Harrison, *supra* note 114, at 78 (“[F]ainting spells in HPV vaccine recipients was determined to be due to vasomotor events that can occur after any needle puncture [Fainting] is not due to the HPV vaccine but the *injection procedure* itself.”).

³²⁰ *Summary of HPV Adverse Event Reports Published in JAMA*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/jama.html> (last updated Feb. 20, 2014).

³²¹ *Id.*

³²² *Frequently Asked Questions About HPV Vaccine Safety*, *supra* note 113.

through clinical review of medical records, death certificates, and autopsy reports.³²³

Detailed evaluation of every death report concluded:

- (1) There is no pattern of death occurring with respect to time after vaccination;
- (2) There is no consistent vaccine dose number or combination of vaccines given; and
- (3) There is no diagnosis at death to suggest the vaccine caused the death.³²⁴

An earlier report on the vaccine's adverse events found that of twenty verifiable deaths, the causes of death could be explained by factors other than the vaccine, such as diabetes, viral illness, seizure disorders, illicit drug use, and heart failure.³²⁵ Despite these official reports, well-known anti-vaccine and anti-science individuals and groups have exaggerated the number of deaths or claimed that the vaccine *caused* ninety-six deaths.³²⁶ These stories incorrectly report a causal link between the vaccine and death.³²⁷ Failure to understand that a death reported to VAERS does not mean the vaccine *caused* the

³²³ *Id.*

³²⁴ *Id.*

³²⁵ Barbara A. Slade et al., *Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine*, 302 J. AM. MED. ASS'N 750, 755 (2009).

³²⁶ See, e.g., Sharyl Attkisson, *Gardasil Researcher Speaks Out*, CBS NEWS (Aug. 19, 2009, 5:13 PM), <http://www.cbsnews.com/news/gardasil-researcher-speaks-out/>; Leslie Carol Botha, *New Death Post-Gardasil Updated VAERS Figures & Report that HPV Vaccines Adverse Reactions are 50% Higher than Other Age-Related Recommended Vaccines*, SANEVAX, INC. (Nov. 29, 2011), <http://sanevax.org/new-death-post-gardasil-updated-vaers-figures-report-that-hpv-vaccines-adverse-reactions-are-50-higher-than-other-age-related-recommended-vaccines/>; Amanda Froelich, *It's Official: 139 Girls Have Died From HPV Vaccinations*, TRUE ACTIVIST (Oct. 11, 2013), <http://www.trueactivist.com/its-official-139-girls-have-died-from-hpv-vaccinations/>.

³²⁷ See sources cited *supra* note 129.

death³²⁸ fuels the fire of vaccine opponents, who use this information to mislead the public about the vaccine's safety.³²⁹ The VAERS website, however, includes a disclaimer stating that a VAERS report "generally does not prove that the identified vaccine(s) caused the adverse event described. It only confirms that the reported event occurred sometime after vaccine was given. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report."³³⁰

Concerns about Gardasil's safety were also influenced by controversy over Merck's promotional efforts targeting HCPs and the public along with its initial lobbying for state vaccine mandates.³³¹ Merck heavily invested in promoting the vaccine. Some of its efforts included:

- Training and recruiting hundreds of doctors to give lectures about Gardasil, paying them \$4,500 per lecture;³³²
- Providing Merck-sponsored meals at the lectures about Gardasil;³³³
- Lobbying politicians urging them to mandate the vaccine in their states;³³⁴
- Recruiting former state officials to lobby their former colleagues;³³⁵

³²⁸ VACCINE ADVERSE EVENT REP. SYS., *VAERS Data*, <https://vaers.hhs.gov/data/index> (last visited Feb. 18, 2015).

³²⁹ Cervical Cancer Action Coal., *Issue Brief: HPV Vaccine Safety*, http://www.rho.org/files/CCA_HP_Vaccine_safety.pdf (last visited Feb. 18, 2015) ("Despite early confusion propagated by the media, not a single death following HPV vaccination appears to have been caused by the vaccine.").

³³⁰ VACCINE ADVERSE EVENT REP. SYS., *supra* note 328.

³³¹ Andrew Pollack & Stephanie Saul, *Merck to Halt Lobbying for Vaccine for Girls*, N.Y. TIMES, Feb. 21, 2007, <http://www.nytimes.com/2007/02/21/business/21merck.html>.

³³² Rosenthal, *supra* note 308.

³³³ *Id.*

³³⁴ *Id.*

- Helping finance cervical cancer awareness conferences and campaigns including the popular “One Less” and “I Chose” campaigns;³³⁶
- Providing the American College Health Association with an “unrestricted grant” to train individuals to speak about Gardasil on college campuses,³³⁷ and
- Donating money to small nonprofits for research or consulting.³³⁸

Some felt that Merck’s aggressive lobbying created “a sense of panic that says you have to have this vaccine now.”³³⁹ After facing heavy criticism, Merck agreed to stop lobbying state legislatures to mandate the vaccine but it continued other lobbying efforts, such as paying into programs run by “Cornerstone Government Affairs,” a Washington firm that lobbies the CDC and Congress to increase federal money for vaccines.³⁴⁰ The heavy promotional push, the vaccine’s profitability for Merck, and the potential influence of Merck-provided money to HCPs and politicians increased concerns that questions about the vaccine’s safety would be disregarded and overpowered by profit motives.

³³⁵ *Id.* For example, Merck hired Sandra D. Bowen, former Virginia secretary of administration, in 2006 as a Virginia lobbyist. Bill Bowen, Virginia’s state lieutenant governor, became an outspoken participant in the “Ending Cervical Cancer in our Lifetime” campaign, which was largely funded by Merck and GlaxoSmithKline. *Id.*

³³⁶ *Id.*; Rich Thomaselli, *As Sales Drop, Fall Brings Big Push for Gardasil Vaccine*, ADVERTISING AGE (Aug. 10, 2009), <http://adage.com/article/news/merck-ups-gardasil-vaccine-push-back-school-checkups/138364/>.

³³⁷ Rosenthal, *supra* note 308.

³³⁸ *Id.*

³³⁹ *Id.*

³⁴⁰ *Id.*

2. Concerns about Sexual Mores and Promotion of Sexual Activity

In addition to safety concerns frequently expressed about all vaccines, the HPV vaccine has an additional controversial component—its connection to an STI and sexual activity. Throughout the vaccine’s history in the United States and other countries, parents, the media, politicians, and even HCPs have argued it may encourage adolescents to become “promiscuous” and sexually active at earlier ages.³⁴¹ The media have played a significant role in perpetuating the idea that “administration of the vaccine to young adolescents has the potential to send mixed messages about the importance of abstinence.”³⁴²

Some in very traditional conservative factions argue the vaccine is unnecessary, particularly at a young age, because HPV is not airborne and can be avoided by practicing abstinence.³⁴³ Andrea Lafferty, executive director of the Traditional Values Coalition, opposes mandatory HPV vaccination for adolescents, reasoning that “HPV is

³⁴¹ Holman et al., *supra* note 21, at 78; Denise Mann, *Why Many U.S. Preteens Aren’t Getting the HPV Shot*, HEALTHDAY (Nov. 25, 2013), <http://consumer.healthday.com/kids-health-information-23/adolescents-and-teen-health-news-719/cost-fear-of-promiscuity-and-lack-of-information-drive-poor-rates-of-hpv-vaccination-682502.html>; Ed Silverman, *Merck & Its HPV Vaccine: Sales & Skepticism Are Both Up*, FORBES (Mar. 27, 2013, 11:00 AM), <http://www.forbes.com/sites/edsilverman/2013/03/27/merck-its-hpv-vaccine-sales-skepticism-are-both-up/> (discussing how parents and social conservatives worried the vaccine “might be seen as a green light by teenage girls to have premarital sex”).

³⁴² Catherine O’Keefe & Meghan Potthoff, *Vaccines: Boon or Bane—A Nurse’s Outlook*, in VACCINOPHOBIA AND VACCINE CONTROVERSIES OF THE 21ST CENTURY 165, 172–73 (Archana Chatterjee ed., 2013).

³⁴³ Andrea Lafferty, *No Mandatory HPV Vaccines for Girls*, GRAYBROOK INST. BLOG (Feb. 22, 2007), <http://graybrook.blogspot.com/2007/02/no-mandatory-hpv-vaccines-for-girls.html>; Michael in MI, *One Less Idiot Please*, AMERICAN-DO ATTITUDE BLOG (Mar. 1, 2008, 1:17 PM), <https://michaelinmi.wordpress.com/category/life/sex/gardasil/> (arguing that Gardasil’s commercials should emphasize the fact that “abstinence is the number 1 prevention technique against HPV and cervical cancer”).

contracted through sexual contact and is not contagious.³⁴⁴ Therefore, almost all cases of HPV could be prevented through responsible sexual behavior, including fidelity in marriage and abstinence outside of marriage.”³⁴⁵ Star Parker, founder of the Coalition on Urban Renewal and Education, believed Merck would specifically target low-income minority girls through welfare programs that would provide Gardasil to this population. She believed this would exacerbate the “main risks” these girls already face that “stem from their promiscuity” (such as HIV and other STIs).³⁴⁶ She argued that “[i]t is the collapse of family values and the attendant sexual promiscuity that drives the deadly poverty cycle in these communities. So mandating Gardasil . . . validate[s] a lifestyle that is already killing them in order to address a risk that is among the least of their problems.”³⁴⁷ Stephen Green, leader of Christian Voice, a Christian advocacy group based in the United Kingdom, argued that

Anyone giving this drug to a girl is telling her, “I think you are a slag.”³⁴⁸ The best way of not getting cervical cancer and genital warts is to stay a virgin and marry a virgin. . . .

³⁴⁴ Lafferty’s suggestion that HPV is not “contagious” is misleading, however, as HPV is communicable and can be spread from person to person through direct skin-to-skin contact during vaginal, anal, and oral sex. It can also be spread from mother to child during birth. *Genital HPV Infection—Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/hpv/stdfact-hpv.htm> (last updated Mar. 20, 2014); *STDs & Pregnancy—CDC Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/pregnancy/stdfact-pregnancy.htm#r17> (last updated Dec. 16, 2014) [hereinafter *STDs and Pregnancy*].

³⁴⁵ Lafferty, *supra* note 343.

³⁴⁶ Star Parker, *The Perverse Politics of Gardasil*, WORLD NEWS DAILY (Feb. 17, 2007), <http://www.wnd.com/2007/02/40218/>.

³⁴⁷ *Id.*

³⁴⁸ A “slag” is a British slang word meaning a “lewd or promiscuous woman.” *Slag Definition*, MERRIAM-WEBSTER.COM, <http://www.merriam-webster.com/dictionary/slag> (last visited Feb. 18, 2015); *see also Slag Definition*, URBAN DICTIONARY (Aug. 13, 2003), <http://www.urbandictionary.com/define.php?term=slag> (defining “slag” as “[a]n individual who cares not for relationships beyond the realm of the sexual, these people sleep with many partners not caring about anything save for the moment of climax”).

[The vaccine] is irresponsible and will raise promiscuity
[and] teenage pregnancy.³⁴⁹

Some HCPs believe the vaccine is relatively unnecessary for adolescents who are not sexually active. This is the view espoused by members of the Association of American Physicians and Surgeons (AAPS), a group of approximately 5,000 doctors³⁵⁰ known to hold conservative views.³⁵¹ Its members include former Representative Ron Paul and his son, Kentucky Senator Rand Paul.³⁵² Dr. Jane Orient, executive director of AAPS, calls HPV a “lifestyle disease.”³⁵³ It is particularly troublesome that such a high-

³⁴⁹ Jenny Hope, *Now Girls Aged NINE are Offered Cervical Cancer Jab*, DAILY MAIL (Dec. 27, 2007, 10:58 PM), <http://www.dailymail.co.uk/health/article-504811/Now-girls-aged-NINE-offered-cervical-cancer-jab.html>.

³⁵⁰ *Association of American Physicians and Surgeons Sues Over Obamacare*, WJLA ABC NEWS CHANNEL 7 (Oct. 30, 2013, 5:09 PM), <http://www.wjla.com/articles/2013/10/association-of-american-physicians-and-surgeons-sues-over-obamacare-96182.html> (citing AAPS spokeswoman Jane Orient).

³⁵¹ Although the AAPS claims it is “non-partisan,” it is commonly associated with conservative values and positions and its website states that it seeks to “counter the emotional arguments for socialized medicine.” *About Us*, ASS’N OF AM. PHYSICIANS & SURGEONS, http://www.aapsonline.org/index.php/about_us/ (last visited Jan. 26, 2014); Sarah Ferris, *Supreme Court Rejects ObamaCare Challenge from Doctors’ Group*, THE HILL (Jan. 12, 2015, 10:15 AM), <http://thehill.com/policy/healthcare/229189-court-dismisses-obamacare-challenge-from-conservative-doctors-group> (calling AAPS a “conservative doctors group”); Terry Krepel, *Note to Media: AAPS is a Right-Wing Group with Fringe Views*, MEDIA MATTERS FOR AM. BLOG (Mar. 31, 2010, 11:01 AM), <http://mediamatters.org/blog/2010/03/31/note-to-media-aaps-is-a-right-wing-group-with-f/162519>; Gabrielle Levy, *Association of American Physicians and Surgeons Calls for Obamacare Defund*, UPI BLOG (Oct. 22, 2013, 4:42 PM), <http://www.upi.com/blog/2013/10/22/Association-of-American-Physicians-and-Surgeons-calls-for-Obamacare-defund/9401382474514/> (noting that the AAPS was formed to “oppose the creation of Medicaid and Medicare” and was founded “to fight socialized medicine and to fight the government takeover of medicine”).

³⁵² Levy, *supra* note 351.

³⁵³ Statement by Jane M. Orient, Executive Director, Ass’n Am. Physicians & Surgeons, “Hands Off Our Kids” Coalition News Conference (Feb. 11, 2007), <http://www.aapsonline.org/vaccines/jmo-statement.php> (opposing Texas Governor Perry’s executive order mandating the HPV vaccine for young girls); Parker, *supra* note 346 (“Where are we going as a country when we start mandating vaccines against diseases resulting from behavior we choose?”).

level official of a professional medical association holds these views because of the important role physician recommendations have in vaccination rates.³⁵⁴

Fortunately, most individual HCPs and larger professional associations support and vigorously recommend the vaccine.³⁵⁵ In 2014, for example, a collaborative letter by leaders of some of the largest leading medical associations asked its members to “firmly and strongly” recommend and “urge your patients” to get the vaccine.³⁵⁶ The letter emphasized the importance of a physician’s recommendation in a patient’s (and parent’s) decision to get the HPV vaccine.³⁵⁷ The letter also highlighted the growing evidence of the vaccine’s safety and efficacy.³⁵⁸ The signatories included the leaders of the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the

³⁵⁴ CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 39–40; Allison Kennedy et al., *Vaccine Attitudes, Concerns, and Information Sources Reported by Parents of Young Children: Results from the 2009 HealthStyles Survey*, 127 PEDIATRICS S92, S94 (2011) (finding that HCPs are the most important source of information in helping parents make decisions about vaccinating their children); Susan T. Vadaparampil et al., *Physicians’ Human Papillomavirus Vaccine Recommendations, 2009 and 2011*, 46 AM. J. PREVENTIVE MED. 80, 91 (2014) (noting that physician recommendation is a key predictor of HPV vaccine uptake).

³⁵⁵ See, e.g., Am. Acad. Pediatrics, *Policy Statement: HPV Vaccine Recommendation*, 129 PEDIATRICS 602 (2012); Comm. Adolescent Health Care, *Committee Opinion No. 588: Human Papillomavirus Vaccination*, AM. COLL. OBSTETRICS & GYNECOLOGISTS (Mar. 2014), available at <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Adolescent-Health-Care/co588.pdf?dmc=1&ts=20150215T1358373596>; Lawrence Friedman et al., *Human Papillomavirus: An Updated Position Statement of the Society for Adolescent Health and Medicine*, SOC’Y FOR ADOLESCENT HEALTH & MED. (June 17, 2010), available at http://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/June-10-SAM_HPV_Position_Statement.pdf; Gwendolyn P. Quinn et al., *A National Survey about Human Papillomavirus Vaccination: What We Didn’t Ask, But Physicians Wanted Us to Know*, 25 J. PEDIATRIC & ADOLESCENT GYNECOLOGY 254, 255 (2012) (finding “overall support for the vaccine” among physician’s personal views).

³⁵⁶ Letter from Reid B. Blackwelder et al., President, Am. Acad. Family Physicians, to member colleagues (2014),

http://www2.aap.org/immunization/illnesses/hpv/HPV_letter_color_1%2021%2014.pdf.

³⁵⁷ *Id.*

³⁵⁸ *Id.*

American Congress of Obstetricians and Gynecologists (ACOG), the American College of Physicians (ACP), the CDC, and the Immunization Action Coalition.³⁵⁹

Membership in these professional associations far outnumber AAPS, illustrating that AAPS should be viewed as expressing the minority opinion among medical professionals about the HPV vaccine. The AAFP, for example, has approximately 115,900 members³⁶⁰ and the AAP is made up of approximately 62,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists.³⁶¹ ACOG includes over 58,000 members³⁶² and ACP has more than 141,000 members worldwide.³⁶³

At the individual level, studies suggest widespread HCP support for the HPV vaccine and likelihood of following official recommendations regarding the vaccine. Even before it was approved by the FDA, for example, a survey found that over ninety percent of physicians would be extremely or somewhat likely to follow the recommendations by the AAP, the CDC, and/or ACIP.³⁶⁴ Additional early and later

³⁵⁹ *Id.*

³⁶⁰ *Become a Member*, AM. ACAD. FAM. PHYSICIANS, <http://www.aafp.org/about/membership/join.html> (last visited Mar. 19, 2015). This number appears to include active and inactive (e.g., retired) physicians as well as residents and medical students. *Id.*

³⁶¹ *AAP Facts*, AM. ACAD. PEDIATRICIANS, <http://www.aap.org/en-us/about-the-aap/aap-facts/Pages/AAP-Facts.aspx> (last visited Feb. 20, 2015).

³⁶² *The American College of Obstetricians and Gynecologists: Overview and Leadership*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, <http://www.acog.org/About-ACOG/Leadership-and-Governance> (last visited Feb. 20, 2015).

³⁶³ This number includes medical students and physicians in general medicine and a variety of subspecialties, including infectious diseases and allergy and immunology. *ACP Services, Inc.: Membership and Governance*, AM. COLL. PHYSICIANS, http://www.acponline.org/about_acp/services/ (last visited Mar. 19, 2015).

³⁶⁴ Jessica A. Kahn et al., *Pediatrician's Intention to Administer Human Papillomavirus Vaccine: The Role of Practice Characteristics, Knowledge, and Attitudes*, 37 J. ADOLESCENT HEALTH 502, 505 (2005).

studies support this finding.³⁶⁵ There is, however, a recognized need to improve the rate and strength of HCP recommendations for the HPV vaccine among all patient populations, particularly young adolescents.³⁶⁶ The collaborative letter acknowledged and emphasized the importance of an HCP recommendation, citing it as one of the best predictors of vaccine acceptance among parents and patients.³⁶⁷ Despite the need to improve physician recommendations, it is clear the views held by the AAPS and some of its members make up a small minority of the medical profession. Their opinions should not be viewed as authoritative compared to the vast number of professional associations and individual physicians supporting the vaccine and emphasizing its importance for individual and public health.

Some HCPs indicate that their willingness to recommend the vaccine varies based on their patient population. HCPs working in urban areas, for example, did not believe it would be difficult to explain the need for the vaccine at age eleven. Some even felt eleven was too late and that parents of even younger children would consent to the

³⁶⁵ Matthew F. Daley et al., *A National Survey of Pediatrician Knowledge and Attitudes Regarding Human Papillomavirus Vaccination*, 118 PEDIATRICS 2280, 2288 (2006) (finding high levels of acceptance of the HPV vaccine, particularly for older adolescents); Matthew F. Daley et al., *Human Papillomavirus Vaccination Practices: A Survey of US Physicians 18 Months After Licensure*, 126 PEDIATRICS 425, 430 (2010) (finding that the vast majority of pediatricians and family physicians offered the HPV vaccine 18 months after it was initially approved and licensed); Abbigail M. Tissot et al., *Effective Strategies' for HPV Vaccine Delivery: The Views of Pediatricians*, 41 J. ADOLESCENT HEALTH 119, 121 (2007) (reporting that the “great majority” of pediatricians surveyed supported universal, rather than targeted, vaccine availability and recommendations).

³⁶⁶ PRESIDENT’S CANCER PANEL, *supra* note 86, at 15–18 (summarizing studies and suggesting the need to decrease barriers to physician recommendations for the vaccine); Daley et al., *A National Survey of Pediatrician Knowledge and Attitudes Regarding Human Papillomavirus Vaccination*, *supra* note 365, at 2284 fig. 1 (reporting that providers were less likely to recommend the HPV vaccine to younger patients); Vadaparampil et al, *supra* note 166 (finding that physicians were less likely to “always” recommend the HPV vaccine for 11- to 12-year-old patients compared to patients ages 13–17 and 18–26).

³⁶⁷ Letter from Reid B. Blackwelder et al., *supra* note 356.

vaccine—“if we brought up the fact that there is a way of preventing even one out of four or five STDs, our parents are going to be banging on the door to get it at 11, 12, 13.”³⁶⁸

In contrast, HCPs with patient populations that have strong spiritual or religious beliefs expressed greater hesitancy to discuss the vaccine.³⁶⁹ Compared to urban doctors, suburban doctors were more likely to believe it would be difficult to get parents to consent to the vaccine because of the perception that their children are at minimal risk.³⁷⁰ Others suggest that both parents *and* HCPs hold biased views, believing that ““rich, white, suburban kids’ are unlikely to be sexually active,” thus leading to fewer concerns about STIs and the importance of the vaccine.³⁷¹ These findings comport with other studies finding that parents with higher incomes and those who live in suburban areas are more likely to refuse other childhood vaccines such as the MMR vaccine.³⁷²

Discussing the vaccine with their patients and parents can be uncomfortable for some HCPs because of its connection to sexual behavior.³⁷³ Even when parents are willing to consent to other vaccines, the HPV vaccine has unique barriers because of its association with sex, particularly if the parents have not yet discussed sex with their

³⁶⁸ Sharon G. Humiston et al., *Health Care Provider Attitudes and Practices Regarding Adolescent Immunizations: A Qualitative Study*, 75 PATIENT EDUC. & COUNSELING 121, 124 (2009).

³⁶⁹ *Id.* at 121.

³⁷⁰ *Id.*

³⁷¹ *Id.*

³⁷² See, e.g., Jennifer A. Reich, *Neoliberal Mothering and Vaccine Refusal: Imagined Gated Communities and the Privilege of Choice*, 28 GEND. & SOC’Y 679, 680 (2014) (discussing research that shows that children who are unvaccinated because of parental choice rather than lack of access to medical care are more likely to be white, have a married college-educated mother, live in a household with an income of over \$75,000, and be geographically-clustered); Smith et al., *supra* note 283, at 143.

³⁷³ See generally Harriet Batista Ferrer et al., *Barriers and Facilitators to HPV Vaccination of Young Women in High-Income Countries: A Qualitative Systematic Review and Evidence Synthesis*, 14 BMC PUB. HEALTH 15 (2014) (discussing numerous studies on the HPV vaccine and barriers to vaccine uptake).

children. According to one HCP, “HPV has so many other implications for parents . . . it’s one they fight you on . . . because you’re suggesting that their child is or will be sexually active soon, and they don’t want to hear that.”³⁷⁴

As noted, some parents refuse or delay the vaccine because they believe their child is not sexually active and therefore does not need protection from a sexually-transmitted disease.³⁷⁵ One mother, for example, said she was not ready for her daughter to get the HPV vaccine “because she’s a good kid and I know she ain’t out there sexually . . . I’m just not worried about that right now.”³⁷⁶

Refusing or delaying the vaccine based on concerns about sexual activity and the belief that one’s child is not sexually active is problematic for numerous reasons. First, this assumes parents know whether their child is currently sexually active. Studies suggest that many parents underestimate their adolescent’s sexual experience.³⁷⁷ One study, for example, found that approximately one-third of adolescents reported being sexually experienced and of these, 46.8% of their mothers inaccurately reported that their child was *not* sexually active, with inaccuracy varying by the child’s age.³⁷⁸ 78.1% of mothers of sexually active 11- to 13-year-olds incorrectly reported their child was not

³⁷⁴ Cayce C. Hughes et al., *HPV Vaccine Decision Making in Pediatric Primary Care: A Semi-Structured Interview Study*, 11 BMC PEDIATRICS 3 (2011).

³⁷⁵ Holman et al., *supra* note 21, at 80.

³⁷⁶ Hughes et al., *supra* note 374, at 5.

³⁷⁷ Stefanie Mollborn & Bethany Everett, *Correlates and Consequences of Parent-Teen Incongruence in Reports of Teens Sexual Experience*, 47 J. SEX RES. 314, 314 (2010) (discussing research indicating that parents are much more likely to *underestimate* rather than *overestimate* their child’s level of sexual activity/experience).

³⁷⁸ Nicole Liddon et al., *Maternal Underestimation of Child’s Sexual Experience: Suggested Implications for HPV Vaccine Uptake at Recommended Ages*, 53 J. ADOLESCENT HEALTH 674, 675 (2013).

sexually active compared to 34.4% of mothers of sexually active 17- to 18-year-olds.³⁷⁹

Other studies support these findings: James Jaccard and colleagues found that 58% of teens reported having sex while only 34% of their mothers reported their teen had engaged in sexual intercourse³⁸⁰ and Hongmei Yang and colleagues reported that among adolescents who reported having sex in the past six months, 53.4% of parents reported their teen had *not* had sex.³⁸¹

Second, and more important, is the fact that the vaccine is most effective if given *before* an individual becomes sexually active.³⁸² Waiting to vaccinate until an adolescent is already sexually active is counterproductive and irrational—it is better to vaccinate if the child is *not* sexually active. Third, there is no evidence the vaccine increases sexual promiscuity or has any impact on risky sexual behavior. Studies conducted in response to public concern about the vaccine and sexual activity consistently find no link between receiving the vaccine and increased sexual promiscuity/activity.³⁸³ In a recent study

³⁷⁹ *Id.*

³⁸⁰ James Jaccard et al., *Parent-Adolescent Congruency in Reports of Adolescent Sexual Behavior and in Communications About Sexual Behavior*, 69 CHILD DEV. 247, 253 (1998)

³⁸¹ Hongmei Yang et al., *Parental Awareness of Adolescent Risk Involvement: Implications of Overestimates and Underestimates*, 39 J. ADOLESCENT HEALTH 353, 356 (2006).

³⁸² Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 70.

³⁸³ See, e.g., Robert A. Bednarczyk et al., *Sexual Activity-Related Outcomes After Human Papillomavirus Vaccination of 11- to 12-Year-Olds*, 130 PEDIATRICS 798 (2012); Bo T. Hansen et al., *Human Papillomavirus (HPV) Vaccination and Subsequent Sexual Behavior: Evidence from a Large Survey of Nordic Women*, 32 VACCINE 4945 (2014); Erica Marchand et al., *HPV Vaccination and Sexual Behavior in a Community College Sample*, 38 J. CMTY. HEALTH 1010 (2013) (finding no difference between vaccinated and unvaccinated women in level of sexual experience, age at first intercourse, number of partners in the past year, or frequency of condom use, concluding that the HPV vaccine is not associated with riskier sexual behavior); Allison Mayhew et al., *Risk Perceptions and Subsequent Sexual Behaviors After HPV Vaccination in Adolescents*, 133 PEDIATRICS 404 (2014) (reporting that risk perceptions after HPV vaccination were not associated with riskier sexual behaviors over a period of six months after vaccination); Mary B. Rysavy et al., *Human Papillomavirus and Sexual Behavior in Young Women*, 27 J. PEDIATRIC & ADOLESCENT GYNECOLOGY 67, 70 (2014) (finding no support for the notion that

comparing 21,000 vaccinated girls with 186,000 unvaccinated girls, the researchers concluded that the vaccine was not associated with increases in other STIs, suggesting the vaccine does not promote unsafe sexual behavior.³⁸⁴ Studies continue to find that administering the HPV vaccine to adolescents “does not offer a license for sexual activity.”³⁸⁵

3. Cost Concerns

Although this thesis focuses on parental consent as a barrier to HPV vaccination rates, another barrier worth mentioning is the vaccine’s cost, as it is a reason potentially cited by parents for refusing the vaccine. As discussed in this section, however, cost should be of less concern in the future because of improved insurance coverage.

As of April 1, 2015, the retail, out-of-pocket cost is \$147.01 per dose for Gardasil and \$128.75 per dose for Cervarix.³⁸⁶ The new 9-valent vaccine is currently priced at

vaccinated young women are more sexually active than unvaccinated young women); Leah M. Smith et al., *Effect of Human Papillomavirus (HPV) Vaccination on Clinical Indicators of Sexual Behavior Among Adolescent Girls: The Ontario Grade 8 HPV Vaccine Cohort Study*, 187 CAN. MED. ASS’N J. E74 (2015).

³⁸⁴ Anupam B. Jena et al., *Incidence of Sexually Transmitted Infections After Human Papillomavirus Vaccination Among Adolescent Females*, J. AM. MED. ASS’N INTERNAL MED. E1 (2015), available at <http://archinte.jamanetwork.com/article.aspx?articleid=2109856> (presenting “strong evidence against” the vaccine having any significant effect on sexual behaviors among adolescent girls and concluding that concerns about increased promiscuity after vaccination “are unwarranted and should not be a barrier to vaccinating at a young age”); see also *infra* Part II(B)(7), for a discussion about how the vaccine may actually be associated with *protective* health behaviors.

³⁸⁵ William T. Basco, *HPV Vaccine in Teens: No License for Sexual Activity*, MEDSCAPE PEDIATRICS: VIEWPOINTS, Mar. 11, 2015, http://www.medscape.com/viewarticle/841148?nlid=78355_785.

³⁸⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, VACCINES FOR CHILDREN PROGRAM: CDC VACCINE PRICE LIST [hereinafter CDC, VACCINE PRICE LIST], <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html> (last updated Apr. 1, 2015).

\$163.00 per dose.³⁸⁷ This does not include the HCP's charge for administering the shot.³⁸⁸ The three-dose vaccine requires three separate visits to an HCP which further increases the vaccine's cost.

The vaccine's cost influences a parent's willingness or ability to consent.³⁸⁹ HCPs offering the vaccine cite patient reimbursement issues as a barrier, with one physician stating that the only reason he and his colleagues could not offer the vaccine to their patients was lack of reimbursement.³⁹⁰ A cost barrier is particularly frustrating because even if a parent *wants* to vaccinate her child, she may be unable to do so because of the cost—"It's not that we don't want to [have our children vaccinated], but it's simply because we can't."³⁹¹

More problematic is when physicians will not even offer vaccines because of reimbursement issues that would result in a loss of money for the physician's office. One provider, for example, said that offering vaccines is not cost-effective for his practice because it costs "an incredible amount of money in terms of time. Because the time we

³⁸⁷ *Id.*

³⁸⁸ *HPV Vaccines*, AM. CANCER SOC'Y, <http://www.cancer.org/acs/groups/cid/documents/webcontent/002780-pdf.pdf> (last revised Dec. 12, 2014).

³⁸⁹ *See, e.g.*, Holman et al., *supra* note 21, at 80; Luiza Braga, *Lack of Awareness for HPV Vaccine Concerns Health Professionals*, DAILY COUGAR (Sept. 9, 2014), <http://thedailycougar.com/2014/09/09/lack-awareness-hpv-vaccine-concerns-health-professionals/> (quoting a Walgreens Pharmacist who indicated that cost often gets in the way of an adolescent's decision to get the vaccine); Janice Neumann, *HPV Vaccination Rates Low Nationwide*, CHI. TRIB. (Sept. 7, 2011), http://articles.chicagotribune.com/2011-09-07/lifestyle/ct-x-0907-hpv-vaccine-20110907_1_hpv-vaccination-hpv-infections-first-vaccine ("Some parents can't afford the vaccine or balk at the cost.").

³⁹⁰ Quinn et al., *supra* note 355, at 256.

³⁹¹ Echo L. Warner et al., *Latino Parents' Perceptions of the HPV Vaccines for Sons and Daughters*, 39 J. CMTY. HEALTH 6 (2014).

spend, the time the nurses spend . . . we're not even close to being reimbursed for the amount of time we spend on vaccines.”³⁹²

Recent and continuing changes in the American health care system, however, may alleviate cost issues and help increase vaccine uptake.³⁹³ Most insurance plans cover the vaccine's cost and the Affordable Care Act requires all new private insurance plans to cover HPV vaccines for the recommended age groups of males and females without consumer cost-sharing.³⁹⁴ The vaccine is also covered through the new health exchanges.³⁹⁵

For those without health insurance or with health insurance that does not cover vaccines, there are a variety of public financing programs that may be able to cover the cost of the vaccine:

- **Vaccines for Children (VFC) Program:** Federally-funded program that pays for vaccines recommended by ACIP for children ages 18 or under who are Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured. “Underinsured” individuals are those whose health insurance does not cover vaccines.³⁹⁶
- **Immunization Grant Program (Section 317):** Federal program through which CDC awards federal grants to state,

³⁹² Humiston et al., *supra* note 368, at 123.

³⁹³ C. Robinette Curtis et al., *National Human Papillomavirus Vaccination Coverage Among Adolescents Aged 13–17 Years—National Immunization Survey—Teen, United States, 2011*, 63 *MORBIDITY & MORALITY WKLY. REP.* 61, 68 (2014) (“Ongoing changes in the U.S. health-care system . . . expands insurance coverage . . . and places a greater emphasis on . . . clinical preventive services, including . . . vaccinations recommended by ACIP.”).

³⁹⁴ KFF, *supra* note 157, at 4.

³⁹⁵ *Id.*

³⁹⁶ *HPV Vaccine Information for Young Women—Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION <http://www.cdc.gov/std/hpv/stdfact-hpv-vaccine-young-women.htm> (last updated July 18, 2012) [hereinafter *HPV Vaccine Information for Young Women*]; KFF, *The HPV Vaccine*, *supra* note 157, at 4.

local, and territorial public health agencies to assist with vaccine costs. Funds can help extend coverage to children who do not qualify for the VFC program.³⁹⁷

- **Children’s Health Insurance Program (CHIP):** State CHIP programs that are separate from their Medicaid programs are required to cover ACIP-recommended vaccines for beneficiaries because they are not eligible for coverage through the VFC program.³⁹⁸

Some states also provide free or low-cost vaccines at public health department clinics to individuals without vaccine coverage. For those nineteen years of age and older who are ineligible for the various child vaccine programs, Merck and GlaxoSmithKline both offer patient assistance programs to provide vaccines free of charge to those without insurance who cannot otherwise afford the vaccine.³⁹⁹

The most effective method to eliminate this commonly-cited barrier is by offering the vaccine free at the point of delivery. Studies suggest that cost is less of a barrier when the vaccine is offered free at the point of delivery.⁴⁰⁰ Parental consent is easier to obtain when the vaccine is free—“They were doing it for free, so mum was like, ‘You’d better go.’”⁴⁰¹ The next part discusses cost and payment concerns specific to lowering the age of consent.

³⁹⁷ KFF, *The HPV Vaccine*, *supra* note 157, at 4.

³⁹⁸ *Id.* at 5.

³⁹⁹ See *GSK Vaccines Access Program*, GLAXOSMITHKLINE, <http://www.gsk-vap.com/> (last visited Feb. 18, 2015); *Merck Helps*, MERCK, <http://www.merckhelps.com/> (last visited Feb. 18, 2015).

⁴⁰⁰ See, e.g., Batista Ferrer et al., *supra* note 373, at 14 (reporting that cost, a frequently-cited and important barrier to providing and accessing the HPV vaccine, “was not evident in studies where the vaccine was offered free at the point of delivery”).

⁴⁰¹ Clare D’Souza et al., *Health Belief Model: Evaluating Marketing Promotion in a Public Vaccination Program*, 23 J. NONPROFIT & PUB. SEC. MTKG., 134, 142 (2011) (quoting an

4. Payment and Confidentiality if Age of Consent is Lowered

In addition to general concerns about the vaccine's cost, a concern specific to lowering the age of consent involves payment and confidentiality—who is responsible for paying for services such as the HPV vaccine when parents do not consent or do not know their adolescent is receiving a particular service?⁴⁰² In certain situations, such as when the minor has private health insurance, this may not be an issue if the minor intends to notify his or her parent(s) about receiving the vaccine or is not opposed to his or her parents finding out *and* if the parents are willing to pay any necessary costs, despite not providing consent. This is of greater concern when non-consenting parents refuse to pay costs related to the vaccine, such as co-payments for the office visits to administer the vaccine.

First, most insurance plans cover the vaccine's cost and the Affordable Care Act requires all new private insurance plans to cover HPV vaccines for the recommended age groups of males and females without consumer cost-sharing.⁴⁰³ The vaccine is also covered through the new health exchanges.⁴⁰⁴

Even if insurance covers the vaccine's cost, however, there is often a co-payment required for the office visit. Although generally a small amount, some adolescents may not have such money available to them. Currently, some state laws allowing minors to

adolescent discussing Australia's "catch up" campaign which offered the vaccine for free for a limited time).

⁴⁰² *Tell Governor Jerry Brown to Veto AB499: Do Not Take Away Parental Healthcare Rights*, AGE OF AUTISM (Sept. 8, 2011, 7:05 PM), <http://www.ageofautism.com/2011/09/tell-governor-jerry-brown-to-veto-ab499-do-not-take-away-parental-healthcare-rights.html> [hereinafter *Tell Governor Jerry Brown to Veto AB499*] ("Who will pay for these vaccinations? The state, through the overburdened taxpayer?").

⁴⁰³ KFF, *The HPV Vaccine*, *supra* note 157.

⁴⁰⁴ *Id.*

consent to services such as STI diagnosis and treatment without parental consent include a provision stating that the parents or guardians are not financially liable for services they did not consent to.⁴⁰⁵ This illustrates that payment concerns related to services provided without parental consent are not insurmountable obstacles for laws allowing minors to consent to the HPV vaccine. If the adolescent has private insurance coverage that covers the vaccine, for example, the state law lowering the age of consent could also include a provision eliminating co-payments/cost-sharing for office visits to receive the vaccine. California's "Medi-Cal" program, for example, reimburses confidential health services for twelve- to twenty-one-year-olds for services related to venereal diseases.⁴⁰⁶ The program allows minors to apply for Medi-Cal without parental consent in order to receive confidential services⁴⁰⁷ and there is no co-payment required.⁴⁰⁸

If the adolescent is not covered by private insurance or her insurance does not cover the HPV vaccine, she may be able to obtain coverage through one of the public financing programs that cover vaccine costs, such as the Vaccines for Children Program,

⁴⁰⁵ See, e.g., ALASKA STAT. § 25.20.025(a)(5) (West 2014); CAL. FAM. CODE § 6926(c) (West 2014); DEL. CODE ANN. tit. 16 § 710 (West 2014); FLA. STAT. ANN. § 384.30(2) (West 2014); IDAHO CODE ANN. § 39-3801 (West 2014); KY. REV. STAT. § 214.185 (West 2014); MASS. GEN. LAW ANN. 112 § 12F (West 2014); MICH. COMP. LAWS ANN. § 333.5127 (West 2014); OHIO REV. CODE ANN. § 3709.241 (West 2014); ORE. REV. STAT. ANN. § 109.610(2) (West 2014); WASH. REV. CODE ANN. § 70.24.110 (West 2014).

⁴⁰⁶ CAL. CODE REGS. tit. 22 § 50063.5 (West 2015).

⁴⁰⁷ CAL. CODE REGS. tit. 22 § 5014.1 (West 2015).

⁴⁰⁸ Marlo Simmons et al. *Understanding Confidentiality and Minor Consent in California: An Adolescent Provider Toolkit*, ADOLESCENT HEALTH WORKING GRP., at A-9 (2002), http://publichealth.lacounty.gov/std/docs/Adolescent_Confidentiality_Toolkit.pdf; *Minor Consent Medi-Cal*, MATERNAL & CHILD HEALTH ACCESS 1, 2 (Apr. 2006), <http://kids-alliance.org/wp-content/uploads/2013/06/MinorConsentMediCal.pdf>.

the Immunization Grant Program, the Children’s Health Insurance Program, or state-sponsored programs providing free vaccines at public health department clinics.⁴⁰⁹

Confidentiality is another issue that arises if the adolescent is covered by private health insurance held by their parent(s). This is not an issue if the adolescent intends to inform his or her parent about receiving the vaccine, but if the adolescent wants his or her care to remain confidential, there are additional issues that must be addressed. If the adolescent wants to use private insurance to pay for the vaccine while also keeping it confidential, there is a risk disclosure could occur through the insurance claims process, which often involves an “explanation of benefits” (EOB) sent to the policyholder (usually a parent).⁴¹⁰

The Health Insurance Portability and Accountability Act’s “Privacy Rule” provides a legal basis and procedure for a minor to request that providers and health plans restrict disclosure of their protected health information, but the effective implementation of these provisions requires the cooperation of HCPs and third-party payers.⁴¹¹ Under 45 C.F.R. § 164.522(b), health plans

Must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.⁴¹²

⁴⁰⁹ See sources cited *supra* notes 396–399 and accompanying text.

⁴¹⁰ Rebecca Gudeman, *The Affordable Care Act and Adolescent Health*, XXXII YOUTH L. NEWS, July–Sept. 2013, available at http://www.youthlaw.org/publications/yln/2013/jul_sep_2013/affordable_care_act_adolescent_health/.

⁴¹¹ Abigail English & Carol A. Ford, *The HIPAA Privacy Rule and Adolescents: Legal Questions and Clinical Challenges*, 36 PERSP. ON SEXUAL & REPROD. HEALTH 80, 83, 84 (2004).

⁴¹² 45 C.F.R. § 164.522(b)(1)(ii) (West 2015).

This provision, however, requires the adolescent to “clearly state” that disclosure could “endanger” him or her, which may be difficult or impossible. In certain situations, an adolescent may indeed fear the reaction of her parents if she believes they will be angry and potentially respond violently (for example, based on their assumption that this means their child is sexually active, which they may vehemently oppose). In other situations, however, the adolescent may not feel in danger but nevertheless want to keep the information confidential (for example, fearing his or her parents will react with disapproval or disappointment, but not necessarily *violence*).

If the adolescent cannot “clearly state” that disclosure could place her in danger, 45 C.F.R. § 164.522 provides that any covered entity (which includes health plans⁴¹³), “must permit an individual to request that the covered entity restrict uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations,” but a covered entity is not *required* to agree to a restriction.⁴¹⁴ Therefore, it is necessary for health plans to be willing to grant such requests and for adolescent HCPs to make sure their patients are aware of these options and to help them seek these protections when desired.

Although concerns about payment and confidentiality are valid, there are ways to overcome these issues and therefore do not impose an insurmountable barrier to lowering the age of consent.

⁴¹³ 45 C.F.R. § 160.103 (West 2015).

⁴¹⁴ 45 C.F.R. § 164.522 (West 2015).

5. Adolescent Inability to Understand Potential Safety Risks

Those questioning the vaccine's safety may oppose lowering the age of consent not only because they simply oppose the vaccine itself, but also because they doubt a young adolescent's ability to adequately understand the vaccine's risks. Continuing its pattern of sensationalistic journalism and opposition to anything related to vaccines, *Age of Autism*, an online newspaper dedicated to the "autism epidemic," expressed strong opposition to California Assembly Bill 499, which was subsequently passed and is codified at California Family Code § 6926 and allows minors twelve years and older to consent to STI treatment and prevention, including vaccines.⁴¹⁵ It argued that the "law could have disastrous results for many reasons," including⁴¹⁶:

- A child will most likely not know his or her family history of allergies, autoimmune diseases, or adverse reactions to other vaccines or medications, all of which are essential to consider before the administration of any vaccine;
- A child is not capable of weighing the risks and benefits of vaccination, and under this bill, a parent will not be present to ask the appropriate questions to elicit this important risk/benefit information;
- A child can be easily swayed by a person of authority, his or her peers, and by misinformation.

Similar sentiments were expressed (with less sweeping rhetoric and sensationalism) by California Assemblyman Tim Donnelly, author of California Assembly Bill 599, which sought to amend § 6926 to explicitly *exempt* vaccines from the services minors may consent to in order to "preserve[] and protect[] the well-being of

⁴¹⁵ *Tell Governor Jerry Brown to Veto AB499*, *supra* note 402.

⁴¹⁶ *Id.*

minors in California, by insuring that medical decisions relating to a minor’s health are made in conjunction with a parent or guardian.”⁴¹⁷ Assemblyman Donnelly stressed the importance of parental involvement because “minors are generally unable to incorporate future values into medical decision making and they tend to look at short term goals and values and ignore long-term factors, such as their own changing interests and priorities.”⁴¹⁸ Donnelly argued that his bill recognized that minor’s competency “is complicated” and should be “determined by medical professionals and not by legislators or school officials.”⁴¹⁹

It is important to note, however, that this statement is contrary to the position of many medical professionals and associations that opposed Donnelly’s bill, including the AAP, ACOG, the California Immunization Coalition, and the California Medical Association, among others.⁴²⁰ Donnelly’s argument that a minor’s competency should be decided by medical professionals is actually not at odds with lowering the age of consent, because informed consent procedures would be put in place to ensure HCPs determine, on an individual basis, whether a young adolescent has the capacity to consent to the vaccine without parental involvement. As consistently argued and supported throughout this thesis, adolescents, contrary to the argument set forth by *Age of Autism* and other vaccine opponents, *are* capable of weighing the risks and benefits of medical treatment. Even though a parent is not “present to ask the appropriate questions,” the HCP still has the professional responsibility to provide all relevant information and ensure the

⁴¹⁷ *Minors: Vaccinations: Parental Consent, Hearing on Cal. A.B. 599 Before the Assemb. Comm. on Health, 2013–14 Reg. Sess. (Cal. 2013).*

⁴¹⁸ *Id.*

⁴¹⁹ *Id.*

⁴²⁰ *Id.*

adolescent has the time and ability to ask any questions or express any concerns about the vaccine.

These arguments doubt an HCP's ability to establish and develop a high-quality provider-patient relationship with adolescents. Laws mandating parental consent can frustrate or prevent an HCP's use of the best medical practice, compromising the quality of care provided. By refusing to recognize adolescent consent capabilities, the law "does not mirror the current state of medical practice in which healthcare providers, particularly pediatricians and specialists in adolescent medicine, have a much broader sense of the ability of young people to understand and meaningfully participate in their own healthcare."⁴²¹

In response to the argument that an adolescent will not know his/her family history and allergy information, it is important to note this is not an issue when the adolescent seeks the vaccine from his or her established pediatrician, who will have access to medical records with this information. This concern is more relevant if the adolescent seeks the vaccine from an HCP she has never seen before, such as at a free or low-cost clinic. Such concerns, however, have not been a barrier to adolescent consent to STI diagnosis or treatment, which implicates allergies to antibiotics and other medications. This should therefore not be a barrier to the HPV vaccine, particularly because the vaccine's contraindications are few and similar to those for commonly-used antibiotics for STIs.

⁴²¹ For additional discussion about an HCP's ability to provide quality, beneficent medical care to adolescent patients, see Part III(B)(3), *infra*.

A contraindication is “a condition in a recipient that greatly increases the chance of a serious adverse reaction.”⁴²² A contraindication for “pfizerpen,” a form of penicillin used to treat syphilis, for example, is “a history of hypersensitivity (anaphylactic) reaction to any penicillin.”⁴²³ Similarly, the only contraindication listed by the CDC for the HPV vaccine is “severe allergic reaction” to a previous dose of the HPV vaccine or another vaccine.⁴²⁴ Under “precautions,” which are conditions “that might increase[] the change or severity of an adverse reaction, or might compromise the ability of the vaccine to produce immunity,”⁴²⁵ the CDC lists a current moderate or severe illness with or without fever and current pregnancy.⁴²⁶ The HPV vaccine is one of the vaccines with the fewest contraindications listed by the CDC, suggesting that they are not a major concern. And if an adolescent had a previous severe allergic reaction to a vaccine, this is likely something they would have been told (if it occurred when they were an infant) or would remember (if it was a reaction to a more recently-provided vaccine). Furthermore, the increasing use of electronic health records (EHR) may make it easier for HCPs and institutions to share patient medical records, allowing HCPs across a variety of settings to access an individual’s health records (with the individual’s consent).⁴²⁷

⁴²² CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 17.

⁴²³ FDA LABEL DATABASE, *Pfizerpen (penicillin G potassium) for Injection Drug Label*, FDA, <https://rm2.scinet.fda.gov/druglabel/rs/spl/by-id/137965/137965.html> (last revised Nov. 2014).

⁴²⁴ *Chart of Contraindications and Precautions to Commonly Used Vaccines for Childhood Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm> (last revised July 7, 2014) [hereinafter *Chart of Contraindications*].

⁴²⁵ CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 17.

⁴²⁶ *Chart of Contraindications*, *supra* note 424.

⁴²⁷ See, e.g., OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., REPORT TO CONGRESS: UPDATE ON THE ADOPTION OF HEALTH INFORMATION TECHNOLOGY AND RELATED

The argument that an adolescent can be “easily swayed” by persons of authority again questions and doubts an HCP’s ability to adhere to professional guidelines and ethical standards prohibiting coercion. Although there are certainly situations in which HCPs have exerted too much authority and sway over their patients, the vast majority of pediatric and adolescent HCPs have the skills necessary to communicate with their young patients in a way that is not paternalistic or coercive. An essential purpose of informed consent is to ensure the patient and provider go through a *joint process* involving patient input and opportunities to ask questions and express concerns, thereby reducing the risk of coercion. As stated by ACOG,

Consenting freely is incompatible with being coerced or unwillingly pressured by forces beyond oneself. . . . In many cases, the physician’s personal and professional values and clinical experiences do, to some degree, influence the presentation and discussion of therapeutic options with patients. Although not considered frank manipulation or coercion, care should be taken that the physician’s perspectives do not unduly influence a patient’s voluntary decision making.⁴²⁸

An HCP’s *recommendation*, however, does not constitute coercion or manipulation when done in an appropriate manner.⁴²⁹ HCPs who treat children and

EFFORTS TO FACILITATE THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION, DEP’T HEALTH & HUMAN SERVS. 11 (Oct. 2014), http://www.healthit.gov/sites/default/files/rtc_adoption_and_exchange9302014.pdf (“EHRs facilitate the collection, storage, and sharing of comprehensive real-time information for health care providers to make informed decisions with their patients”); Nir Menachemi & Taleah H. Collum, *Benefits and Drawbacks of Electronic Health Record Systems*, 4 RISK MGMT. & HEALTHCARE POL’Y 47, 48 (2011) (stating that one of the benefits of EHRs is that they facilitate the sharing of patient information and can increase efficiency in health care delivery).

⁴²⁸ Comm. on Ethics, *Informed Consent*, AM. COLL. OBSTETRICS & GYNECOLOGY COMM. OP. NO. 439, at 3 (Aug. 2009, reaffirmed 2012), available at <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf?dmc=1&ts=20150212T1221378414>.

⁴²⁹ *Id.* at 5.

adolescents, like all HCPs in general, have a duty to ensure their methods of treatment and obtaining informed consent are not coercive, deceptive, or unethical. It is also ironic that vaccine opponents are concerned about adolescents being “misinformed,” when they themselves spread misinformation, based on the plethora of scientific data refuting their positions about the vaccine’s risks.

Because informed consent policies and procedures can ensure HCPs make individualized determinations about their adolescent patient’s consent capabilities, concern about an adolescent’s ability to understand the vaccine’s risks and benefits is an insufficient reason to oppose and prevent a lower age of consent.

6. Role of Parent and Family: The Importance of “Parent-Child Unity”

Although a majority of adults in the United States support laws allowing minors to consent to STI diagnosis and treatment without parental consent, a national poll of over 2,000 adults found that a slight majority still support requiring consent for the HPV vaccine, with 54% opposed to state laws allowing 12- to 17-year-old females to consent to the vaccine without parental involvement and 55% opposed to allowing 12- to 17-year-old males to consent to vaccine.⁴³⁰ The primary reason for opposing HPV vaccination without parental consent was the belief that it should be the *parent’s* sole decision.⁴³¹ Other reasons included the vaccine’s risks, moral or ethical concerns about the vaccine, and a belief that twelve- to seventeen-year-old adolescents are too young to receive the

⁴³⁰ C.S. Mott Children’s Hosp., *Public Reluctant to Support Teen HPV Vaccine Without Parental Consent*, 16 NAT’L POLL ON CHILDREN’S HEALTH, July 18, 2012, available at <http://www.mottnpch.org/sites/default/files/documents/071812HPVreport.pdf>.

⁴³¹ *Id.*

vaccine.⁴³² Despite the vaccine’s connection to sexual activity and the importance of vaccination before sexual initiation, this study suggests that adults view STI vaccines differently than STI diagnosis and treatment.

Some are in favor of parental involvement in a minor’s health care decisions because it preserves parental control and “family autonomy,” which the Supreme Court has shown special solicitude to on numerous occasions.⁴³³ Others similarly argue that parental involvement laws “protect the health and welfare of minors, as well as foster family unity.”⁴³⁴ Those with extreme anti-vaccination views place tremendous weight on arguments about a parent’s role in making decisions for his or her child, and at times seem to suggest that parents are the *only* ones with such decision-making authority.

Barbara Loe Fisher, founder of the “National Vaccine Information Center” (which many place in the category of “junk science” and “propaganda”⁴³⁵) argued against California

⁴³² *Id.*

⁴³³ *Parental Consent Requirements and Privacy Rights of Minors: The Contraceptive Controversy*, 88 HARV. L. REV. 1101, 1015 (1975); see also *Wisconsin v. Yoder*, 406 U.S. 205 (1972) (holding that Amish parents have a right to direct the religious training of their children); *Pierce v. Soc’y of Sisters*, 268 U.S. 510 (1925) (striking down a state statute requiring children to attend public schools as an unreasonable interference with parental liberty to direct their child’s upbringing); *Meyer v. Nebraska*, 262 U.S. 390 (1923) (protecting the right of parents to have their child taught a foreign language).

⁴³⁴ Denise M. Burke, *Parental Notification of Abortion Act: Model Legislation and Policy Guide*, AM. UNITED FOR LIFE 3 (2012), <http://www.aul.org/wp-content/uploads/2012/11/Parental-Notice-2013-LG.pdf>.

⁴³⁵ After NVIC started advertising via billboards and other media outlets, including “CBS Outdoor,” the AAP wrote a letter objecting to NVIC’s paid advertisements that were being shown on the CBS Jumbotron in Times Square in April 2013. The AAP argued that this type of advertisement “promote[d] the unscientific practice of delaying or skipping vaccines altogether” and that the NVIC’s information was “unfounded and unscientific.” See Elyse Anders, *Anti-Vax Times Square Ad Progress*, SKEPCHICK (Apr. 14, 2011), <http://skepchick.org/2011/04/anti-vax-times-square-ad-progress/> (providing a copy of the AAP letter from AAP’s president Dr. O. Marion Burton to Wally Kelly, Chairman and CEO of CBS Outdoor); see also David Gorski, *Ringling in 2012 With . . . Antivaccine Propaganda?*, SCIENCE-BASED MED. (Dec. 28, 2011), <http://www.sciencebasedmedicine.org/ringing-in-2012-with-antivaccine-propaganda/> (referring to

Assembly Bill 499 (AB 499), which (as passed) allows minors twelve and older to obtain STI-prevention (including vaccines) without parental consent, with impassioned, emotionally-charged statements about the necessity of informed parental consent. She argues parental consent is the law and also a *moral imperative*:

We as parents, who know and love our children better than anyone else, we, by U.S. law and a larger moral imperative, are the guardians of our children until they are old enough to make life and death decisions for themselves. We are responsible for their welfare and we are the ones who bear the grief and burden when they are injured or die from any cause. We are their voice and by all that is right in this great country and in the moral universe, we should be allowed to make a rational, informed, voluntary decision about which diseases and which vaccines we are willing to risk their lives for—without fearing retribution from physicians employed by the state.⁴³⁶

In its calls for California Governor Jerry Brown to veto AB 499, vaccine opponents at *Age of Autism* similarly argued that “[s]ince ancient times, parents have had the authority and responsibility to make decisions regarding the health and well-being of their children. . . . California’s AB 499 is *an outrageous usurping of a parent’s authority and rights.*”⁴³⁷

Fisher as an “antivaccine propagandist”); Will Kinney, *Junk Science: More Research is Needed*, UNIV. BUFFALO DEP’T PHYSICS, <http://www.acsu.buffalo.edu/~whkinney/notevenwrong.html> (last visited Feb. 12, 2015) (arguing that despite its “official” sounding name, NVIC is not “official” and is merely “science by publicity”); Phil Plait, *Antivaxxers Using Billboards to Promote Their Dangerous Message*, SLATE (Mar. 15, 2013, 8:00 AM), http://www.slate.com/blogs/bad_astronomy/2013/03/15/vaccines_and_autism_antivaccination_group_advertising_on_billboards.html (arguing that “NVIC is an antivax group, plain and simple . . . They are convinced vaccines cause injuries, and ignore evidence that there isn’t.”).

⁴³⁶ *A Parent’s Horrid Nightmare: Coming Soon to YOUR State?*, MERCOLA (Sept. 16, 2011), <http://articles.mercola.com/sites/articles/archive/2011/09/16/vaccine-wake-up-call-for-parents-your-children-are-being-taken.aspx>.

⁴³⁷ *Tell Governor Jerry Brown to Veto AB499*, *supra* note 402.

Other Supreme Court jurisprudence, lower court cases, and state laws, however, refute these arguments, indicating that parental rights and authority are not absolute.⁴³⁸ The Court has held, for example, that minors have rights to obtain certain health care services, such as abortions, without parental consent.⁴³⁹ The interest in family unity thus does not necessarily justify limiting adolescent autonomy or suggest that young adolescents are always incapable of making informed, reasoned decisions in confidential consultation with their HCPs.⁴⁴⁰

The results of the previously-discussed survey suggest that a slight majority of parents still support requiring parental consent for the vaccine, indicating that proposals to lower the age of consent will face public opposition if not pursued with caution and with adequate evidence and support that minors can make reasoned and informed

⁴³⁸ See Part I(C)(2) for a more detailed discussion on state laws recognizing minor's rights to consent in certain situations and for certain medical services. *See also* Am. Acad. of Pediatrics v. Lungren, 940 P.2d 797, 828–29 (Cal. 1997) (invalidating a statutory provision requiring a minor to obtain parental consent or judicial authorization before obtaining an abortion and rejecting the state's argument that the statute promoted its interest in fostering parent-child relationships).

⁴³⁹ A number of cases involving parental consent and notification laws for abortion have been deemed unconstitutional, with the Court concluding that society's interest in safeguarding the rights of mature minors to obtain an abortion without parental consent outweighs society's interest in safeguarding parental authority and preserving family unity. *See, e.g.,* Belotti v. Baird, 443 U.S. 622, 647 (1979); Planned Parenthood v. Danforth, 428 U.S. 75 (1976). The Court has also struck down statutes that completely prohibited distributing contraception to minors. *Carey v. Pop. Serv.*, 431 U.S. 678, 694 (1977) (“Since the state may not impose a blanket prohibition, or even a blanket requirement of parental consent, on the choice of a minor to terminate her pregnancy, the constitutionality of a blanket prohibition of the distribution of contraceptives to minors is a fortiori foreclosed.”).

⁴⁴⁰ *See, e.g.,* Lungren, 940 P.2d, at 828–29; Kimberly M. Mutcherson, *Whose Body is it Anyway?: An Updated Model of Healthcare Decision-Making Rights for Adolescents*, 14 CORNELL J. L. & PUB. POL'Y 251, 293 (2005) (discussing many HCP's beliefs that adolescents are capable of substituted judgment and independent health care decisions); John Loxterman, *Adolescent Access to Confidential Health Services*, ADVOCATES FOR YOUTH (July 1997), <http://www.advocatesforyouth.org/publications/publications-a-z/516-adolescent-access-to-confidential-health-services> (“In situations where parental notification might deter adolescents from seeking . . . health services, states have determined that protecting the minor's confidentiality is more important than promoting parental consent and family autonomy.”).

decisions about these vaccines. California’s success in passing and sustaining its law eliminating parental consent requirements for STI-related vaccines, however, illustrates that laws lowering the age of consent for the HPV vaccine can survive despite initial controversy⁴⁴¹ and subsequent attempts to amend the law.⁴⁴²

7. Effect on the Use of Cancer Screenings and Other Preventive Care

The HPV vaccine targets two of the highest risk HPV strains but does not protect against all high-risk strains.⁴⁴³ Therefore, vaccinated women should continue to receive cervical cancer screenings.⁴⁴⁴ There are concerns the vaccine will reduce the use of cancer screening among vaccinated women “because of an exaggerated sense of security from being vaccinated,” which could potentially cause an *increase* in cervical cancer.⁴⁴⁵ Although a few studies have found that a small percentage of women may change their

⁴⁴¹ “Jerry Brown is deceptively telling preteen girls it will protect them from HPV, giving them a false sense of security that they can have the sexual activity they want without risking developing cervical cancer or a raft of other negative consequences.” Mikaela Conley, *California 12-Year-Olds to Get HPV Vaccine Without Parental Consent*, ABC NEWS (Oct. 11, 2011, 3:42 PM), <http://abcnews.go.com/blogs/health/2011/10/11/california-12-year-olds-to-get-hpv-vaccine-without-parental-consent/> (quoting Randy Thomasson, a spokesperson for “SaveCalifornia.org”).

⁴⁴² CAL. A.B. No. 599, 2013–14 Reg. Sess. (Cal. 2013) (failed to pass).

⁴⁴³ Katie A. Ports et al., *Young Women's Sexual and Reproductive Health Post HPV Vaccination* 1 WOMEN’S REPROD. HEALTH 43, 44 (2014).

⁴⁴⁴ *Id.*

⁴⁴⁵ Chris T. Bauch et al., *Adherence to Cervical Screening in the Era of Human Papillomavirus Vaccination: How Low is Too Low?*, 10 LANCET INFECTIOUS DISEASES 133, 133 (2010); see also M. Adams et al., *Human Papillomavirus (HPV) Prophylactic Vaccination: Challenges for Public Health and Implications for Screening*, 25 VACCINE 3007, 3011 (2007); Dianne M. Harper et al., *Cervical Cancer Incidence Can Increase Despite HPV Vaccination*, 10 LANCET INFECTIOUS DISEASES 594 (2010); Shalini L. Kulasingam et al., *Potential Effects of Decreased Cervical Cancer Screening Participation After HPV Vaccination: An Example from the U.S.*, 25 VACCINE 8110 (2007); M. Stanley, *Human Papillomavirus Vaccines Versus Cervical Cancer Screening*, 20 CLINICAL ONCOLOGY 388, 392 (2008); Richard K. Zimmerman, *Ethical Analysis of HPV Vaccine Policy Options*, 24 VACCINE 4812, 4816 (2006).

sexual health attitudes and behaviors after vaccination,⁴⁴⁶ there is also evidence that screening rates have not decreased and are unlikely to decrease to a level that will increase cervical cancer prevalence. Chris T. Bauch and colleagues developed a simple mathematical model of vaccination, screening, and disease incidence, showing that for a population with opportunistic screening⁴⁴⁷ and thirty percent vaccination coverage, screening rates in vaccinated women would have to decline by at least eighty percent before the incidence of cervical cancer would be higher than when the vaccine was first introduced.⁴⁴⁸ In a population with seventy percent vaccine coverage and an organized screening program,⁴⁴⁹ a screening decline of at least forty-nine percent would have to occur.⁴⁵⁰ Although the decline needed in populations with highly effective and organized cancer screening programs is lower than opportunistic screening scenarios, the authors concluded that the vaccine's introduction is unlikely to increase cervical cancer rates due to lower rates of cancer screening.⁴⁵¹ Furthermore, these concerns can be addressed through education and information stressing the importance of continual screening for

⁴⁴⁶ In a study of 102 Australian university students, for example, researchers found that 19% of participants felt less concerned about sexual health, 11% felt less need to have regular Pap smears, and 10% felt less concerned about protection against STIs. Rebekah C. Laidsaar-Powell et al., *Vaccination Decision-Making and HPV Knowledge: How Informed and Engaged are Young Adult HPV Recipients in Australia?*, J. VACCINES 1, 4 (2014), available at <http://www.hindawi.com/journals/jv/2014/495347/>.

⁴⁴⁷ "Opportunistic screening" occurs when a patient asks their HCP for a screening or a screening is offered by the HCP. *Organised and Opportunistic Screening*, NAT'L SCREENING UNIT, <https://www.nsu.govt.nz/about-us-national-screening-unit/what-screening/organised-and-opportunistic-screening> (last updated Dec. 2014).

⁴⁴⁸ Bauch et al., *supra* note 445, at 133.

⁴⁴⁹ An organized screening program involves standardized, monitored screening services that are tracked. *Organised and Opportunistic Screening*, *supra* note 447.

⁴⁵⁰ Bauch et al., *supra* note 445, at 133.

⁴⁵¹ *Id.* at 137.

cervical cancer caused by HPV strains not targeted by the vaccine.⁴⁵² With the introduction of the new nonavalent vaccine, however, even greater coverage against high-risk strains is possible.⁴⁵³ Nevertheless, an important component of the vaccine consent process should be providing information about the importance of continued cancer screening and continued condom use and other safe-sex practices to reduce the risk of HPV exposure.⁴⁵⁴

There is also evidence suggesting HPV vaccination may *facilitate* protective health behaviors and use of preventive services.⁴⁵⁵ In a small qualitative study exploring the vaccine's impact on thirty college-aged women's reproductive and sexual health, twenty-eight of the participants reported that despite receiving the vaccine, continuing to receive routine Pap smears was "very important to their health regimen," and that receiving the vaccine did not make screening any less important than for those who had not received the vaccine.⁴⁵⁶ The two women who thought Pap smears were not important

⁴⁵² After the vaccine was introduced in Australia, for example, widespread publicity helped inform women that screening is still necessary after vaccination. A Victorian population-based phone survey for example, found that 96% of women 18–28 years old knew that Pap tests were still needed after vaccination. Julia M. Brotherton et al., *Early Effect of the HPV Vaccination Programme on Cervical Abnormalities in Victoria, Australia: An Ecological Study*, 377 LANCET 2085, 2090 (2011).

⁴⁵³ News Release, FDA Approves Gardasil 9, *supra* note 94.

⁴⁵⁴ Regardless of whether parental consent is obtained, informing adolescent girls (and boys) about the need to continue cancer screenings (for cervical cancer, anal cancer, and all other HPV-related cancers) is extremely important. See Lorraine A. Valley et al., *Informing Adolescents About Human Papillomavirus Vaccination: What Will Parents Allow?*, 26 VACCINE 2203, 2203 (2008) ("Engaging adolescent girls is critical to avoid misconceptions about the protection afforded by HPV vaccination and the future need for cervical screening.").

⁴⁵⁵ Ports et al., *supra* note 443, at 52.

⁴⁵⁶ *Id.* at 51.

had reasons other than the vaccine that made them less concerned about Pap smears. For example, one considered herself low risk for HPV because she was not sexually active.⁴⁵⁷

Receiving the vaccine had little impact on the participants' sexual practices. It did not influence condom use, with one woman reporting she "would still use all forms of protection, and do anything in order to just NOT get those things. I know a few people who have taken those chances and it's really hurt them in the end."⁴⁵⁸ The authors of this study concluded that this and previous studies suggest the vaccine may facilitate protective health behaviors because many women indicated that receiving the vaccine made them more aware of STIs "and prompted them to continue to take care of their sexual and reproductive health."⁴⁵⁹ Another study of 760 women ages 14 to 25 found no reason to believe there is a "trade-off" between screening and vaccination.⁴⁶⁰ 89.5% of participants said they would prefer to take both preventive measures (vaccination and screening) and 93.9% were aware that regular screening was still necessary even after vaccination.⁴⁶¹ The authors thus concluded "there is little cause to worry that HPV vaccination might lead to neglect of screening."⁴⁶²

⁴⁵⁷ *Id.*

⁴⁵⁸ *Id.* at 50.

⁴⁵⁹ *Id.* at 52; see also Kati Kuitto et al. *Attitudinal and Socio-Structural Determinants of Cervical Cancer Screening and HPV Vaccination Uptake: A Quantitative Multivariate Analysis*, 18 J. PUB. HEALTH 179, 184 (2010); Tanya Mather et al., *Does HPV Vaccination Affect Women's Attitudes to Cervical Cancer Screening and Safe Sexual Behaviour?*, 30 VACCINE, 3196, 3201 (2012) (finding "no evidence [of] a detrimental impact of vaccination on cervical cancer prevention and sexual behavior").

⁴⁶⁰ Kuitto et al., *supra* note 459, at 184.

⁴⁶¹ *Id.*

⁴⁶² *Id.* at 187.

Other research suggests vaccinated women may place *more* importance on their sexual health than unvaccinated women.⁴⁶³ Vaccinated women exhibit higher rates of cervical cancer screenings,⁴⁶⁴ higher levels of condom use,⁴⁶⁵ and greater awareness that screening is still necessary after vaccination.⁴⁶⁶ A study conducted in the United Kingdom reviewed the medical records of 363 young women born after September 1, 1990 who attended English clinics and found that vaccinated young women engaged in *less* risky behavior than unvaccinated young women.⁴⁶⁷ Two-thirds of these women had received at least one dose of the vaccine.⁴⁶⁸ Researchers reviewed the women's histories of risky behaviors such as not using condoms, having sex for the first time at fifteen years old or younger, having six or more sexual partners, and drinking alcohol two or more times a week. Unvaccinated women were significantly more likely to (1) have had three sex partners in the last six months, (2) have attended the clinic with symptoms of an STD,

⁴⁶³ It is not precisely clear by these studies whether these women are more health-conscious in all areas of healthcare, whether they are motivated *because* of the vaccine, or whether they are motivated *in spite* of the vaccine. Nevertheless, there appears to be a correlation between receiving the vaccine and *less risky* sexual behaviors rather than high-risk behaviors.

⁴⁶⁴ Erich V. Kliewer, *Human Papillomavirus Vaccination and Pap Testing Profile in Manitoba, Canada*, 32 VACCINE 33, 35 (2014) (finding that vaccinated females had a significantly higher probability of having a Pap test (83.3%) than non-vaccinated females (66.1%) over a period of three years); Mather et al. *supra* note 459, at 3199.

⁴⁶⁵ Nicole C. Liddon et al., *Human Papillomavirus Vaccine and Sexual Behavior Among Adolescent and Young Women*, 42 AM. J. PREVENTIVE MED. 44, 49–50 (2012).

⁴⁶⁶ Madelief Mollers et al., *Equality in Human Papilloma Virus Vaccination Uptake?: Sexual Behavior, Knowledge, and Demographics in a Cross-Sectional Study in (Un)vaccinated Girls in the Netherlands*, 14 BMC PUB. HEALTH (2014), <http://www.biomedcentral.com/content/pdf/1471-2458-14-288.pdf> (finding that 71% of vaccinated girls versus 66% of unvaccinated girls knew they should still participate in cervical screening after vaccination).

⁴⁶⁷ Laura Sadler et al., *Comparing Risk Behaviors of Human Papillomavirus-Vaccinated and Non-Vaccinated Women*, J. FAM. PLANNING & REPROD. HEALTH CARE (2015); Roxanne Nelson, *Contrary to Parents' Concerns, HPV Vaccine Linked to Less Risky Sexual Behavior*, REUTERS (Feb. 12, 2015, 1:12 PM), <http://www.reuters.com/article/2015/02/12/us-womens-health-hpv-behavior-idUSKBN0LG2GE20150212>.

⁴⁶⁸ Sadler et al., *supra* note 467.

(3) have had anal intercourse with their last sexual contact, and (4) have tested positive for Chlamydia at their clinic visit.⁴⁶⁹ In contrast, vaccinated women were less likely to engage in risky behaviors and were more likely to use condoms.⁴⁷⁰ The study's authors concluded that failing to receive the HPV vaccine is a marker of high-risk behaviors.⁴⁷¹ Researchers note, however, that the study does not prove that vaccination *causes* less risky behaviors.⁴⁷²

Although it is not precisely clear why women receiving the vaccine engage in less risky sexual behaviors, the research suggests that contrary to popular concerns, receiving the HPV vaccine is actually linked to lower-risk sexual behaviors rather than higher-risk behaviors. First, those receiving the vaccine may already be more health-conscious with regard to all aspects of health care and thus more likely to engage in preventive health care. They may already be less likely to take risks regardless of whether they are vaccinated.⁴⁷³ Second, it is possible that getting vaccinated provides opportunities for education about sexual health and how to reduce risks of other STIs.⁴⁷⁴ Receiving the vaccine provides HCPs the opportunity to educate and inform their patients. These women may also be motivated after receiving the vaccine to continue to manage their sexual health and ensure they protect themselves from other STIs. The vaccine and education provided when receiving the vaccine may motivate these women to take greater control of their health and thereby decrease high-risk sexual behaviors.

⁴⁶⁹ *Id.*

⁴⁷⁰ *Id.*

⁴⁷¹ *Id.*

⁴⁷² Nelson, *supra* note 467.

⁴⁷³ Sadler et al., *supra* note 467; Nelson, *supra* note 467.

⁴⁷⁴ Sadler et al., *supra* note 467; Nelson, *supra* note 467.

Regardless of whether vaccine recipients are more or less likely to receive cervical cancer screenings, use condoms, or engage in other positive health behaviors, HCPs and public health officials should continue to stress to all patients that receiving the vaccine does not change the importance of continued cancer screenings and safe-sex behaviors.

8. **Additional Doses and Follow-Up Care**⁴⁷⁵

If parents are not involved in the adolescent's vaccination and the adolescent does not wish to inform them, some may doubt the adolescent's likelihood of remembering the need to receive two additional doses. Although it may be possible to administer the vaccine in two doses in the future,⁴⁷⁶ it is currently still administered in three doses, with the second dose one to two months after dose one and the third dose administered six months after dose one.⁴⁷⁷ Adolescents must be aware of this and HCPs must have a "reminder/recall" policy in place to (1) remind adolescents about an upcoming appointment and (2) track missed appointments to alert HCPs when an appointment for the second or third dose is missed to allow the HCP to contact the adolescent and re-schedule the appointment.⁴⁷⁸ The appointments for the second and third doses should be

⁴⁷⁵ The precise mechanism for promoting the vaccine and implementing programs once a lower age of consent is legalized is beyond the scope of this thesis. There are various possibilities and different settings to consider, including private physicians' offices, school-based health clinics, and community/low-cost clinics such as Planned Parenthood. The exact method of distributing the vaccine may depend on the setting in which it is administered and the needs of the particular community/population. Legalizing a lower age of consent is the first step in the process and paves the way for HCPs, public health officials, school officials, and others to develop policies to ensure adolescents have the opportunity to access and consent to the vaccine.

⁴⁷⁶ See sources cited *infra* notes 646–647 and accompanying text.

⁴⁷⁷ *Vaccine Information Statement: Gardasil*, *supra* note 101, at 1.

⁴⁷⁸ *AAP Immunization Resources: Immunization Reminder & Recall System*, AM. ACAD. PEDIATRICS, <https://www2.aap.org/immunization/pediatricians/pdf/ReminderRecall.pdf> (last updated May 2014).

made at the time of the first dose, but with the recognition that the appointments may have to be rescheduled if conflicts arise in the adolescent's schedule (e.g., school activities, sports, inability to get to the office at that time).

For adolescents who do not want their parents to know about the vaccine, it will be important for HCPs to have a procedure in place for contacting the adolescent with appointment reminders in a way that reduces the risk of disclosure, such as an e-mail or a phone call or text message to the adolescent's personal cell phone if they have one (and they likely will based on survey data from 2012 finding that 78% of teens had their own cell phone).⁴⁷⁹ A guide published by the Centers for Medicaid and Medicare Services and the United States Department of Health promotes and recommends the use of texting and social media to send reminders to adolescents about upcoming appointments and needed care.⁴⁸⁰ State and local health departments could also create television commercials targeting adolescents and publish advertisements in popular magazines read by teens to inform them about talking to their HCP about the vaccine and acting as reminders if they have a second or third dose appointment in the near future. New York City, for example, currently airs commercials and publishes advertisements targeting parents to recommend that they talk to their child's HCP about the vaccine.⁴⁸¹ To avoid previous controversy

⁴⁷⁹ Mary Madden et al., *Teens and Technology 2013*, PEW RES. CTR. 2 (Mar. 13, 2013), http://www.pewinternet.org/files/old-media/Files/Reports/2013/PIP_TeensandTechnology2013.pdf.

⁴⁸⁰ *Paving the Road to Good Health: Strategies for Increasing Medicaid Adolescent Well-Care Visits*, CTRS. FOR MEDICAID & MEDICARE SERVS. & U.S. DEP'T HEALTH & HUMAN SERVS. 19–20 (Feb. 2014), <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/Paving-the-Road-to-Good-Health.pdf>.

⁴⁸¹ *See Toolkit: HPV Vaccine is Cancer Prevention*, N.Y. STATE DEP'T HEALTH, available at https://www.health.ny.gov/diseases/communicable/human_papillomavirus/docs/hpv_toolkit.pdf (last visited Feb. 18, 2015) (detailing the NY State Department of Health's campaign to increase

about pharmaceutical companies promoting the vaccine and lobbying for HPV vaccine mandates,⁴⁸² it is important these advertisements be developed and funded by state health departments rather than the pharmaceutical companies who develop, sell, and profit from the vaccines.

Another approach is to explore the possibility of school-based vaccine clinics where students twelve and older can receive the vaccine. The vaccine would be offered at the same time the student receives other school-based care or undergoes school-based health assessments to help protect the students' privacy, as they may not want other students to know they are receiving the vaccine. School-based HCPs would first discuss whether to involve the parents before administering the vaccine but would be able to administer the vaccine if the adolescent did not want to involve his parents. A school-based program would increase the likelihood of an adolescent completing all three doses by making follow-up appointments easier to track and easier for the adolescent to attend. Students are essentially a "captive audience," making a school-based vaccination program more efficient than trying to reach vaccine-eligible students on an individual

adolescent vaccination rates throughout the state); Press Release, NYC Dep't of Health & Mental Hygiene, Health Department Launches New Ad Campaign Highlighting Cancer-Prevention Benefits of Human Papillomavirus (HPV Vaccine) (Aug. 11, 2014), <http://www.nyc.gov/html/doh/html/pr2014/pr026-14.shtml>; NYC HEALTH: HPV TODAY (NYC Health 2014), <http://youtu.be/IIzUq1Jz5o.1>.

⁴⁸² See, e.g., Editorial, *Flogging Gardasil*, 25 NATURE BIOTECHNOLOGY 261 (2007), available at <http://www.nature.com/nbt/journal/v25/n3/pdf/nbt0307-261.pdf>; Ed Silverman, *Merck & Its HPV Vaccine: Sales & Skepticism Are Both Up*, FORBES (Mar. 27, 2013, 11:00 AM), <http://www.forbes.com/sites/edsilverman/2013/03/27/merck-its-hpv-vaccine-sales-skepticism-are-both-up/> (calling Merck's campaign to have Gardasil mandated "sneaky"); Ryan Borg, *The Gardasil "One Less" Campaign: How a Power Coercion Approach Will Fail to Address the Public Health Problem of HPV*, CHALLENGING DOGMA BLOG (Dec. 10, 2007), <http://sb721blog.blogspot.com/2007/12/gardasil-one-less-campaign-how-power.html>.

basis through private HCPs or non-school based health clinics.⁴⁸³ However, school-based programs are resource intensive and may not be an option in all areas. Nevertheless, state health departments and state legislators should consider funding such programs given the individual and public health benefits and potential long-term cost savings provided by the vaccine through cancer prevention.

Increasing the likelihood that an adolescent will complete the three vaccine doses when parents are not involved can be addressed in many different ways and can be tailored at the local level to address the specific barriers in a particular population. Concerns about follow-up should not preclude a lower age of consent, because these issues can be addressed and reassessed if problems arise.

Many of the previously-discussed concerns about the vaccine and lowering the age of consent are based on misinformation and a lack of knowledge. These concerns can be ameliorated, at least in part, through improvements in physician-patient communication/education and public dissemination of *credible*, scientifically-sound information.⁴⁸⁴ A consistent and significant problem for the HPV vaccine has been the

⁴⁸³ See Tania Bellia-Weiss et al., *Promoting HPV Prevention in the School Setting*, 28 NASN SCH. NURSING 86, 91 (2013); Steven G. Federico et al., *Addressing Adolescent Immunization Disparities: A Retrospective Analysis of School-Based Health Center Immunization Delivery*, 100 AM. J. PUB. HEALTH 1630, 1633 (2010); Allison Kempe et al., *Effectiveness and Cost of Immunization Recall at School-Based Health Centers*, 129 PEDIATRICS e1447, e1449 (2012); see also *School-Based Vaccination Clinics: Guidance for Schools*, N.Y. STATE EDU. DEP'T & N.Y.S. DEP'T OF HEALTH BUREAU OF IMMUNIZATION (Nov. 2009), <http://www.p12.nysed.gov/sss/schoolhealth/schoolhealthservices/SchoolBasedVaccinationGuidance.pdf> (commenting on the “improved efficiency and cost savings from a public health perspective” as a benefit of coordinating vaccination with schools).

⁴⁸⁴ Indeed, this is a problem for many childhood vaccines. There is a growing need for trustworthy and credible educational/informational campaigns to combat misconceptions. See, e.g., *Global Immunization: Vaccine Coverage is Variable*, CHILDREN'S HOSP. PHILA. (Jan. 2013), <http://vec.chop.edu/service/parents-possessing-accessing-communicating-knowledge-about-vaccines/global-immunization/global-immunization-vaccine-coverage-is-variable.html>

need to address knowledge gaps and misperceptions about the vaccine's safety, effectiveness, impact on sexual activity, and accessibility of programs to assist individuals in paying for the vaccine.⁴⁸⁵ The next Part further responds to the previously-discussed concerns and provides robust medical, ethical, and policy reasons for lowering the age of consent.

III. MEDICAL, ETHICAL, AND POLICY ARGUMENTS FOR LOWERING THE AGE OF CONSENT FOR THE HPV VACCINE

Much of the discussion about how to increase HPV vaccination rates focuses on increasing HCP and parent knowledge about the vaccine, improving and increasing HCP recommendations for the vaccine, and/or mandating the vaccine for school attendance. Despite the fact that parental consent can impose a significant barrier to HPV vaccination, the idea of lowering the age of consent for the vaccine has not been widely discussed. California⁴⁸⁶ and Missouri⁴⁸⁷ are currently the only states that clearly and explicitly recognize a minor's right to consent to vaccinations.⁴⁸⁸ The following Parts discuss the medical, ethical, and policy reasons for lowering the age of consent for the HPV vaccine.

(discussing misinformation and sources of misinformation about immunizations such as the polio and pertussis vaccine).

⁴⁸⁵ Many parents cite lack of knowledge as a main reason why they have not vaccinated their children. Holman et al., *supra* note 21, at 78; Stokley et al., *supra* note 127, at 620–21. *But see* Fishman et al., *supra* note 19 (finding that those with higher level of knowledge about HPV and the vaccine were not more likely to obtain the vaccine).

⁴⁸⁶ CAL. FAM. CODE § 6926 (West 2014).

⁴⁸⁷ MO. STAT. § 431.061 (West 2014).

⁴⁸⁸ As noted above, however, there are other state statutes that could potentially be interpreted to allow consent to *preventive* treatment, which arguably includes vaccines. *See* sources cited *supra* notes 259–265 and accompanying text.

A. MEDICAL REASONS FOR LOWERING THE AGE OF CONSENT

From a medical and scientific perspective, increasing HPV vaccine uptake among younger adolescents is the best way to ensure the vaccine's effectiveness in lowering rates of HPV and HPV-related cancers. Importantly, the vaccine is prophylactic, meaning it does not prevent an *existing* infection's progression or treat/cure an existing infection but rather *prevents* HPV entirely.⁴⁸⁹ The vaccine is therefore most effective when given *prior* to sexual initiation before potential exposure and infection.⁴⁹⁰ ACIP recommends routine vaccination with the quadrivalent or bivalent vaccine for eleven- or twelve-year-old females and routine vaccination with the quadrivalent vaccine for eleven- or twelve-year-old males.⁴⁹¹ ACIP recommends “catch up” vaccinations for thirteen- to twenty-six-year-old females and males.⁴⁹² For both males and females, the vaccine can be started as early as nine years of age.⁴⁹³

The vaccine's opponents argue it is too new to support claims about its actual ability to prevent HPV-related cancers because most of these cancers occur many years after initial infection, if at all.⁴⁹⁴ To predict the vaccine's impact on HPV-related cancer rates, however, more proximal outcomes are being monitored, such as vaccine-type HPV

⁴⁸⁹ Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 70.

⁴⁹⁰ *Id.*

⁴⁹¹ Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 1 (2014).

⁴⁹² *Id.*

⁴⁹³ *Id.* at 20.

⁴⁹⁴ Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 23; *see also* Charlotte J. Huang, *Human Papillomavirus Vaccination—Reasons for Caution*, 359 N. ENGL. J. MED. 861, 861 (2008) (“The bad news is that the overall effect of the vaccines on cervical cancer remains unknown.”); *HPV Vaccination*, *supra* note 134 (“We have no way of knowing what the effect of the vaccine will be on risk of developing cervical cancer, because it can take decades to appear.”).

prevalence, genital warts, and cervical precancers.⁴⁹⁵ Although the vaccines will not *completely* eliminate HPV-related cancers (because they do not prevent *all* high-risk/oncogenic HPV strains),⁴⁹⁶ because the vaccines effectively reduce the prevalence of some of the most *common* high-risk HPV strains, a significant reduction in future HPV-related cancer rates should be expected.⁴⁹⁷

As previously discussed, initial data suggest the vaccine is effective in preventing vaccine-type HPV and various HPV-related cancers.⁴⁹⁸ Not only is the vaccine effective at the individual level, but recent studies show evidence of herd immunity.⁴⁹⁹ The HPV vaccine's ability to create herd immunity would be shown by a decrease in HPV prevalence among vaccinated *and* unvaccinated individuals.⁵⁰⁰

The vaccine's effectiveness even at low uptake rates and its potential for herd immunity suggest it could have a tremendous impact on the prevalence of HPV and HPV-related cancer rates if more adolescent males and females received the vaccine, particularly if given prior to sexual initiation. This could have extremely important implications for individual and public health.

Allowing minors to consent to the HPV vaccine provides HCPs the opportunity to inform adolescents about the vaccine's risks and benefits and hopefully eliminate

⁴⁹⁵ Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 23.

⁴⁹⁶ High-risk HPV strains currently include types 16, 18, 31, 33, 34, 39, 45, 51, 52, 56, 58, 59, 68, 69, 73, and 82. CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 139. The new 9-valent HPV vaccine targets the following high-risk strains: 16, 18, 31, 33, 45, 52, and 58. News Release, FDA Approves Gardasil 9, *supra* note 94.

⁴⁹⁷ Gardasil 9, the new 9-valent vaccine approved by the FDA in December 2014 has the potential to prevent 90% of cervical, vulvar, vaginal and anal cancers. *Id.*

⁴⁹⁸ See *supra* Part (I)(B)(3).

⁴⁹⁹ Kahn et al., *Vaccine-Type HPV*, *supra* note 5; Tabrizi et al., *supra* note 5.

⁵⁰⁰ Kahn et al., *Vaccine-Type HPV*, *supra* note 5, at e250.

misconceptions about the vaccine that minors may have developed from their parents and/or the media’s sensationalistic reports about the vaccine. Although the media have portrayed the vaccine in positive, neutral, and negative ways, “it is often the unrealistic, *negative* vaccine fears that become salient to the public, which then tends to sensationalize potential side effects of vaccination. These rumors then filter down to adolescents and become further exaggerated.”⁵⁰¹ Prior to obtaining an adolescent’s consent, it is important HCPs clarify misconceptions to ensure the adolescent understands the likely (rather than exaggerated) risks and benefits. And although mutual parental-adolescent consent and involvement is preferable, parental involvement is not always possible nor in the minor’s best interest.

Increasing access and uptake of the HPV vaccine is also important as more adolescents use birth control methods other than the male condom, such as oral contraceptives (OCs) and “user-independent” methods that do not require a female’s daily action, such as injectables, intrauterine devices (IUDs) and other forms of implants.⁵⁰² “User-independent” methods are also referred to as long-acting reversible contraceptives (LARCs). OCs and LARCs are more effective than condoms at preventing pregnancy, but unlike condoms they do not protect against STIs such as HPV.⁵⁰³ Dual-method use—using a condom in addition to an effective non-barrier contraceptive—

⁵⁰¹ Gregory D. Zimet et al., *Beliefs, Behaviors and HPV Vaccine: Correcting the Myths and the Misinformation*, 57 PREVENTIVE MED. 414, 416 (2013) (emphasis added).

⁵⁰² Karen Pazol et al., *Condoms for Dual Protection: Patterns of Use with Highly Effective Contraceptive Methods*, 125 PUB. HEALTH REP. 208, 209 (2010); see also David L. Eisenberg et al., *Correlates of Dual-Method Contraceptive Use: An Analysis of the National Survey of Family Growth (2006–2008)*, 2012 INFECTIOUS DISEASES IN OBSTETRICS & GYNECOLOGY (2012).

⁵⁰³ Pazol et al., *supra* note 502, at 209.

therefore, is the best option for adolescents seeking to prevent pregnancy and STIs.⁵⁰⁴ But if adolescents are inadequately informed about the importance of dual-method use, they may “perceive no need to use condoms as backup pregnancy protection and may therefore have less incentive to use condoms.”⁵⁰⁵ If OC or LARC use decreases condom use, the increasing adolescent use of OCs and LARCs could affect STI prevalence among this population.

Research suggests OC and LARC use may indeed impact condom use, raising concerns that adolescent use of OCs and LARCs may increase adolescent STI rates. A recent study of women under twenty-five documented a decline in women’s consistent condom use after beginning OCs.⁵⁰⁶ Among these young, mostly African American and Hispanic women of low socioeconomic status (a population at high risk for STIs), forty-eight percent of women who used condoms consistently before OCs stopped consistent condom use and almost none increased condom use.⁵⁰⁷ Only four percent reported consistent dual-method use.⁵⁰⁸ Another study looking at OCs and LARCs found that compared to women using OCs, the odds of using condoms were reduced among women

⁵⁰⁴ Chelsea Morroni et al., *The Impact of Oral Contraceptive Initiation on Young Women’s Condom Use in 3 American Cities: Missed Opportunities for Intervention*, PLOS ONE e101804 (2014).

⁵⁰⁵ Philip D. Darney et al., *Condom Practices of Urban Teens Using Norplant Contraceptive Implants, Oral Contraceptives, and Condoms for Contraception*, 180 AM. J. OBSTETRICS & GYNECOLOGY 929, 930 (1999); see also Megan L. Kavanaugh et al., *Long-Acting Reversible Contraception for Adolescents and Young Adults: Patient and Provider Perspectives*, 26 J. OF PEDIATRIC & ADOLESCENT GYNECOLOGY 87, 90 (2013) (citing family planning providers’ concerns about reduced condom use among young LARC users); Susan E. Rubin et al., *New York City Physicians’ Views of Providing Long-Acting Reversible Contraception to Adolescents*, 11 ANNALS OF FAM. MED. 130, 134 (2013) (documenting providers’ concerns that LARCs (“forgettable contraception”) would decrease condom use).

⁵⁰⁶ Morroni et al., *supra* note 504, at e101804.

⁵⁰⁷ *Id.* at e101804.

⁵⁰⁸ *Id.*

using IUDs/Norplant as well as among the group of women relying on all user-independent methods combined.⁵⁰⁹ An older study of urban teens similarly found that adolescent Norplant users were less likely than OC users to also use a male condom.⁵¹⁰ These results may be related to different characteristics and risk factors among the population using a particular method. For example, some studies suggest that users are more likely to be in long-term relationships, which mitigates STI risk and decreases the perceived need for condom use.⁵¹¹ Long-term relationships, however, are not necessarily *monogamous* relationships and therefore are not risk-free. These and other studies⁵¹² thus suggest that it is possible adolescent condom use may decrease as adolescent OC and LARC use increases. And adolescent LARC use is likely to increase in light of the AAP's recently-revised recommendations on adolescent contraceptive use. The AAP now recommends that pediatricians consider LARCs such as IUDs as the “first-line contraceptive choices for adolescents.”⁵¹³ If greater adolescent use of LARCs decreases adolescent's dual-use of condoms, this could unfortunately increase STIs among adolescents. It is important that HCPs inform their adolescent patients about the

⁵⁰⁹ Pazol et al., *supra* note 502, at 211.

⁵¹⁰ Darney et al., *supra* note 505.

⁵¹¹ “Longer, more stable relationships are associated with less frequent condom use.” *Id.* at 934; see also Leighton Ku et al., *The Dynamics of Young Men's Condom Use During and Across Relationships*, 26 FAM. PLANNING PERSP. 246 (1994); Jennifer Manlove et al., *Condom Use and Consistency Among Male Adolescents in the United States*, 43 J. ADOLESCENT HEALTH 325 (2008) (finding that longer sexual relationships were associated with reduced and inconsistent condom use).

⁵¹² Abbey B. Berenson & Constance M. Wiemann, *Use of Levonorgestrel Implants Versus Oral Contraceptives in Adolescence: A Case Control Study*, 172 AM. J. OBSTETRICS & GYNECOLOGY 1128, 1132 (1995) (observing some decrease in condom use among adolescent OC and Norplant users); Carol F. Roye, *Condom Use by Hispanic and African-American Adolescent Girls Who Use Hormonal Contraception*, 23 J. ADOLESCENT HEALTH 205 (finding that adolescent girls using hormonal contraceptives were less likely to use condoms than other sexually active teens).

⁵¹³ Comm. on Adolescence, *Contraception for Adolescents*, 134 PEDIATRICS e1244, e1251 (2014).

importance of dual-method use,⁵¹⁴ but because adolescents may not always receive this information or may not adhere to this advice, the HPV vaccine will be even more important in the battle against the most common STI in the United States.⁵¹⁵

Despite the potential impact of increasing OC/LARC use on condom use, there is other evidence suggesting that girls and women who receive the HPV vaccine—even if they use OCs/LARC—exhibit greater sensitivity and attention to safe sex practices. This evidence was discussed in Part II(B)(7), and it indicates that receiving the vaccine is correlated with condom use and protective health behaviors, suggesting (1) there is something inherently different about these women’s protective health and sex behaviors, regardless of whether they receive the vaccine, and/or (2) receiving the vaccine provides HCPs the opportunity to remind girls and women about the importance of maintaining safe-sex practices. Further studies would need to specifically look at the pre- and post-vaccine behaviors of girls and women who use OCs/LARCs and whether there is any change in condom use.

The medical benefits of improving HPV vaccination rates by lowering the age of consent are numerous and are increasingly replicated through robust scientific studies. But the medical benefits are far from the only reasons for lowering the age of consent, which is further supported for ethical and policy reasons.

⁵¹⁴ Darney et al., *supra* note 505, at 935 (“Teen users of oral contraceptives and condoms require counseling on the importance of consistent use of both to prevent sexually transmitted infections, as well as unintended pregnancies.”).

⁵¹⁵ *What is HPV?*, *supra* note 27.

B. ETHICAL REASONS FOR LOWERING THE AGE OF CONSENT

Four principles of bioethics frequently discussed in modern bioethical decision-making and debates are autonomy, nonmaleficence, beneficence, and justice.⁵¹⁶ These principles were introduced by Tom L. Beauchamp and James F. Childress in 1977 in the *Principles of Biomedical Ethics*, now in its seventh edition.⁵¹⁷ Although these are not the only principles used to approach bioethical issues, they are some of the most influential and widely used.⁵¹⁸ The four principles are “non-hierarchical”—one principle generally does not trump another.⁵¹⁹ The following parts discuss how each of these principles supports lowering the age of consent for the HPV vaccine.

1. Autonomy

Autonomy is generally defined as “self-governance” or “self-determination.”⁵²⁰ Autonomy is an extremely important concept in health care decision-making and emphasizes the “right of autonomous decision makers to determine for themselves what will be done to their bodies.”⁵²¹ Individuals act autonomously when they make decisions

⁵¹⁶ The articulation of these four principles is generally credited to James Childress and Thomas Beauchamp. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (7th ed., 2013).

⁵¹⁷ *Id.*

⁵¹⁸ See Markus Christen et al., *How “Moral” are the Principles of Biomedical Ethics?—A Cross-Domain Evaluation of the Common Morality Hypothesis*, 15 BMC MED. ETHICS 47 (2014) (stating that Beauchamp’s and Childress’s “contribution has been celebrated as one of the most important methodological inventions of modern practical ethics”). Critics of the four principles, however, argue they are too general and lack “the necessary resources satisfactorily to handle the ethically complex situations created in the interface between medicine and social justice.” Soren Holm, *Not Just Autonomy—The Principles of American Biomedical Ethics*, 21 J. MED. ETHICS 332, 332 (1995); see also K. Danner Clouser & Bernard Gert, *A Critique of Principlism*, 15 J. MED. & PHIL. 219 (1990).

⁵¹⁹ Thomas R. McCormick, *Principles of Bioethics*, ETHICS IN MED. (2013), available at <https://depts.washington.edu/bioethx/tools/princpl.html>.

⁵²⁰ THOMAS A. MAPPE & DAVID DEGRAZIA, *BIOMEDICAL ETHICS* 41 (6th ed. 2006).

⁵²¹ *Id.* at 40.

that are “(1) intentional, (2) based on sufficient understanding, (3) sufficiently free of external constraints, and (4) sufficiently free of internal constraints.”⁵²²

When parental consent is required for a minor to obtain health care, the minor’s autonomy is either limited or completely ignored. Although it would be unacceptable to limit a competent adult’s autonomy in this way, minors are generally considered incompetent to make legally binding health care decisions and parents or guardians are empowered to make decisions on their behalf.⁵²³ In any context, an irrebuttable presumption that adolescents lack decisional capacity is inappropriate, as illustrated by the numerous exceptions to parental consent requirements⁵²⁴ and the growing recognition of adolescents’ capacity to make certain health care decisions.⁵²⁵ The Supreme Court has also recognized that, at least in the context of abortion, “absolute rules” regarding parental consent or notification “create an inflexibility that often would allow for no consideration of [adolescents’] rights and interests.”⁵²⁶ To recognize the importance of adolescent autonomy, Rhonda Gay Hartman argues that laws and policies should approach “adolescents from the standpoint of decisional *ability* rather than presumptive decisional *incapacity*.”⁵²⁷ Laws should not treat all minors the same and should distinguish *children* from *adolescents* “due to the discerning ability of adolescents and

⁵²² *Id.* at 41.

⁵²³ WALKER ET AL., *supra* note 168, at 141–42.

⁵²⁴ *See supra* Part (I)(C)(2).

⁵²⁵ *See, e.g.*, Rhonda Gay Hartman, *Adolescent Autonomy: Clarifying an Ageless Conundrum*, 51 HASTINGS L. J. 1265, 1268 (2000) (arguing that scientific evidence and data do not support a *presumption* of adolescent decisional incapacity).

⁵²⁶ *H.L. v. Matheson*, 450 U.S. 398, 420 (1980) (upholding a Utah statute requiring parental notification of abortions under certain circumstances, but stating that “a State may not validly require notice to parents in *all* cases”).

⁵²⁷ Hartman, *supra* note 525, at 1269.

accountment of distinctive concerns.”⁵²⁸ In appropriate circumstances, acknowledging and respecting adolescent decisional capacity optimizes “personal development, individual dignity, and respect for adolescent expression of values.”⁵²⁹

Any statutory scheme establishing age limitations or requirements requires line-drawing, and the lines often seem arbitrary. For example, why does United States law believe an eighteen-year-old is mature enough to go to war but not mature enough to drink alcohol? Why is a minor in Minnesota capable of consenting to the hepatitis B vaccine but not any other vaccine?⁵³⁰ Why can a minor in Connecticut consent (without any parental involvement or notification) to an abortion⁵³¹ but not to a vaccine?⁵³² A potential reason for not allowing adolescents to consent to STI *prevention* when they can consent to diagnosis and treatment may relate to the fact that at the time the statutes were enacted, STI prevention was limited to methods such as abstinence and condom use. A vaccine to prevent an STI like HPV may not have been contemplated and therefore not addressed in the legislation. But over the last decade, several new vaccines have been recommended for adolescents, making vaccination a larger component of adolescent primary health care than in the past.⁵³³ Although the law is often slow to respond to

⁵²⁸ *Id.* at 1355.

⁵²⁹ *Id.* at 1361. The concept of an adolescent’s right to an “open future” is further discussed in Part (III)(B)(4).

⁵³⁰ MINN. STAT. ANN. § 144-3441 (West 2014) (“A minor may give effective consent for a hepatitis B vaccination. The consent of no other person is required.”).

⁵³¹ CONN. GEN. STAT. ANN. § 19a-601 (West 2014) (requiring minors to receive pre-abortion counseling to discuss whether her parents should be involved but not requiring such involvement).

⁵³² Connecticut law allows a minor to consent to treatment for venereal diseases, but this probably would not include vaccines. CONN. GEN. STAT. ANN. § 19a-216 (West 2014)

⁵³³ These vaccines include the meningococcal conjugate, tetanus-diphtheria-acellular pertussis, seasonal flu, and HPV. Charitha Gowda et al., *Understanding Attitudes Toward Adolescent Vaccination and the Decision-Making Dynamic Among Adolescents, Parents and Providers*, 12

medical advancements,⁵³⁴ it must change to reflect changing health care options and capabilities. Laws allowing minors to consent to STI treatment and prevention implicitly recognize that adolescents have the capacity to consent to health care services. There is little reason to think that an adolescent deemed capable of consenting to STI *treatment* is not also capable of consenting to STI *prevention*.

Lowering the age of consent will allow HCPs to respect their adolescent patients' autonomy without fearing legal liability.⁵³⁵ There is support among medical professionals for increasing the recognition of adolescent consent to improve the delivery of necessary health care services, particularly those related to sexual and reproductive health. The Society for Adolescent Health and Medicine, for example, supports policies and strategies to “maximize opportunities for minors to receive vaccinations when parents are not physically present,” including “legal options for allowing minor adolescents with capacity for informed consent to give their own consent for vaccinations.”⁵³⁶ When

BMC PUB. HEALTH 509, 510 (2012); Abigail English et al., *Adolescent Consent for Vaccination: A Position Paper of the Society for Adolescent Health and Medicine*, 53 J. ADOLESCENT HEALTH 550 (2013).

⁵³⁴ See, e.g., Gary E. Marchant, *The Growing Gap Between Emerging Technologies and the Law*, in THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT 19, 22 (Gary E. Marchant et al. eds., 2011) (discussing the difficulty that legislation, regulation, and case law have keeping up with “increasingly rapid progression of science and technology”).

⁵³⁵ If the law does not clearly allow adolescent consent, HCPs may fear tort liability because competent, informed consent is required to perform medical treatment. Without such consent, the HCP could be liable for battery. Sarah Katz, *When the Child is a Parent: Effective Advocacy for Teen Parents in the Child Welfare System*, 79 TEMP. L. REV. 535, 545 (2006); Claire D. Brindis et al., *Improving Adolescent Health: An Analysis and Synthesis of Health Policy Recommendations*, NAT'L ADOLESCENT HEALTH INFO. CTR., DIV. OF ADOLESCENT HEALTH MED, DEP'T OF PEDIATRICS & INST. FOR HEALTH POL'Y STUD., SCH. OF MED., UNIV. OF CAL., SAN FRANCISCO 17 (1998), http://nahic.ucsf.edu/wp-content/uploads/2011/01/IAH_Full.pdf (arguing that HCPs “need consistent information” about adolescent consent laws “to ensure appropriate planning and reduce fear concerning provider liability”).

⁵³⁶ Soc'y Adolescent Health & Med., *supra* note 533, at 552; see also Am. Med. Ass'n, *Opinion 2.015—Mandatory Parental Consent to Abortion*, in AMA CODE OF MEDICAL ETHICS (issued

parental consent is required, an HCP providing care without parental consent could be held liable for battery⁵³⁷ and/or medical malpractice.⁵³⁸ Providing treatment without parental consent could also be considered unprofessional conduct, resulting in suspension of their license to practice medicine.⁵³⁹

Respecting adolescent autonomy by lowering the age of consent does not, however, mean an HCP is required to provide the vaccine to *every* adolescent who is eligible or who requests it. Even if the law allows minors to consent, “the minor’s consent will only be effective if the minor is mature enough to give truly *informed* consent.”⁵⁴⁰ If an HCP determines a patient is incapable of making an autonomous and informed decision, refusing to accept his “consent” does not disrespect patient autonomy because one must *have* autonomy for it to be disrespected. Even when dealing with adult

1994), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2015.page?> (“Physicians should not feel or be compelled to require minors to involve their parents before deciding whether to undergo an abortion.”); Comm. on Adolescence, *The Adolescent’s Right to Confidential Care When Considering Abortion*, 97 PEDIATRICS 746, 750 (1996) (“Genuine concern for the best interests of minors argues strongly against mandatory parental consent and notification laws.”).

⁵³⁷ Katz, *supra* note 535, at 545; see also *Kozup v. Georgetown Univ.*, 851 F.2d 437, 439 (D.C. Cir. 1988) (noting that to avoid committing a battery, a surgeon must obtain a patient’s consent and “in the case of a minor, the relevant consent is that of the parents”); *Canterbury v. Spence*, 464 F.2d 772, 783 (D.C. Cir. 1972) (“[I]t is the settled rule that therapy not authorized by the patient may amount to a tort—a common law battery—by the physician.”); *Bonner v. Moran*, 126 F.2d 121, 122 (D.C. Cir. 1941) (stating that “the general rule is that the consent of the parent is necessary for an operation on a child” and that surgery is “a technical battery, regardless of its results, and is excusable only when there is express or implied consent of the patient [or parents, if a minor]”); *Rogers v. Sells*, 61 P.2d 1018 (Okla. 1936) (finding a physician guilty of assault and battery for amputating 14-year-old’s foot without parental consent).

⁵³⁸ See, e.g., *Harrison v. United States*, 284 F.3d 293, 298 (1st Cir. 2002) (stating that under Massachusetts law, failure to obtain adequate informed consent “constitutes medical malpractice”); *Murriello v. Crapotta*, 51 A.2d 381, 382 (N.Y. 1976) (stating that a medical malpractice action exists when a physician fails to obtain adequate informed consent).

⁵³⁹ See, e.g. Ann Bittinger, *Legal Hurdles to Leap to Get Medical Treatment for Children*, 80 FLA. BAR. J., Jan. 2006, at 24, 24.

⁵⁴⁰ Vukadinovich, *supra* note 232, at 677.

patients, who are *presumed* competent to make health care decisions, an HCP can conclude an adult is incompetent to make their own medical decisions.⁵⁴¹

Regardless of a patient's age, an HCP must obtain a patient's (or the patient's authorized representative's) informed consent before providing any service or performing any procedure.⁵⁴² Even if informed consent is presumed, it is important for the physician to determine whether a patient can make autonomous and informed decisions. This is particularly important when treating minors because of the vast individual differences in child and adolescent development and maturation. Research suggests, for example, that the adolescent brain continues to mature well into the twenties.⁵⁴³ The frontal lobes, which guide "executive functions" such as planning, working memory, impulse control, and decision making, may not be fully developed until the mid-twenties.⁵⁴⁴ But this does not mean that adolescents are incapable of *any* decision-making until their brains have fully matured nor does this mean all adolescents mature at the same rate.⁵⁴⁵ Autonomy

⁵⁴¹ ALLEN E. BUCHANAN & DAN W. BROCK, DECIDING FOR OTHERS: THE ETHICS OF SURROGATE DECISION MAKING 70 (1990) (discussing the measurement of competence by HCPs in the medical setting for patients of any age).

⁵⁴² See *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (holding that a physician has a "duty to impart information which the patient has every right to expect. . . [and] must seek and secure his patient's consent before commencing an operation or other course of treatment"); President's Comm'n for the Study of Ethical Problems in Med. & Biomedical & Behavioral Research, *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship, Volume One: Report 2* (October 1982), available at <http://kie.georgetown.edu/nrcbl/documents/pcemr/makingdecisions.pdf> (stating that "informed consent . . . is ethically required of health care practitioners in their relationships with all patients").

⁵⁴³ Sara B. Johnson et al., *Adolescent Maturity and the Brain: The Promise and Pitfalls of Neuroscience Research in Adolescent Health Policy*, 45 J. ADOLESCENT HEALTH 216, 216 (2009).

⁵⁴⁴ *Id.* at 216.

⁵⁴⁵ See, e.g., James M. Bjork & Dustin A. Pardini, *Who Are Those "Risk-Taking Adolescents"?*—*Individual Differences in Developmental Neuroimaging Research*, DEV. COGNITIVE NEUROSCIENCE, Aug. 12, 2014, at 5, available at <http://ac.els-cdn.com/S1878929314000504/1->

and decision-making capacity are not all-or-nothing—there is no “chronological cut-point for behavioral or cognitive maturity . . . [it is] highly variable from person to person.”⁵⁴⁶

The problem with relying on neuroscience data on adolescent brain development and maturation is that much remains unclear. This uncertainty allows policy makers and others to manipulate the data to support almost any position, whether for or against increased recognition of adolescent autonomy. For example, opponents of the death penalty for juveniles argue that neuroscience suggests that because their brains are still developing, adolescent offenders are fundamentally different from adults in terms of culpability and their punishments should reflect this difference.⁵⁴⁷ On the other hand, those supporting an adolescent’s right to make health care decisions argue that adolescent decision-making capabilities are almost indistinguishable from those of adults, indicating they should be allowed to make their own decisions without parental involvement.⁵⁴⁸

s2.0-S1878929314000504-main.pdf?_tid=064164ac-62cd-11e4-bfed-0000aab0f26&acdnat=1414959524_15f03200fa64e735fdb20fd2d4153aa6 (arguing that although adolescent brain function is different as a *group*, there are also many *individual* differences between adolescents in “neurocircuit” function which influences various risk-taking behaviors); B.J. Casey et al., *The Adolescent Brain*, 28 DEV. REV. 62, 71 (2008) (noting that there are individual differences in risk-taking behaviors and the development of impulse control).

⁵⁴⁶ Johnson et al., *supra* note 543, at 216, 218.

⁵⁴⁷ See, e.g., *Roper v. Simmons*, 543 U.S. 551, 571 (2005) (holding that the death penalty of individuals under eighteen at the time of their capital crimes is unconstitutional, citing their “diminished culpability”); Brief for the Am. Med. Ass’n et al. as Amici Curiae Supporting Respondent at 5, *Roper v. Simmons*, 543 U.S. 551 (2005) (No. 03-633), 2004 WL 1633549 (opposing the juvenile death penalty and arguing that adolescents’ brains are “physiologically underdeveloped in the areas that control impulses, foresee consequences, and temper emotions”).

⁵⁴⁸ Brief for the Am. Psychol. Ass’n et al. as Amici Curiae in Support of Petitioners/Cross-Respondents in Nos. 88-1125, 88-1309 and in Support of Appellees in No. 88-805 at 21, *Hodgson v. Minnesota*, 497 U.S. 417 (Nos. 88-805, 88-1125, and 88-1309), 1989 WL 1127529 (arguing that “evidence does not support the assumption . . . that adolescents lack an adult’s capacity to understand and reason about problems and decisions, including medical and psychological treatment alternatives, or the ability to comprehend and consider risks and benefits regarding treatment alternatives”).

The evidence clearly shows, however, that adolescents mature at different rates and HCPs can take this into consideration when determining whether a particular adolescent patient has the capacity to understand the risks and benefits of the HPV vaccine. “Informed consent is a process, not just a form,” and must be tailored to the individual to ensure their understanding.⁵⁴⁹ Various iterations of the process exist, but generally consist of the following elements⁵⁵⁰:

- 1) Discussing the patient’s role in the decision-making process;
- 2) Describing the clinical issue and suggested treatment;
- 3) Discussing alternatives to the suggested treatment (including the option of no treatment);
- 4) Discussing risks and benefits of the suggested treatment (and comparing them to the risks and benefits of alternatives);
- 5) Discussing related uncertainties;
- 6) Assessing the patient’s understanding of the information provided; and
- 7) Eliciting the patient’s preference (and thereby consent).

The information provided generally must be all the details necessary for a “reasonable person” to make a decision, such as the risk of all serious complications, regardless of how infrequently they occur, and common, less serious risks.⁵⁵¹ In addition to the above seven elements, when obtaining an adolescent’s consent to the HPV vaccine,

⁵⁴⁹ Office for Human Research Protections, *Tips on Informed Consent*, DEP’T HEALTH & HUMAN SERVS. (Revised Apr. 16, 1993), <http://www.hhs.gov/ohrp/policy/ictips.html>.

⁵⁵⁰ Kristina M. Cordasco, *Obtaining Informed Consent from Patients: Brief Update Review*, in MAKING HEALTH CARE SAFER II: AN UPDATED CRITICAL ANALYSIS OF THE EVIDENCE FOR PATIENT SAFETY PRACTICES 461, 462 (March 2013), <http://www.ahrq.gov/research/findings/evidence-based-reports/services/quality/ptsafetyII-full.pdf>.

⁵⁵¹ *Id.*

it is important for the HCP to discuss whether the adolescent wants to notify his/her parent(s) or whether the information should remain confidential.⁵⁵²

Regardless of whether a patient is a minor or an adult, HCPs must take the time to go through an adequate informed consent process to determine if the particular patient is capable of consent. Not all adults, for example, are capable of providing informed consent. Adults with low literacy rates, limited English proficiency, cognitive deficits, and those of older ages, for example, are more likely to be found incapable of giving informed consent.⁵⁵³ These issues (except older age) will also exist in the adolescent population. In the context of the HPV vaccine, HCPs must ensure the information given to adolescent patients is sufficient, understandable, provided in an unbiased manner, and tailored to the individual needs and maturity of the individual patient. The informed consent process, when appropriately implemented, allows the HCP to respect adolescent autonomy while still acknowledging individual differences in adolescent capacity to consent.

2. Nonmaleficence

The principle of nonmaleficence prohibits HCPs from acting in ways that harm or injure patients and is often viewed as equivalent to the maxim “*Primum non nocere*”: “Above all [or first] do no harm.”⁵⁵⁴ Although never stated in the Hippocratic Oath, it is related to concepts encapsulated by the Oath, which includes an obligation of

⁵⁵² The issue of ensuring confidentiality is discussed *supra* Part (II)(B)(4).

⁵⁵³ Cordasco, *supra* note 550, at 462–64.

⁵⁵⁴ BEAUCHAMP & CHILDRESS, *supra* note 516, at 150.

nonmaleficence and beneficence: “I will use treatment to help the sick according to my ability and judgment, *but I will never use it to injure or wrong them.*”⁵⁵⁵

Discussions about nonmaleficence and vaccines often focus on how *administering* a vaccine may be harmful. Sharon Kling, for example, argues that when a vaccine comes with risks, such as the pertussis vaccine’s “risk of encephalopathy in children with underlying neurological disorders, it may be justified to withhold vaccination from an individual child.”⁵⁵⁶ Indeed, in some situations nonmaleficence justifies withholding certain services and treatments, such as if a patient has a legitimate allergy to a vaccine component or is otherwise immunocompromised in a way that makes vaccination dangerous.⁵⁵⁷

Simply because vaccination involves risks (like *all* medical treatment), however, should not mean providing them automatically violates nonmaleficence. If this were the case, then *all* medical treatments would violate nonmaleficence because all medical services come with at least a *minimal* level of risk. In contrast to the discussions in much of the literature, there are many situations in which *failing* to provide the vaccine is more likely to violate the principle. This is particularly true in the case of HPV, because once

⁵⁵⁵ *Id.* (emphasis added).

⁵⁵⁶ Sharon Kling, *Vaccination and Ethical Issues*, 22 CURRENT ALLERGY & CLINICAL IMMUNOLOGY 178 (2009). Dr. Richard Zimmerman notes the “potential, theoretical harms that fall under the non-maleficence category” such as a decline in safe sex practices and subsequent increase in STDs and unwanted pregnancies, declines in cervical cancer screenings, and misunderstanding that the vaccine only covers certain types of HPVs and not all STDs. Zimmerman, *supra* note 445, at 4816. It is important to note, however, that these “theoretical” harms have largely proven false in follow-up studies on the vaccine’s effects on sexual behavior. See Ports et al., *supra* note 443, at 52.

⁵⁵⁷ The CDC, for example, states that individuals with “severe” or “life-threatening” allergies to vaccine components should not receive the vaccine. *Vaccines and Immunizations: Who Should NOT Get Vaccinated with these Vaccines?*, CTNS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/should-not-vacc.htm#hpvgardasil> (last updated Aug. 14, 2014).

infection occurs, the vaccine is not as effective in preventing both vaccine-type and non-vaccine type HPV.⁵⁵⁸ Delaying vaccination because of a parent’s refusal to consent, therefore, may delay vaccination until an age when the individual is already sexually active and potentially infected with HPV. In a 2003 to 2006 survey of high-risk and low-risk HPV prevalence, approximately 21% and 25% of 14- to 19-year-old females had low-risk or high-risk HPV, respectively.⁵⁵⁹ For 20- to 24-year-old females, prevalence increased to approximately 35% low-risk HPV and 45% high-risk HPV.⁵⁶⁰ And although the vaccine has helped reduce HPV rates, “the earlier the better” is still the correct approach to the vaccine because the longer one waits, the more likely sexual activity will begin, increasing the risk of HPV infection.⁵⁶¹ Barriers to vaccination created by parental consent requirements prohibit an HCP from preventing harm to his patient, even if the HCP considers a particular adolescent ready, willing, and *capable* to consent.

3. Beneficence

The principle of beneficence requires HCPs to act in ways that promote patient welfare.⁵⁶² The requirements of beneficence are generally more demanding than nonmaleficence because it requires HCPs to take *positive* steps to prevent harm and *help*

⁵⁵⁸ The CDC states that the vaccines “have no therapeutic effect on HPV-related disease, so they will not treat existing diseases or conditions caused by HPV.” *HPV Vaccine Information for Clinicians: Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-hcp.htm> (last updated Jan. 26, 2015) (emphasis added). Although the vaccine may prevent *future* infections, it will not impact the *current, existing* infection. *Id.*

⁵⁵⁹ Hariri et al., *supra* note 133, at S70.

⁵⁶⁰ *Id.*

⁵⁶¹ N.Y.C. Dep’t Health & Mental Hygiene, *Protect Your Children from HPV—Vaccinate: The Earlier the Better*, 12 HEALTH BULL., Jan./Feb. 2008, available at <http://www.nyc.gov/html/doh/downloads/pdf/public/dohmhnews12-02.pdf>.

⁵⁶² MAPPES & DEGRAZIA, *supra* note 520, at 27.

patients (rather than just *refrain* from harming them).⁵⁶³ Beneficence can be understood as maximizing benefits and minimizing harms, which requires an HCP to weigh a procedure's or service's risks and benefits.⁵⁶⁴

The goal of beneficence can apply to individuals and broader society—"the good health of a particular patient is an appropriate goal of medicine, and the prevention of disease through research and employment of vaccines is the same goal expanded to the population at large."⁵⁶⁵ Vaccinations are arguably better viewed as beneficent rather than solely nonmaleficent because the benefits generally far outnumber the risks, an assertion supported by many health organizations and professionals including the World Health Organization,⁵⁶⁶ the CDC,⁵⁶⁷ and the AAP,⁵⁶⁸ among others.⁵⁶⁹ In fact, a vaccine is FDA

⁵⁶³ BEAUCHAMP & CHILDRESS, *supra* note 516, at 202; McCormick, *supra* note 519.

⁵⁶⁴ See, e.g. Nat'l Comm. for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research* (Apr. 18, 1979), available at <http://www.hhs.gov/ohrp/policy/belmont.html>.

⁵⁶⁵ *Id.*

⁵⁶⁶ *What are Some of the Myths—and Facts—About Vaccination?*, WORLD HEALTH ORG. (Apr. 2013), <http://www.who.int/features/qa/84/en/> (“[T]he benefits of vaccination greatly outweigh the risk, and many, many more injuries and deaths would occur without vaccines.”).

⁵⁶⁷ *Possible Side-Effects from Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Aug. 19, 2014), <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm#dtap> (stating, for example, that getting diphtheria, tetanus, or pertussis “is much riskier” than getting the DTaP vaccine).

⁵⁶⁸ [Healthychildren.org](http://www.healthychildren.org), *Weighing the Risks and Benefits*, AM. ACAD. PEDIATRICS (last updated Dec. 3, 2013), <http://www.healthychildren.org/English/safety-prevention/immunizations/Pages/Weighing-the-Risks-and-Benefits.aspx>.

⁵⁶⁹ See, e.g., *Vaccine Education Center: A Look at Each Vaccine*, CHILDREN'S HOSP. OF PHILA. (last reviewed Mar. 2013), <http://vec.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/> (stating that the benefits of numerous vaccines outweigh the risks); *Fact or Fiction: Benefits Versus Risks*, COLO. CHILDREN'S IMMUNIZATION COAL., <http://www.immunizeforgood.com/fact-or-fiction/benefits-vs.-risks> (“[T]he risk of serious side effects is very small compared to the benefits vaccination provides.”) (last visited Mar. 19, 2015).

approved only if pre-approval and post-approval studies and evidence show the vaccine's benefits outweigh the potential risks.⁵⁷⁰

As argued by Dr. Richard Zimmerman, applying beneficence to the HPV vaccine is “fairly straightforward” because it reduces the risk of genital warts and numerous cancers.⁵⁷¹ These benefits are now well-established by scientific studies and follow-up data.⁵⁷² The vaccine has the additional, albeit less acknowledged and discussed benefit of potentially preventing the stigma⁵⁷³ and psychosocial implications⁵⁷⁴ of STIs.

Providing the beneficial HPV vaccine allows an HCP to act in the best interest of the adolescent patient, and lowering the age of consent is consistent with professional

⁵⁷⁰ *Ensuring the Safety of Vaccines in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, (last reviewed Feb. 2013), <http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf>.

⁵⁷¹ Zimmerman, *supra* note 445, at 4812.

⁵⁷² See text and sources cited in *supra* Part (I)(B)(3) for a discussion of the vaccine's efficacy.

⁵⁷³ See, e.g., Eileen F. Dunne et al., *Updates on Human Papillomavirus and Genital Warts and Counseling Messages From the 2010 Sexually Transmitted Diseases Treatment Guidelines*, 53 CLINICAL INFECTIOUS DISEASES S143, S146 (2011) (“Patients who receive a diagnosis of HPV infection may struggle with the stigma of a sexually transmitted infection.”); Allison L. Friedman & Hilda Sheppard, *Exploring the Knowledge, Attitudes, Beliefs, and Communication Preferences of the General Public Regarding HPV: Finding from CDC Focus Group Research and Implications for Practice*, 34 HEALTH EDU. & BEHAV. 471, 475 (2007) (reporting that when study participants were asked to say what came to mind when they heard the term “sexually transmitted infections,” many mentioned “promiscuity,” “infidelity,” “shame,” “embarrassment,” “guilt,” and “divorce”); Bowen Lichtenstein et al., *The Stigma of Sexually Transmitted Infections: Knowledge, Attitudes, and an Educationally-Based Intervention*, 25 HEALTH EDU. MONOGRAPH SERIES, 2008, at 28, 32 (2008) (finding that many STIs, including genital warts, are stigmatized), available at <http://etasigmagamma.org/content/uploads/2013/03/THEMS-V25-N2-Sp-2008-The-Seventh-Special-Issue-on-AIDS-STD-Ed-Prevention-in-Rural-Communities.pdf>; Jillian Jorgensen, *Council Speaker Wants HPV Vaccine Available Without Parental Approval*, OBSERVER (Jan. 8 2015, 5:28 PM), <http://observer.com/2015/01/council-speaker-wants-hpv-vaccine-available-without-parental-approval/> (“Some people with cervical cancer from HPV tell people they have ovarian cancer instead . . . to avoid the stigma around sexually transmitted illnesses.”).

⁵⁷⁴ Studies have found that women with STIs “report feeling permanent damage to their sexual selves,” and “HPV-related shame” which can significantly impact their quality of life. See generally Heather R. Royer & Elizabeth C. Falk, *Young Women's Beliefs About Human Papillomavirus*, 41 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 92, 93(2012).

medical associations that support expanding adolescent rights.⁵⁷⁵ Despite this support from medical professionals⁵⁷⁶ to give greater recognition to adolescent rights and consent capability, “questions about the law remain” and this uncertainty concerns HCPs who wish to provide important care to their patients but fear liability if they do so without parental consent.⁵⁷⁷ These legal uncertainties act as a barrier to recognizing adolescent autonomy and prevent HCPs from providing beneficent care because “most state legislatures seem to think that adolescents . . . are incapable of making informed consent or informed refusal decisions about treatment options, [and] must be protected from their

⁵⁷⁵ See, e.g., Am. Acad. Pediatrics Comm. on Bioethics, *supra* note 211, at 314 (stating their position that although physicians should usually obtain parental consent, “they must focus on the goal of providing appropriate care [to the patient] and be prepared to seek legal intervention when parental refusal places the patient at clear and substantial risk”); Heather Boonstra & Elizabeth Nash, *Minors and the Right to Consent to Health Care*, GUTTMACHER REP. ON PUB. POL’Y, Aug. 2000, at 4, 8 (“Most youth-serving agencies and medical professionals believe that access to confidential services is essential, because many sexually active adolescents will not seek care if they have to inform a parent or have their parent’s consent.”); English et al., *supra* note 533 (taking the position that “[c]linicians, public health personnel, and policy makers should explore all available legal options for allowing minor adolescents with capacity for informed consent to give their own consent for vaccinations”); Carol A. Ford et al., *Minor Consent and Delivery of Adolescent Vaccines*, 54 J. ADOLESCENT HEALTH 183, 188 (2014) (finding, from a survey of adolescent HCPs, that many would support minors having the ability to self-consent for vaccines at age 14); Weir & Peters, *supra* note 234, at 32–33.

⁵⁷⁶ This support is further illustrated by a 2012 California law allowing minors as young as twelve to receive the HPV vaccine without parental consent. The law was sponsored by ACOG and several other state health agencies including the California Medical Association and the California Nurses Association. Dr. Mark Einstein, director of the departments of gynecologic oncology and obstetrics at Montefiore Medical Center in New York said parental consent laws in the United States are significant barriers to HPV vaccination, whereas in other countries such as the UK and Australia, where parental consent is not required, vaccine rates among eligible girls exceed 80%. Mikaela Conley, *California 12-Year-Olds to Get HPV Vaccine Without Parental Consent*, ABC NEWS (Oct. 11, 2011, 3:42 PM), <http://abcnews.go.com/blogs/health/2011/10/11/california-12-year-olds-to-get-hpv-vaccine-without-parental-consent/>; Robert Lowes, *California Minors No Longer Need Parental Okay for HPV Shot*, MEDSCAPE MED. NEWS, Oct. 11, 2011, <http://www.medscape.com/viewarticle/751366>; see also CAL. FAM. CODE § 6926(b) (West 2012) (“A minor who is 12 years of age or older may consent to medical care related to the prevention of a sexually transmitted disease.”) (emphasis added).

⁵⁷⁷ Weir & Peters, *supra* note 234, at 32–33.

own lack of judgment, or simply should not be permitted to [make] legally binding” medical decisions.⁵⁷⁸

HCPs acknowledge, however, that even young adolescents engage in sexual activity and as a result they want to provide counseling, contraception, and other reproductive health care to protect adolescents from unwanted pregnancies and STIs.⁵⁷⁹ These barriers are particularly problematic in the context of sexual and reproductive health care when many adolescents seek care without their parents present.⁵⁸⁰ Although in many states an HCP may *treat* an adolescent’s *existing* STIs without parental consent, they cannot also administer the HPV vaccine to *prevent* an STI.⁵⁸¹ Such laws have prevented “STD clinics, where almost all underage clients show up unaccompanied by a parent, from offering the vaccine.”⁵⁸² This frustrates adolescent HCPs such as Dr. Angela Diaz, director of the Mount Sinai Adolescent Health Center, who believes that

⁵⁷⁸ *Id.* at 33.

⁵⁷⁹ Hartman, *supra* note 525, at 1346.

⁵⁸⁰ A study evaluating the effect of mandatory parental notification for prescribed contraceptives on use of sexual health care services by girls younger than 18 seeking services at Wisconsin Planned Parenthood clinics found that 59% reported they would stop using all sexual health care services, delay testing or treatment for HIV or other STDs, or discontinue use of specific health care services if their parents were informed they were seeking contraceptives. The authors concluded that mandatory parental notification laws for prescription contraceptives impeded adolescent girls’ use of sexual health care services. Diane M. Reddy et al., *Effect of Mandatory Parental Notification on Adolescent Girls’ Use of Sexual Health Care Services*, 288 J. AM. MED. ASS’N 710, 713 (2002).

⁵⁸¹ Erin Durkin, *Council Considers Resolution Promoting HPV Vaccine Without Parental Consent*, N.Y. DAILY NEWS (Jan. 8, 2015, 6:15 PM), <http://www.nydailynews.com/blogs/dailypolitics/resolution-pushes-hpv-vaccine-parental-consent-blog-entry-1.2070979> (noting that in New York, teens can get tested and treated for STDs without parental consent but cannot get the HPV vaccine without parental consent).

⁵⁸² *Id.*

adolescents of any age should be able to provide consent for all vaccines, particularly vaccines to prevent STIs such as HPV and hepatitis B.⁵⁸³ Dr. Diaz states that

By 9th Grade, 33 percent of kids are having vaginal intercourse, and by 12th grade its 63%. . . . [i]f you can administer these vaccines before they become sexually active or very early, all the better. . . . What we want is for the kids to be protected, so we have better outcomes. Teens are trying to do the right thing by getting services. . . . We have these tools that have been shown to be effective, so why not help them do that?⁵⁸⁴

Indeed, there seems little reason not to help them. “Preventive care is the cornerstone of pediatrics, and vaccination represents one of the most important strategies in the prevention of disease.”⁵⁸⁵ A lower age of consent will allow HCPs to provide the care that, in their professional opinion, is in their patients’ best interests.

4. Justice

There are many different concepts of justice, making the term difficult to concisely define. In health care, the theory of justice influences how one believes social benefits (e.g., health care services) and social burdens (e.g., health care costs, limited access, taxes) should be distributed.⁵⁸⁶ For example, a libertarian concept of justice holds liberty as the ultimate goal and emphasizes *negative* rights—individuals have a right to *non-interference* with their life, liberty, and property.⁵⁸⁷ Redistribution to ensure a degree of equality in social benefits and burdens is not a primary concern. Under this theory,

⁵⁸³ Katherine Kahn, *Unaccompanied Teens Often Unable to Get Needed Vaccines*, CTR. FOR ADVANCING HEALTH (Oct. 8, 2013), <http://www.cfah.org/hbns/2013/unaccompanied-teens-often-unable-to-get-needed-vaccines>.

⁵⁸⁴ *Id.*

⁵⁸⁵ Daniel R. Bronfin, *Childhood Immunization Controversies: What are Parents Asking?*, 8 OCHSNER J., 151, 151 (2008).

⁵⁸⁶ MAPPE & DEGRAZIA, *supra* note 520, at 27.

⁵⁸⁷ *Id.* at 617.

providing for the welfare of individuals who cannot provide for themselves is not a morally justifiable government function because to do so would require the government to “take from some against their will in order to give to others.”⁵⁸⁸ A libertarian concept of justice rejects a moral right to health care and thus opposes methods like income taxes to help fund government health care for those unable to afford it on their own— “individuals have the right to whatever income or wealth their labor can earn in a free marketplace, and no one has the right to take part of that income to provide health care or other goods for other persons.”⁵⁸⁹ Although inequalities in health care access “may be unfortunate, [they are] not unfair, unless some intentional violation of another’s liberty or property rights is responsible for the inequalities.”⁵⁹⁰

An egalitarian (or “socialist”) concept of justice, on the other hand, views social equality as justice’s primary goal.⁵⁹¹ This theory believes in a universal moral right to health care and supports governmental or collective measures, such as taxation, to achieve this goal.⁵⁹² Although *exact* equality is not necessarily required, a strong egalitarian view favors a right to the level of health care necessary “to provide an opportunity for a level of health equal as far as possible to the health of other people.”⁵⁹³ Proponents of this theory argue that for individuals lacking “the money needed to buy food and health care needed to sustain life, the libertarian right to life is an empty sham.

⁵⁸⁸ *Id.* at 617–18.

⁵⁸⁹ *Id.* at 618; Madison Powers & Ruth Faden, *Inequalities in Health, Inequalities in Health Care: Four Generations of Discussion about Justice and Cost-Effectiveness Analysis*, 10 KENNEDY INST. OF ETHICS J. 109, 110 (2000).

⁵⁹⁰ Powers & Faden, *supra* note 589, at 110.

⁵⁹¹ MAPPE & DEGRAZIA, *supra* note 520, at 617–18.

⁵⁹² *Id.* at 618; Powers & Faden, *supra* note 589, at 110.

⁵⁹³ ROBERT M. VEATCH, *A THEORY OF MEDICAL ETHICS* 275 (1981).

Liberty rights, such as the right to exchange goods freely, are meaningless to those who cannot exercise such rights because of economic limitations.⁵⁹⁴ This theory stresses *positive* rights—the rights to be provided with certain things like health care.⁵⁹⁵

This thesis takes the approach advocated by Amartya Sen in *The Idea of Justice*, in which he “aims to address questions of enhancing justice and removing injustice, rather than to offer resolutions of questions about the nature of perfect justice.”⁵⁹⁶ Sen takes the position that a major failing of contemporary philosophy is its “transcendental” approach, which seeks to identify a *perfectly* just society.⁵⁹⁷ The transcendental approach relates to the “contractarian” method of thinking initiated by Thomas Hobbes and further developed by John Locke, Jean-Jacques Rousseau, Immanuel Kant, and John Rawls, among others.⁵⁹⁸ Sen finds this approach generally unhelpful because it is extremely difficult to agree on what actually constitutes justice and an ideal state.⁵⁹⁹ Instead of the transcendental approach, Sen uses a “realization-focused comparison,” which focuses on “actual realizations in the societies involved, rather than only on institutions and rules.”⁶⁰⁰

⁵⁹⁴ MAPPES & DEGRAZIA, *supra* note 520, at 618.

⁵⁹⁵ *Id.*

⁵⁹⁶ AMARTYA SEN, *THE IDEA OF JUSTICE* ix (2009).

⁵⁹⁷ *Id.* at 10–11.

⁵⁹⁸ *Id.* at 6–8.

⁵⁹⁹ Even Rawls admitted that “citizens will of course differ as to which conceptions of political justice they think most reasonable.” JOHN RAWLS, *THE LAW OF PEOPLES* 137 (1999). Despite this concession, Sen notes that Rawls does not clearly address how to deal with it under his particular theory of justice. SEN, *supra* note 596, at 12.

⁶⁰⁰ SEN, *supra* note 596, at 8–9. In this way, Sen identifies more with other Enlightenment theorists who took a comparative, rather than transcendental approach, such as Adam Smith, the Marquis de Condorcet, Jeremy Bentham, Mary Wollstonecraft, John Stuart Mill, Karl Marx, and others. *Id.* at 7.

Rather than trying to identify a possibly unavailable, perfectly just society, we must instead engage in a reasoned consideration of what feasible alternatives are available.⁶⁰¹

The transcendental approach also places too much emphasis on identifying the “right” institutions and basic structure of society.⁶⁰² Although Sen agrees institutions are important, they are important because and to the extent that they influence the lives people are able to lead.⁶⁰³ The mere existence of institutions and rules does not necessarily mean that “justice is being done.”⁶⁰⁴ Therefore, we must also consider what freedoms we actually have to make certain choices and consider how institutions, rules, and organization actually work and the “world that actually emerges, not just the institutions or rules we happen to have.”⁶⁰⁵ This is important because “[j]ustice is ultimately connected with the way people’s lives go, and not merely with the nature of institutions surrounding them,”⁶⁰⁶ and it “cannot be indifferent to the lives that people can actually live.”⁶⁰⁷

Because a perfectly just world is not attainable, we must focus on the injustices we *can* remedy.⁶⁰⁸ Justice is shaped by recognizing the injustice of the community we are embedded in and working to enact the structural changes that reconfigure society to address injustices to the greatest extent possible.

⁶⁰¹ *Id.* at 9.

⁶⁰² *Id.* at 6, 18, 26.

⁶⁰³ *Id.* at xii, 18.

⁶⁰⁴ *Id.* at 10.

⁶⁰⁵ *Id.* at 20.

⁶⁰⁶ *Id.* at x.

⁶⁰⁷ *Id.* at 18.

⁶⁰⁸ Sen argues that “[t]he identification of redressable injustice is not only what animates us to think about justice and injustice, it is also central . . . to the theory of justice.” *Id.* at vii.

In the context of adolescent health care and particularly the HPV vaccine, our current institutions and legal rules treat adolescents unjustly. Under the current scheme requiring parental consent, adolescents may be denied access to a beneficial vaccine they desire and in many cases have the capacity and maturity to consent to. Justice in this situation is thus deeply intertwined with the concept of autonomy. Indeed, “injustice has been adduced by adherence to presumptive incapacity, resulting in injustice . . . for adolescents.”⁶⁰⁹ Through tradition and formal laws, our country established institutions and rules that often denied minors freedoms and rights in most areas of life,⁶¹⁰ at times even treating them like property.⁶¹¹ And although significant improvements have been made with growing recognition of minors as persons with (limited) Constitutional rights,⁶¹² they are still treated differently in many ways, sometimes justifiably and sometimes not. And the idea that parents “own” their children has not disappeared—one need only look to Kentucky Senator Rand Paul’s recent comment in a discussion on mandatory vaccinations. In an interview on CNBC’s *Closing Bell*, Senator Paul stated: “The state doesn’t own your children, *parents own the children*, and it is an issue of freedom and public health.”⁶¹³ And although he almost certainly did not mean “own” in the traditional property-like sense, the use of the word “own” is telling and indicates a continued belief that parents have, and should have, complete say over decisions related

⁶⁰⁹ Hartman, *supra* note 525, at 1361.

⁶¹⁰ *See supra* Part I(C)(1).

⁶¹¹ WALKER ET AL., *supra* note 168, at 20.

⁶¹² *Belotti v. Baird*, 443 U.S. 622, 634 (1979); *In re Gault*, 387 U.S. 1, 13 (1967).

⁶¹³ David Knowles, *Rand Paul’s ‘Own Your Children’ Argument is About More than Vaccines*, BLOOMBERG POL. (Feb. 4, 2015, 2:52 PM), <http://www.bloomberg.com/politics/articles/2015-02-04/rand-paul-s-own-your-children-argument-is-about-more-than-vaccines> (emphasis added).

to their children. But in some situations, it is neither the state nor the parents that should have the final say—it is the *minor herself*.

If we recognize that our current institutions do an injustice to adolescents who want and need the HPV vaccine but are prevented from doing so because their parents refuse to consent, we can change our institutional and social structures accordingly to address this failing. In many situations, parents do indeed know what is best for their children and will act in their best interests. But when sexual behavior and reproductive health is involved, parents may *not* know what is best because frequently they are not completely aware of their adolescent's current or future sexual activity. One study, for example, found that fifty percent of all teens feel uncomfortable talking with their parents about sex⁶¹⁴ and other studies have shown that adolescents are concerned about confidentiality when seeking medical care and advice related to sensitive issues such as sex, contraception, and pregnancy.⁶¹⁵ Justice involves recognizing the importance of “the freedom to choose our lives,”⁶¹⁶ which should include an adolescent's (and *all*

⁶¹⁴*Half of All Teens Feel Uncomfortable Talking to their Parents About Sex While Only 19 Percent of Parents Feel the Same, New Survey Shows*, PLANNED PARENTHOOD FED'N OF AM. (Oct. 2, 2012), <http://www.plannedparenthood.org/about-us/newsroom/press-releases/half-all-teens-feel-uncomfortable-talking-their-parents-about-sex-while-only-19-percent-parents>.

⁶¹⁵ See, e.g., Jane Carlise et al., *Concerns Over Confidentiality May Deter Adolescents from Consulting their Doctors: A Qualitative Exploration*, 32 J. MED. ETHICS 133, 137 (2006) (concluding that adolescents' willingness to be open in discussions with their HCPs could be enhanced by HCPs explicitly discussing confidentiality practices and guarantees); Carol A. Ford et al., *Influence of Physician Confidentiality Assurances on Adolescents' Willingness to Disclose Information and Seek Future Health Care*, 275 J. AM. MED. ASS'N 1023, 1033 (1997) (finding that assurances of confidentiality increased the number of adolescents willing to disclose sensitive information about topics such as sexuality); Jeannie S. Thrall et al., *Confidentiality and Adolescents' Use of Providers for Health Information and for Pelvic Examinations*, 154 AM. ARCHIVES PEDIATRIC ADOLESCENT MED. 883, 887–88 (2000) (finding that the likelihood of teens discussing issues such as pregnancy prevention and sex with their HCP was greater among those who received a confidentiality assurance than those who did not).

⁶¹⁶ SEN, *supra* note 596, at 18.

individual's) right to make certain health care decisions that impact their lives now (e.g., preventing immediate or near-in-the-future HPV exposure/infection) and in the long-range future (e.g., HPV-associated cancers in later life; romantic relationship complications resulting from HPV; HPV/STI-related stigma).

Granting adolescents the right to consent to the HPV vaccine acknowledges their right to, and importance of, an “open future.”⁶¹⁷ In his 1980 essay *The Child's Right to an Open Future*, Joel Feinberg identified four kinds of rights: First, there are rights that adults and children have in common, such as the right not to be stolen from or killed.⁶¹⁸ Second, there are rights thought to belong only to adults (“A-rights”), such as legal rights to vote and drink, and autonomy rights such as the free exercise of religion.⁶¹⁹ Third, there are rights generally possessed only by children (and adults only in “unusual or abnormal circumstances”).⁶²⁰ These “dependency rights” derive from a child's dependence on others for basic necessities such as food, shelter, and protection.⁶²¹ Fourth, there are “rights-in-trust,” which are similar to “A-rights” held by adults, “except that the child cannot very well exercise his free choice until later when he is more fully formed and capable.”⁶²² Rights-in-trust are saved for the child until she is an adult, but can nevertheless be violated before the child can exercise them—“The violating conduct guarantees *now* that when the child is an autonomous adult, certain key options will

⁶¹⁷ Joel Feinberg, *The Right to an Open Future*, in *WHOSE CHILD?: CHILDREN'S RIGHTS, PARENTAL AUTHORITY, AND STATE POWER* 124 (William Aiken & Hugh LaFollette eds. 1980).

⁶¹⁸ *Id.* at 124–25.

⁶¹⁹ *Id.* at 125.

⁶²⁰ *Id.*

⁶²¹ *Id.*

⁶²² *Id.*

already be closed to him.”⁶²³ Protecting these “rights-in-trust,” for example, would prohibit Jehovah’s Witness parents from refusing life-saving blood transfusions for their minor children, because the children “have the right to grow into their own futures where they will decide such issues for themselves.”⁶²⁴

Children have a right to a future that is as healthy and disease-free as possible, one that will allow them to take advantage of their full set of rights. Denying them access to the HPV vaccine unjustly infringes this right by drastically increasing their risk of contracting HPV and potentially developing HPV-related cancers, both which can cause stigma, shame, and issues in developing and maintaining intimate relationships. Furthermore, because most adolescents are capable of providing informed consent to a preventive treatment like the HPV vaccine, there is no need for adult involvement that could potentially violate rights-in-trust.⁶²⁵ Legally recognizing the minor’s capacity to

⁶²³ *Id.* at 125–26.

⁶²⁴ Dena S. Davis, *The Child’s Right to an Open Future: Yoder and Beyond*, 26 *CAP. U. L. REV.* 93, 94 (1997).

⁶²⁵ The idea of an “open future” could certainly be taken to illogical extremes suggesting that parents have extremely limited rights because *every* decision parents make impact their child’s future. However, in the context of this thesis, the argument is that these adolescents already have some capacity to consent, and therefore should be given control over the decision that impacts their future. This does *not* necessarily mean they have such capacity to make any and all decisions that impact their futures. Using a child’s right to an open future to support the right to consent to the vaccine also does not involve *state* intrusion on parental rights, as is the case in other situations invoking the child’s right to an open future, which increases the controversy over an idea. Because it is the *adolescent*, rather than the *state*, that is making the decision, the idea of protecting and promoting a minor’s right to an open future is not only just, it also promotes the adolescent’s autonomy without implicating state intrusion into parental rights. The issue of whether a state may intrude on a parent’s right would be implicated, for example, if the state mandated the vaccine and took the right to decide out of the hands of *either* the parent or the minor. *See, e.g.,* Joseph Millum, *The Foundation of the Child’s Right to an Open Future*, 45 *J. SOC. PHIL.* 522, 522 (2014) (noting that the child’s right to an open future is often cited in discussions about various types of vaccine, including yet-to-be created vaccines such as one against smoking or other drugs); *see also* Lance K. Stell, *Responsibility for Health Status*, in *MEDICINE AND SOCIAL JUSTICE: ESSAYS ON THE DISTRIBUTION OF HEALTH CARE* 179, 193

consent gives her control over her future health and well-being and the vaccine's proven safety and effectiveness increases her chances of a healthy future. And indeed, without health, the ability to take full advantage of one's "open future" would be drastically limited.

Parents should not have complete control over their child's "health destiny"⁶²⁶ when doing so infringes the child's right to an open future. And delaying HPV vaccination (often until an age when the *parent* thinks their child is sexually active) may mean the vaccine is not administered until *after* sexual initiation because many parents underestimate their adolescent's sexual experiences.⁶²⁷ As previously mentioned, one study found that about one-third of adolescents reported being sexually experienced and of these, 46.8% of their mothers inaccurately reported that their child was *not* sexually active, with inaccuracy varying by the child's age.⁶²⁸ 78.1% of mothers of sexually active 11- to 13-year-olds incorrectly reported their child was not sexually active compared to 34.4% of mothers of sexually active 17- to 18-year-olds.⁶²⁹ Because underestimation is more likely among parents of younger adolescents, this provides even more reason to allow young adolescents to consent to the vaccine.

(Rosamond Rhodes et al. eds., 2nd ed. 2012) (discussing the right to an open future in debating the ethics of a hypothetical vaccine for addiction-susceptible individuals).

⁶²⁶ The idea of a "health destiny" and the child's right to an "open future" is also currently discussed as an important issue in the context of genetic counseling and screening, with some viewing the issue as a tension between parental autonomy and the child's future autonomy to decide whether to know certain genetic information about themselves. *See, e.g.,* Dena S. Davis, *Genetic Dilemmas and the Child's Right to an Open Future*, 27 HASTINGS CTR. REP. 7 (1997); J. Scott Roberts et al., *Emerging Issues in Public Health Genomics*, 15 ANNUAL REV. OF GENOMICS & HUMAN GENETICS 461, 471 (2014) (noting that leading professional organizations tend to suggest genetic testing should be deferred until adulthood when the child, once an adult, can make his or her own decisions about what information they want to know).

⁶²⁷ See sources cited *supra* notes 377–381.

⁶²⁸ Nicole Liddon et al., *supra* note 378, at 675.

⁶²⁹ *Id.*

Although very young adolescents frequently are not sexually active,⁶³⁰ allowing them to consent to the vaccine without parental involvement will increase the likelihood that adolescents considering sexual activity or those most at risk for early sexual activity can seek the vaccine and/or HCPs can feel free to offer the vaccine and discuss sexual activity and safe sex practices in a confidential setting. The confidential nature of these discussions and subsequent vaccination increases the likelihood adolescents will be honest and open with their HCPs about their sexual behaviors.⁶³¹ If given after sexual initiation, the vaccine will be far less effective, rendering the adolescent more vulnerable to infection and its many negative consequences that will affect the adolescent for the rest of his or her life in minor and potentially major ways. Furthermore, there is no reason to treat the idea of a lower age of consent for the HPV vaccine differently than the lower age of consent already allowed for consent to STI diagnosis and treatment, pregnancy-related care, contraceptive access, and abortion in some states.⁶³²

Lowering the age of consent can also address other injustices related to access and disease burden. As stated by Jessica A. Kahn and colleagues:

In addition to reducing the overall burden of cervical cancer, widespread HPV vaccination has the potential to narrow existing racial, ethnic, and socioeconomic disparities in cancer incidence and mortality. However, if poor and minority women have lower rates of HPV vaccination [initiation or completion] than other women, vaccination could have the unintended effect of widening even further cervical cancer disparities among U.S. women. Because the HPV vaccine is highly effective, even small

⁶³⁰ *Id.*

⁶³¹ See sources cited *supra*, note 615.

⁶³² See sources cited *supra* notes 244–269 and accompanying text.

differences in access to vaccination could lead to significant worsening of disparities.⁶³³

HPV and HPV-related cancers disproportionately burden minority and uninsured women in the United States⁶³⁴ and minority adolescents are less likely to complete the three-dose vaccine series.⁶³⁵ It is therefore extremely important to offer and administer the HPV vaccine to minority adolescents whenever they seek health care—whether with or without a parent present. If a parent is not present, which is more likely when an adolescent seeks reproductive-related care,⁶³⁶ this should not be a barrier to offering the HPV vaccine. Allowing adolescents to consent to the vaccine will open doors to HPV vaccination that were previously shut to HCPs treating adolescents without a parent present.

⁶³³ Jessica A. Kahn et al., *Sociodemographic Factor Associated with High-Risk Human Papillomavirus Infection*, 110 *OBSTETRICS & GYNECOLOGY* 87, 87 (2007).

⁶³⁴ See Marc Brisson et al., *Inequalities in Human Papillomavirus (HPV)-Associated Cancers: Implications for the Success of HPV Vaccination*, 105 *J. NAT'L CANCER INST.* 158 (2013); Ctrs. for Disease Control & Prevention, *HPV-Associated Cancers Rates by Race and Ethnicity*, <http://www.cdc.gov/cancer/hpv/statistics/race.htm> (last updated June 5, 2014); Ahmedin Jemal et al., *Annual Report to the Nation on the Status of Cancer, 1975–2009, Featuring the Burden and Trends in Human Papillomavirus (HPV)-Associated Cancers and HPV Vaccination Coverage Levels*, *J. NAT'L CANCER INST.* 1, 11 (2012), available at <http://jnci.oxfordjournals.org/content/early/2013/01/03/jnci.djs491.full.pdf+html> (reporting markedly higher cervical cancer rates among women living in low versus high socioeconomic status areas and elevated HPV-associated anal and penile cancers among men living in low versus high socioeconomic status areas); see also H.P. Freeman & B.K. Wingrove, *Excess Cervical Cancer Mortality: A Marker for Low Access to Health Care in Poor Communities*, *NAT'L CANCER INST.: CTR. TO REDUCE CANCER HEALTH DISPARITIES* (May 2005) (“Cervical cancer is overwhelmingly a disease of poor women with low educational attainment who are not receiving Pap tests.”), available at <http://crchd.cancer.gov/attachments/excess-cervcanmort.pdf>; Laura M. Kester et al., *A National Study of HPV Vaccination of Adolescent Girls: Rates, Predictors, and Reasons for Non-Vaccination*, 17 *MATERNAL & CHILD HEALTH* 879, 880 (2013).

⁶³⁵ Robert L. Cook et al., *Factors Associated with Initiation and Completion of Human Papillomavirus Vaccine Series Among Young Women Enrolled in Medicaid*, 47 *J. ADOLESCENT HEALTH* 596 (2010) (finding a relatively slow initial uptake and completion of the HPV vaccine series in black females, a population at increased risk for cervical cancer); Christina G. Dorell et al., *Human Papillomavirus Vaccination Series Initiation and Completion, 2008–2009*, 128 *PEDIATRICS* 830, 834 (2011).

⁶³⁶ See sources cited *supra* note 615.

This thesis proposes statutory changes, which are a form of structural change that can ameliorate the injustices created by (1) granting too much control to parents, (2) allowing parents to ignore science and fall victim to sensationalistic rhetoric of vaccine opponents, and (3) ignoring adolescent ability/capacity to consent to a relatively (if not extremely) safe, effective, and fairly minor treatment that can significantly impact health and well-being now and in future.

There are many ethical reasons for lowering the age of consent for the HPV vaccine. Applying the four bioethical principles of autonomy, nonmaleficence, beneficence, and justice suggests that lowering the age of consent is ethically and morally sound.

C. POLICY REASONS FOR LOWERING THE AGE OF CONSENT

The implications of the HPV vaccine go far beyond sex and debates and discussion about the vaccine should not focus on or even emphasize the vaccine's connection to sex, particularly in the context of recommending the vaccine to young adolescents. Instead, HCPs, public health officials, and policy makers should stress the vaccine's cost-effectiveness, ability to save lives by preventing deadly cancers, and ability to reduce or prevent the emotional and psychosocial consequences of STIs, cancer scares, cancer diagnosis, and cancer treatment.⁶³⁷

1. Cost-Effectiveness

A primary reason for lowering the age of consent for the HPV vaccine relates to the previously discussed evidence that the vaccine's efficacy is significantly increased

⁶³⁷ Robert Steinbrook, *The Potential of Human Papillomavirus Vaccines*, 354 N. ENGL. J. MED. 1109, 1110 (2006).

when given at younger ages prior to sexual initiation.⁶³⁸ It is generally more cost-effective and simply better health policy to *prevent* rather than *treat* a disease.⁶³⁹

Lowering the age of consent reduces barriers to the vaccine's uptake at the recommended ages and therefore promotes the cost-effective use of the vaccine.

As a policy matter, most states already allow minors, sometimes of any age, to consent to STI diagnosis and treatment⁶⁴⁰—so why should they not be able to consent to *preventing* an STI by a vaccine? It may be related to the fact that the prevention comes in the form of a *vaccine*—a topic that riles some of the loudest opposing voices against a proven effective, evidence-based medical practice.⁶⁴¹ These opponents parade their views under official-sounding organizations such as the “Think Twice Global Vaccine Institute” and the “National Vaccine Information Center,” among others.⁶⁴² Regardless of the reason for such controversy and resistance to the vaccine, allowing minors to consent to diagnosis and treatment recognizes that adolescents have the capacity to make decisions

⁶³⁸ *HPV Vaccine—Questions & Answers*, *supra* note 312; Dunne et al., *CDC Grand Rounds*, *supra* note 16, at 70.

⁶³⁹ See, e.g., Ramanan Laxminarayan et al., *Intervention Cost-Effectiveness: Overview of Main Messages*, in *DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES* 35, 46 (Dean T. Jamison et al. eds., 2nd ed. 2006) (“In general, cancer prevention, when feasible, is far more cost-effective than treatment.”); HealthyPeople.gov, *Immunization and Infectious Diseases*, U.S. DEP’T HEALTH & HUMAN SERVS., <https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases> (last updated Feb. 20, 2015) (Vaccines are among the most cost-effective clinical preventive services.”).

⁶⁴⁰ See sources *supra* notes 237–269 and accompanying text.

⁶⁴¹ *Vaccine Safety: Examine the Evidence*, AM. ACAD. PEDIATRICS (updated Apr. 2013), <https://www2.aap.org/immunization/families/faq/vaccinestudies.pdf> (“[S]tudies continue to find vaccines to be a safe and effective way to prevent serious disease.”).

⁶⁴² NAT’L VACCINE INFO. CTR., <http://www.nvic.org/> (last visited Feb. 8, 2015); THINK TWICE GLOBAL VACCINE INST., <http://thinktwice.com/> (last visited Feb. 8, 2015); see also VACCINES ARTICLES, MERCOLA.COM, <http://vaccines.mercola.com/> (listing a variety of anti-vaccination articles on a website devoted to providing “natural” health information); VACCINATION LIBERATION, <http://www.vaclib.org/> (last visited Feb. 8, 2015); VACTRUTH.COM, <http://vactruth.com/> (last visited Feb. 8, 2015).

and consent to certain medical services. This recognition should be extended to preventive services. Prevention is in everyone's best interest—parents, the adolescent's future sexual partner(s), the adolescent's potential future children,⁶⁴³ society in general, and most importantly the adolescent him or herself. In their opposition to California Assembly Bill 599, which sought to amend an existing law to provide that minors *cannot* consent to vaccines, ACOG and the Association of University Women argued that “it does not make sense to restrict minors from being able to protect themselves against costly and even life-threatening diseases. Prevention is far better medicine and more cost-effective than treatment.”⁶⁴⁴ And while the California Medical Association acknowledged that parental involvement is preferable, it also recognized that there are “situations where parental consent is not possible . . . and barriers to access [to the vaccine] should not be implemented.”⁶⁴⁵

Admittedly, the HPV vaccine is expensive compared to many other vaccines and the cost is exacerbated by the fact it requires three doses. There is some hope that fewer

⁶⁴³ When a woman has HPV, genital wart outbreaks frequently increase in number and size during pregnancy. Genital warts at time of labor and delivery can complicate a vaginal delivery and therefore a Cesarean section is often recommended, even though C-sections can have negative consequences for the mother and child. Also, a mother's infection may be linked to the development of laryngeal papillomatosis in the newborn, a rare growth in the larynx that is not cancer. See Michael J. Silverberg et al., *Condyloma in Pregnancy is Strongly Predictive of Juvenile-Onset Recurrent Respiratory Papillomatosis*, 101 *OBSTETRICS & GYNECOLOGY* 645 (2003); Am. Coll. of Obstetricians & Gynecologists & Soc'y for Maternal-Fetal Med., *Safe Prevention of the Primary Cesarean Delivery*, 1 *OBSTETRIC CARE CONSENSUS* 1 (2014) (noting that although C-sections can be life-saving for the fetus, mother, or both, they come with risks and should be avoided when possible); *Risks of a Cesarean Procedure*, AM. PREGNANCY ASS'N, <http://americanpregnancy.org/labor-and-birth/cesarean-risks/> (last updated Jan. 2014); *STDs and Pregnancy*, *supra* note 344.

⁶⁴⁴ *Minors: Vaccinations: Parental Consent, Hearing on Cal. A.B. 599 Before the Assemb. Comm. on Health*, 2013–14 Reg. Sess. (Cal. 2013), available at http://www.leginfo.ca.gov/pub/13-14/bill/asm/ab_0551-0600/ab_599_cfa_20130412_170719_asm_comm.html.

⁶⁴⁵ *Id.*

doses will be required for the same level of effectiveness in the near future.⁶⁴⁶ In fact, the National Health Service in England recently changed its HPV program offered to twelve- to thirteen-year-old girls to provide two rather than three vaccine doses based on recent research showing “that antibody response to two doses in adolescent girls is as good as a three dose course in the age group where efficacy against persistent infection and precancerous lesions has been demonstrated.”⁶⁴⁷

As previously discussed, most insurance plans cover the vaccine, particularly when given at the younger, recommended ages, and the Affordable Care Act requires all new private insurance plans to cover the vaccine for the recommended age groups of males or females without consumer cost-sharing.⁶⁴⁸ The vaccine is also covered through the new health exchanges. And for individuals who are under-insured or uninsured, there are various public financing programs that may assist with vaccine coverage.⁶⁴⁹ This suggests cost should not present an insurmountable barrier for most families and adolescents.

⁶⁴⁶ Simon R. M. Dobson et al., *Immunogenicity of 2 Doses of HPV Vaccine in Younger Adolescents vs 3 Doses in Young Women: A Randomized Clinical Trial*, 309 J. AM. MED. ASS’N 1793 (2013) (concluding that among girls who received 2 doses of the HPV vaccine 6 months apart, responses to HPV-16 and HPV-18 one month after the last dose were not inferior to those among young women who received 3 doses of the vaccine in 6 months); Mark Jit et al., *Comparison of Two Dose and Three Dose Human Papillomavirus Vaccine Schedules: Cost Effectiveness Analysis Based on Transmission Model*, 350 BRIT. MED. J. (2015) (concluding that 2 doses of the vaccine are likely to be the most cost-effective option as long as protection lasts for 20 years, which is not yet known).

⁶⁴⁷ Letter from Dame Barbara Harkin, Chief Operation Officer & Deputy Chief Exec., Nat’l Health Serv. Eng., Dr. Paul Cosford, Med. Dir. & Dir. for Health Prot., Pub. Health Eng., & Dr. Felicity Harvey, Dir. Gen. Pub. Health, Dep’t of Health, to health professionals (May 14, 2014), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/310958/HPV_Joint_Letter_14_May.pdf.

⁶⁴⁸ KFF, *The HPV Vaccine*, *supra* note 157, at 4.

⁶⁴⁹ See sources cited *supra* notes 396–399 and accompanying text.

Regardless of the immediate financial cost of the vaccine itself and who bears the cost, the potential long-term cost savings should neither be ignored nor forgotten. It can be difficult to keep such savings in mind, because the idea of “spending money now” to *possibly* save money later by preventing disease and avoiding higher health care costs will interest those who are risk averse but not necessarily those with more of an “invincibility” attitude who believe they will not get cancer and/or believe that HPV itself “not a disease.”⁶⁵⁰ These attitudes are reflected in public comments on articles about the vaccine, such as the following by “Babs,” who questioned the vaccine’s “cost-effectiveness” because

[O]nly 20,000 American women out of a population of over 300,000,000 people may develop cancer (that’s about 0.0007% of the population) Having HPV (because apparently about 80% of us do to no ill effect) is not the problem. Having HPV is not a disease, because if it was, then most of us would be diseased. It’s the subsequent development of cancer that’s the problem, and to my knowledge, no one has determined the reasons why one person develops cancer and another person doesn’t. In my opinion, someone really ought to look into who is making gobs of money off this vaccine that will only protect about 0.0007% of the population—maybe. Doesn’t sound very cost-effective to me.⁶⁵¹

⁶⁵⁰ Babs, Comment to *So Should my Daughter Get the HPV Vaccine?*, WBUR COMMONHEALTH: REFORM & REALITY (Sept. 25, 2011, 1:30 PM), <http://commonhealth.wbur.org/2011/09/so-should-my-daughter-get-the-hpv-vaccine#comment-1170618639>. This commenter’s view about what constitutes a “disease,” however, is medically incorrect. HPV *is* a disease and simply because a large percentage of the population is infected with HPV does not make it any less of a disease than those that are less common, such as rare mitochondrial diseases.

⁶⁵¹ *Id.*; see also Judy Wilyman, *HPV Vaccines Are Not Effective, Safe, or Necessary*, HORMONES MATTER (June 5, 2014), <http://www.hormonesmatter.com/hpv-vaccines-not-safe-effective-necessary/> (“The fact that HPV infections are mostly harmless on their own means that vaccinating all women in developed countries results in the majority of women being on a drug for a disease that they are not at risk of getting. This is not cost-effective and it is also not necessary because the vaccine has not been proven to be safer or more effective than Pap screening combined with surgery.”).

What this quote fails to acknowledge is that while “only” 20,000 women are diagnosed with *cervical* cancer, the HPV vaccine also decreases the risk and prevalence of numerous other cancers.⁶⁵² Reducing the risk and prevalence of these cancers not only decreases cancer treatment costs but also diagnostic costs. The annual cost of cervical cancer screening and treatment of HPV-related outcomes was recently estimated at eight billion dollars.⁶⁵³ While most of this was spent on routine cervical cancer screening and follow-up, \$1 billion was spent on cancer, \$0.3 billion for genital warts, and \$0.2 billion for recurrent respiratory papillomatosis.⁶⁵⁴ The economic burden of HPV exceeds that of any other STI except for human immunodeficiency virus.⁶⁵⁵

Furthermore, because most sexually active men and women will get HPV at some point in their lives, *many* are at risk for the more serious HPV-related outcomes, but there is no way to know in advance who these individuals are. Although high-risk populations (such as MSM) could be “targeted” to receive the vaccine, the *actual* target population should be the entire sexually active population. The best way to avoid the most serious and potentially deadly HPV-related outcomes for *some* is thus to vaccinate *all*.

⁶⁵² See Part (I)(B)(3) discussing the vaccine’s efficacy in preventing various types of cancers.

⁶⁵³ Harrell W. Chesson et al., *Estimates of the Annual Direct Medical Costs of the Prevention and Treatment of Disease Associated with Human Papillomavirus in the United States*, 30 *VACCINE* 6016, 6017 (2012) [hereinafter Chesson et al., *Estimates of the Annual Direct Medical Costs of HPV*].

⁶⁵⁴ *Id.* at 6016.

⁶⁵⁵ EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 142–43.

Although Pap smears are still recommended for vaccinated women and girls because the vaccine does not prevent all high-risk HPV types,⁶⁵⁶ because the vaccine is effective in preventing *some* of the most high-risk HPV types, then the number of abnormal Pap smear results should decrease.⁶⁵⁷ And if there are fewer abnormal results, then there will be fewer, more expensive, follow-up diagnostic procedures performed such as colposcopies and biopsies⁶⁵⁸ as well as fewer precancerous lesions to treat (which is even more expensive),⁶⁵⁹ and so-on and so-forth. Therefore, the cost of cancer treatment is not the only cost that must be considered. The steps between an abnormal Pap smear and an actual cancer diagnosis and treatment are often many, with costs that rapidly add up.

The following is a break-down of some of the estimated costs for a woman seeking to prevent and detect potential cervical abnormalities and cervical cancer,

⁶⁵⁶ *Id.* at 143; Am. Cancer Soc’y, *American Cancer Society Guidelines for the Prevention and Early Detection of Cervical Cancer*, <http://www.cancer.org/cancer/cervicalcancer/moreinformation/cervicalcancerpreventionandearlydetection/cervical-cancer-prevention-and-early-detection-cervical-cancer-screening-guidelines> (last revised Dec. 11, 2014); *HPV Vaccine Information for Young Women*, *supra* note 396.

⁶⁵⁷ Harrell W. Chesson et al., *Modeling the Impact of Quadrivalent HPV Vaccination on the Incidence of Pap Test Abnormalities in the United States*, 31 *VACCINE* 3019, 3023 (2013) (suggesting that the vaccines have a "discernable impact on the incidence of Pap abnormalities").

⁶⁵⁸ *Work-Up of Abnormal Pap Test Results*, AM. CANCER SOC’Y, <http://www.cancer.org/cancer/cervicalcancer/moreinformation/cervicalcancerpreventionandearlydetection/cervical-cancer-prevention-and-early-detection-abn-pap-work-up> (last revised Dec. 11, 2014) (describing follow-up tests frequently performed after abnormal Pap smear results).

⁶⁵⁹ *How Women with Abnormal Pap Test Results or Pre-Cancers are Treated*, AM. CANCER SOC’Y, <http://www.cancer.org/cancer/cervicalcancer/moreinformation/cervicalcancerpreventionandearlydetection/cervical-cancer-prevention-and-early-detection-treat-pre-cancer-changes> (last Revised Dec. 11, 2014), (discussing treatments for precancerous lesions such as laser surgery or cryosurgery).

assuming she has no insurance (and therefore an *over-estimate* of what most women will pay because even those without insurance can often obtain low-cost care at clinics⁶⁶⁰).

- **Gardasil Cost:** $147.005^{661} * 3 \text{ doses} = \441.02
- **Pap Smear Cost** (with no additional tests added on):
\$30⁶⁶²
- **Additional Pap Smear after abnormal test results:** \$30
- **Colposcopy⁶⁶³ after second abnormal Pap + Biopsy:**
 $\$500 + \$500 = \$1,000^{664}$
- **Total:** \$1,501.02

Even if the tests stop here (and these costs do not include the costs for the office visit/physician's time), it is clear that once a woman requires a colposcopy (which costs an estimated \$500), the costs of diagnosing and treating potential cervical cancer are greater than the initial three-dose vaccine (\$447.02).

⁶⁶⁰ For example, the CDC's National Breast and Cervical Cancer Early Detection Program provides breast and cervical cancer screenings and diagnostic services to low-income, uninsured, and underinsured women. Women between 21 and 64 without insurance or whose insurance does not cover cancer screening exams are eligible for free or low-cost screenings. Nat'l Breast & Cervical Cancer Early Detection Program, *Find a Screening Provider Near You*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/cancer/nbccedp/screenings.htm> (last updated Jan. 28, 2013).

⁶⁶¹ CDC, VACCINE PRICE LIST, *supra* note 386.

⁶⁶² Brenda Goodman, *How a Routine Pap Smear Ends Up Costing \$1,000*, HEALTH DAY (Oct. 16, 2013), <http://consumer.healthday.com/general-health-information-16/doctor-news-206/how-does-a-routine-pap-smear-end-up-costing-1-000-681191.html> (discussing how a routine pap smear, on its own, generally costs \$20–\$30).

⁶⁶³ A colposcopy is “a procedure to closely examine [the] cervix, vagina, and vulva for signs of disease” that is often recommended after abnormal Pap test results. Mayo Clinic Staff, *Colposcopy Definition*, MAYO CLINIC (May 16, 2014), <http://www.mayoclinic.org/tests-procedures/colposcopy/basics/definition/prc-20014027>.

⁶⁶⁴ *See, e.g., Colposcopy Cost*, COSTHELPER.COM, <http://health.costhelper.com/colposcopy.html> (last visited Feb. 8, 2015).

As previously mentioned, the annual cost of cervical cancer screening and treatment of HPV-related outcomes has been estimated at eight *billion* dollars.⁶⁶⁵ At the individual level, the cost of the vaccine is much less than the cost of individual cancer treatment. A study of over 100,000 enrollees of the Kaiser Permanent Northwest Plan in Portland, Oregon, for example, found that for women diagnosed with a cervical HPV-related disease, the annual health care cost was \$26,415.⁶⁶⁶ The highest costs occurred among those 20 to 29 years of age, totaling \$51,863.⁶⁶⁷ Ten percent of these total costs (still more than the cost of the vaccine) were related specifically to cases of cervical cancer.⁶⁶⁸ An earlier study of cervical cancer patients in California reported a total hospital cost of \$18.2 million, representing an average cost of \$8,389 per patient.⁶⁶⁹

In addition to direct, individual costs are indirect costs due to losses in productivity from premature deaths and morbidity, which are even greater than direct costs.⁶⁷⁰ The total direct cost of cervical cancer in the California study was approximately \$47 million whereas the indirect cost was over \$158 million.⁶⁷¹ It is also important to note that these studies do not include the cost of pain and suffering, a difficult if not

⁶⁶⁵ Chesson et al., *Estimates of the Annual Direct Medical Costs of HPV*, *supra* note 653, at 6017.

⁶⁶⁶ Ralph P. Insinga et al., *The Health Care Costs of Cervical Human Papillomavirus-Related Disease*, AM. J. OBSTETRICS & GYNECOLOGY 114, 117 (2004).

⁶⁶⁷ *Id.*

⁶⁶⁸ *Id.*; see also Ralph P. Insinga et al., *Healthcare Resource Use and Costs Associated with Cervical, Vaginal, and Vulvar Cancers in a Large U.S. Health Plan*, 111 GYNECOLOGIC ONCOLOGY 188, 192 tbl. 3 (2008) (reporting that in the four years after a cervical cancer diagnosis, patients spent an average of \$18,799 on healthcare related to the cancer).

⁶⁶⁹ Wendy Max et al., *The Economic Burden of Gynecologic Cancers in California, 1998*, 88 GYNECOLOGIC ONCOLOGY 96, 98 (2003).

⁶⁷⁰ *Id.* at 101–02.

⁶⁷¹ *Id.* at 102.

impossible cost to quantify.⁶⁷² The emotional, psychosocial, and psychological consequences of HPV and HPV-related outcomes are discussed in the following sections.

Currently, it is difficult to precisely determine the vaccine's cost-effectiveness because the vaccine is still too new to know how long its effectiveness lasts and whether a booster shot will be needed. But studies suggest that if the vaccine's effectiveness is thirty years or more, it will be a cost-effective use of public health resources.⁶⁷³ And lowering the age of consent to increase the number of young adolescents receiving the vaccine promotes cost-effectiveness because the vaccine's cost-effectiveness will decrease the later the adolescent receives the vaccine (because they are more likely to already be sexually active). Predictive models suggest the vaccine is most cost-effective if given by or before the age of twelve.⁶⁷⁴

Research is consistently providing support for the vaccine's cost-effective prevention of cervical and other cancers.⁶⁷⁵ For example, using decision-analytic models to estimate the direct health and economic outcomes of the quadrivalent HPV vaccine, Jane J. Kim concluded that HPV vaccination of MSM is likely a cost-effective

⁶⁷² *Id.* (recognizing the omission of the costs of pain and suffering and the fact that some diseases, such as gynecologic cancers, “impose more suffering than others”).

⁶⁷³ Markowitz et al., *HPV: Recommendations of ACIP*, *supra* note 133, at 19.

⁶⁷⁴ *Id.*

⁶⁷⁵ Brisson et al., *Economic Evaluation of Human Papillomavirus Vaccination in Developed Countries*, *supra* note 76; Sue J. Goldie et al., *Projected Clinical Benefits and Cost-Effectiveness of a Human Papillomavirus 16/18 Vaccine*, 96 *J. NAT'L CANCER INST.* 604 (2004); Jane J. Kim & Sue J. Goldie, *Health and Economic Implications of HPV Vaccination in the United States*, 359 *N. ENGL. J. MED.* 821 (2008); J. Luttjeboer et al., *Cost-Effectiveness of the Prophylactic HPV Vaccine: An Application to the Netherlands Taking Non-Cervical Cancers and Cross-Protection Into Account*, 31 *VACCINE* 3922, 3927 (2013) (finding the HPV vaccine “highly cost effective” when non-cervical cancers are included in cost-effectiveness models and analyses); Gillian D. Sanders & Al V. Taira, *Cost Effectiveness of a Potential Vaccine for Human Papillomavirus*, 9 *EMERGING INFECTIOUS DISEASES* 37 (2003); Al V. Taira et al., *Evaluating Human Papillomavirus Vaccination Programs*, 10 *EMERGING INFECTIOUS DISEASES* 1915 (2004).

intervention for preventing genital warts and anal cancer.⁶⁷⁶ She noted, however, that the “benefits are expected to be greater when vaccination is done earlier.”⁶⁷⁷ Future studies will likely further assess the vaccine’s impact and cost-effectiveness on non-cervical cancers such as head and neck cancers,⁶⁷⁸ which may soon surpass cervical cancer as the most common HPV-related cancer.⁶⁷⁹

Despite uncertainties about the long-term cost-effectiveness of the HPV vaccine, evidence is growing that it has a strong likelihood of being cost-effective, an outcome that is easy for all sides of the debate and all political views to support.⁶⁸⁰ Furthermore, the fact that this vaccine will save lives from cancer should add much weight to the “benefit” side of the cost-benefit calculus. For many, protecting human life cannot be priced.⁶⁸¹

⁶⁷⁶ Kim, *supra* note 78, at 849–50.

⁶⁷⁷ *Id.*

⁶⁷⁸ Wanrudee Isaranuwatthai et al., *Could the Human Papillomavirus Vaccination be Cost-Effective in Males for the Prevention of Oropharyngeal Cancer?*, 14 EXPERT REV. PHARMACOECONOMICS & OUTCOMES RES. 763 (2014) (commenting on the possibility that the HPV vaccine may be a cost-effective method to prevent oropharyngeal cancer in males).

⁶⁷⁹ Anil K. Chaturvedi et al., *Human Papillomavirus and Rising Oropharyngeal Cancer Incidence in the United States*, 29 J. CLINICAL ONCOLOGY 4294, 4300 (2011) (reporting that by 2020, the number of HPV-positive oropharyngeal cancers is expected to surpass the number of cervical cancers and suggesting that current cost-effectiveness studies on the vaccine have “underestimated the proportion of OPSCCs caused by HPV infection”).

⁶⁸⁰ See, e.g., Al Franken, *Senator’s View: Common Ground Can be Found in Congress*, DULUTH NEWS TRIB., Jan. 2, 2015, <http://www.franken.senate.gov/?p=news&id=3013> (arguing that “both sides [of Congress] agree we need to cut wasteful spending One area I hope we can work together is . . . mak[ing] health care more efficient and cost-effective”).

⁶⁸¹ See Lisa Heinzerling & Frank Ackerman, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, GEO. ENVL. L. & POL’Y INST. 16 (2002), <http://ase.tufts.edu/gdae/publications/c-b%20pamphlet%20final.pdf>; see also FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING 9 (2004); Jim Holt, *The Human Factor*, N.Y. TIMES MAG. (Mar. 28, 2004), <http://www.nytimes.com/2004/03/28/magazine/28WWLN.html>; (arguing that translating life and health into monetary amounts “is not a fruitful way of deciding how much protection to give them”).

2. Emotional and Psychological Costs of HPV-Related Outcomes

In addition to the financial costs of HPV-related outcomes, there are significant and often ignored or forgotten intangible costs of an STI diagnosis, genital warts, and HPV-related cancers. These emotional, psychological, and psychosocial consequences are as, if not more, important and life-altering than any financial cost.⁶⁸²

a. Emotional Impact of Abnormal Test Results, Cancer Diagnosis, and Treatment

As previously mentioned, because the HPV vaccine protects against two of the highest-risk HPV-types, 16 and 18,⁶⁸³ the number of abnormal Pap smear results should decline.⁶⁸⁴ And the recent FDA approval of a nonavalent HPV vaccine will likely result in further declines because this vaccine protects against *seven* high-risk HPV types.⁶⁸⁵ Avoiding abnormal test results is important for women's psychological health and well-being. Studies have found severe psychological distress in women receiving abnormal Pap smear results, with one doctor suggesting these psychological costs outweigh the test's benefits.⁶⁸⁶ The distress may cause women to engage in avoidant behavior and

⁶⁸² Chesson et al., *Modeling the Impact of Quadrivalent HPV Vaccination on the Incidence of Pap Test Abnormalities in the United States*, *supra* note 657, at 3020; Ralph P. Insinga et al., *Abnormal Outcomes Following Cervical Cancer Screening: Event Duration and Health Utility Loss*, 2007 MED. DECISION MAKING 414 (2007) [hereinafter Insinga et al., *Abnormal Outcomes Following Cervical Cancer Screening*]; Eileen Shinn et al., *Distress After an Abnormal Pap Smear Result: Scale Development and Psychometric Validation*, 39 PREVENTIVE MED. 404 (2004)

⁶⁸³ CDC, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES, *supra* note 32, at 139.

⁶⁸⁴ Chesson et al., *Modeling the Impact of Quadrivalent HPV Vaccination on the Incidence of Pap Test Abnormalities in the United States*, *supra* note 657, at 3023.

⁶⁸⁵ News Release, FDA Approves Gardasil 9, *supra* note 94.

⁶⁸⁶ James S. McCormick, *Cervical Smears: A Questionable Practice?*, 2 LANCET 207, 207 (1989) ("Screening for carcinoma of the cervix by cervical smears satisfies none of the criteria which would provide its justification. It is an expensive contribution to ill health because the harms exceed the possible benefits by a substantial margin.").

thereby act as a barrier to recommended follow-up.⁶⁸⁷ The psychological and emotional consequences of an abnormal Pap smear are many and include tangible “QALY” losses,⁶⁸⁸ increased anxiety, depression, anger, intrusive thoughts, avoidance, decreased compliance with follow-up care, impaired sexual function, decreased sexual desire, and impaired body image.⁶⁸⁹

For women whose abnormal Pap smears result in a cancer diagnosis, the psychological and emotional consequences generally increase in scope and magnitude. Many of the negative consequences are similar, but are generally longer-lasting and potentially permanent. Gynecological cancer treatment has the potential to alter a woman’s physical appearance and sexual and reproductive functions in ways far beyond that of an abnormal Pap smear, which are typically more temporary⁶⁹⁰ and less physically obvious. Gynecological surgery and laser ablation, for example, have been shown to result in loss of attractiveness, low-self-esteem, anxiety, changes in sexual

⁶⁸⁷ Caryn Lerman et al., *Adverse Psychologic Consequences of Positive Cytologic Cervical Screening*, 165 AM. J. OBSTETRICS & GYNECOLOGY 658 (1991)

⁶⁸⁸ Insinga et al., *Abnormal Outcomes Following Cervical Cancer Screening*, *supra* note 682, at 421. A “QALY” (Quality-Adjusted Life Year) is a measure of the value of health outcomes, including the quality and quantity of life lived and is used to assess the cost-effectiveness of a medical treatment. The basic idea of a QALY is that it assumes that a year of life lived in perfect health is worth 1 QALY. Luis Prieto & José A. Sacristán, *Problems and Solutions in Calculating Quality-Adjusted Life Years (QALYs)*, HEALTH & QUALITY OF LIFE OUTCOMES (2003), available at <http://www.hqlo.com/content/1/1/80>.

⁶⁸⁹ Stephen Bell et al., *Psychological Response to Cervical Screening*, 24 PREVENTIVE MED. 610, 610 (1995); M.J. Campion et al., *Psychosexual Trauma of Abnormal Cervical Smear*, 95 BRIT. J. OBSTETRICS & GYNAECOLOGY 154 (1998); Thomas W. McDonald et al., *Impact of Cervical Intraepithelia Neoplasia Diagnosis and Treatment on Self-Esteem and Body Image*, 34 GYNECOLOGIC ONCOLOGY 345 (1989); K.E. Rogstad, *The Psychological Impact of Abnormal Cytology and Colposcopy*, 109 BRIT. J. OBSTETRICS & GYNAECOLOGY 364 (2002).

⁶⁹⁰ Rogstad, however, notes that although studies of psychological adjustment show that anxiety and other psychological distress decrease over time after an abnormal smear result and follow-up treatment, there is no study that has assessed whether anxiety reduces all the way to pre-screening levels. Rogstad, *supra* note 689, at 397.

responsiveness, feelings of trauma, depression, and vulnerability.⁶⁹¹ Gynecological cancer and treatment can negatively impact all four “stages” of a woman’s sexual response: sexual desire, excitement, orgasm, and sexual resolution, resulting in decreased sexual satisfaction⁶⁹² and potential negative consequences for existing intimate relationships and inhibitions that prevent women from entering into new intimate relationships.⁶⁹³

The anatomic, hormonal, and other changes resulting from cervical cancer treatment have a variety of adverse effects, with studies finding that thirty to sixty-three percent of women experienced long-term issues including shortened vaginas, vaginal dryness, and dyspareunia (painful intercourse), all of which impact sexual interest and satisfaction.⁶⁹⁴ In discussing the literature, Carter et al. report that cancer “[s]urvivors experiencing more physical sequelae report a lower level of meaning in their life. The type or extent of surgery, menopausal symptoms, and surgical scares can be constant reminders of the cancer experience, and for some, losses or changes may be viewed as an insult to womanhood or femininity.”⁶⁹⁵

⁶⁹¹ F.C. Boag et al., *Assessment of Psychiatric Morbidity in Patients Attending a Colposcopy Clinic Situated in a Genitourinary Medicine Clinic*, 67 GENITOURINARY MED. 481, 483 (1991).

⁶⁹² See generally Luciana Lagana et al., *Psychosexual Dysfunction Among Gynecological Cancer Survivors*, 8 J. CLINICAL PSYCHOL. IN MED. SETTINGS 73, 74 (2001) (summarizing empirical findings related to the assessment and treatment of sexual difficulties experienced by many gynecological cancer survivors).

⁶⁹³ Rebecca Caldwell Sacerdoti et al., *Altered Sexuality and Body Image After Gynecological Cancer Treatment: How Can Psychologists Help?*, 41 PROF. PSYCHOL., RES. & PRAC. 533, 537–38 (2010).

⁶⁹⁴ See generally Kristine A. Donovan et al., *Sexual Health Characteristics for Cervical Cancer: Characteristics and Correlates*, 104 GYNECOLOGIC ONCOLOGY 428, 428–29 (2007) (discussing numerous studies on cervical cancer patients’ post-operative/treatment outcomes).

⁶⁹⁵ Jeanne Carter et al., *The Physical Consequences of Gynecologic Cancer Surgery and their Impact on Sexual, Emotional, and Quality of Life Issues*, 10 J. SEXUAL MED. 21, 22 (2013).

For married women undergoing gynecological cancer treatment, long-lasting sexual dysfunction and intimacy-related issues may increase the chance of divorce. In a Norwegian study, cervical cancer was one of two cancer types resulting in an increased divorce rate among study participants.⁶⁹⁶ The study's authors posited that this is related to the greater number of intimacy-related consequences of cervical cancer compared to non-reproductive tract cancers such as leukemia, lung cancer, and skin cancer.⁶⁹⁷ Other studies support these findings, finding a higher rate of divorce when a spouse, particularly the woman, experiences a serious physical illness.⁶⁹⁸ One study⁶⁹⁹ found higher rates of divorce among cervical cancer survivors and another⁷⁰⁰ found that young adult female cancer survivors were approximately eighty percent more likely to be divorced or separated compared to a control group. And while divorce rates may be higher for women experiencing serious illness, sexual dysfunction of either spouse—

⁶⁹⁶ Astri Syse & Øystein Kravdal, *Does Cancer Affect the Divorce Rate?*, 16 DEMOGRAPHIC RES. 469 (2007), available at <http://www.demographic-research.org/volumes/vol16/15/16-15.pdf>.

⁶⁹⁷ *Id.* at 486–87. There is little research specifically looking at divorce rates after gynecological cancer diagnosis and treatment, and whether this study is replicable or transferrable to the United States is unclear.

⁶⁹⁸ See, e.g., Michael J. Glantz et al., *Gender Disparity in the Rate of Partner Abandonment in Patients with Serious Medical Illness*, 115 CANCER 5237 (2009). A recent study, however, while confirming that women experience a higher rate of divorce after serious illness onset, found that the higher risk was not present for women with cancer but rather for other illnesses such as lung disease. Amelia Karraker & Kenzie Latham, *In Sickness and in Health?: Physical Illness as a Risk Factor for Marital Dissolution in Later Life*, 56 J. HEALTH & SOC. BEHAV. 59 (2015) One reason for higher rates of divorce among couples when the woman is diagnosed with cervical cancer may be influenced by the fact that cervical cancer tends to strike at young ages, and younger couples may be at greater risk for divorce than older couples. See Anne C. Kirchhoff et al. *Marriage and Divorce Among Young Adult Cancer Survivors*, 6 J. CANCER SURVIVORSHIP: RES. & PRAC. 441, 442 (2012) (suggesting that “younger marriages may be less resilient to the stressors of cancer treatment and recovery”).

⁶⁹⁹ Kathrine Carlsen et al., *Are Cancer Survivors at an Increased Risk for Divorce?: A Danish Study*, 43 EURO. J. CANCER 2093 (2007).

⁷⁰⁰ Kirchhoff et al. *supra* note 698, at 448.

male *or* female—regardless of the cause may contribute to marital discord, thereby increasing the risk of divorce.⁷⁰¹

Because HPV is now linked to other types of cancer affecting both men and women, men’s emotional and psychological well-being could also benefit from the vaccine’s ability to reduce abnormal cancer screening results, need for follow-up tests, and eventual cancer diagnosis. Although there are few studies evaluating the psychological impact of anal cancer screenings, the process is similar to cervical cancer screenings in several ways and thus the procedure and results (normal or abnormal) may have similar psychosocial effects.⁷⁰² A 2013 study concluded that anal cancer-specific anxiety increased throughout the screening process and the group receiving “high grade” histology results remained worried the longest.⁷⁰³

Even if anal cancer screenings do not have the same degree of psychological consequences as cervical cancer screenings and abnormal results, the impacts of a cancer

⁷⁰¹John Rust et al., *Marital Problems and Sexual Dysfunction: How are they Related?*, 152 BRIT. J. PSYCHIATRY 629, 629 (1988) (“There has always been considerable overlap in symptomology between clients presenting for marital therapy and patients presenting at sexual dysfunction clinics.”); Leslie R. Schover & Andrew C. von Eschenbach, *Sexual and Marital Relationships after Treatment for Nonseminomatous Testicular Cancer*, XXV UROLOGY 251, 254 (1985) (finding that treatment for nonseminomatous testicular cancer disrupted marital and sexual happiness in 10–20% of patients and among those who divorced after treatment, sexual dysfunction and cancer treatment were cited as significant sources of stress); Kelly B. Smith et al., *Sexual and Relationship Functioning in Men with Chronic Prostatitis/Chronic Pelvic Pain Syndrome and Their Partners*, 36 ARCHIVES SEXUAL BEHAV. 301, 302 (2007) (noting that men with CP/CPPS report a “high frequency of sexual relationship dissolution greater sexual and relationship problems . . . [and] avoiding sexual relationships”).

⁷⁰²Jodie M.B. Landstra et al., *The Psychological Impact of Anal Cancer Screening on HIV-Infected Men*, 22 PSYCHO-ONCOLOGY 614, 614–15 (2013).

⁷⁰³*Id.* at 618. This particular group of study participants may have experienced lower levels of anxiety than non-HIV positive men because in comparison to their experiences with the HIV diagnosis, this process may seem relatively minor. *Id.* Other studies have found similar results and recommended that further research be conducted. Jill Tinmouth et al., *The Psychological Impact of Being Screened for Anal Cancer in HIV-Infected Men Who Have Sex With Men*, 54 DISEASES COLON & RECTUM 352 (2011).

diagnosis and subsequent treatment are likely similar. Any cancer, HPV-related or not, comes with physical, mental, emotional, and social consequences.⁷⁰⁴ After treatment concludes and even for those considered “cancer free,” many survivors continue to “cope with the long-term effects of treatment, as well as psychological concerns such as fear of recurrence.”⁷⁰⁵

The HPV vaccine provides a significant—and *rare*⁷⁰⁶— opportunity to prevent the multiple burdens of HPV-related cancers. Any and all methods to promote its use and increase the number of pre-sexually active adolescents receiving the vaccine should be used, including lowering the age of consent. These methods ensure our society “take[s] advantage of the rare opportunity to prevent cancer through a simple vaccine.”⁷⁰⁷ It is difficult, if not impossible, to argue that preventing and/or mitigating the emotional and

⁷⁰⁴ See Barbara L. Anderson, *Psychological Interventions for Cancer Patients to Enhance the Quality of Life*, 60 J. CONSULTING & CLINICAL PSYCHOL. 552 (1992) (discussing the correlation between the “magnitude” of a disease and treatment and the psychological and behavioral outcomes); A. van’t Spikjer et al., *Psychological Sequelae of Cancer Diagnosis: A Meta-Analytical Review of 58 Studies After 1980*, 59 PSYCHOSOMATIC MED. 280, 290 (1997) (finding that cancer patients have somewhat higher levels of depression than the “normal” population); Kathryn E. Weaver et al., *Mental and Physical Health-Related Quality of Life Among U.S. Cancer Survivors: Population Estimates from the 2010 National Health Interview Survey*, 21 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2108, 2114 (2012) (reporting that cancer survivors were significantly more likely than those without cancer to report poor physical and mental health-related quality of life).

⁷⁰⁵ Rebecca Siegel, *Cancer Treatment and Survivorship Statistics, 2012*, 62 CA: CANCER J. FOR CLINICIANS 220, 234–37 (2012).

⁷⁰⁶ See PRESIDENT’S CANCER PANEL, *supra* note 86, at v (“Such a significant opportunity to prevent cancers in the U.S. and around the world is rare.”); Denise Mann, *Study Shows Benefits of HPV Vaccine in Men Who Have Sex With Men*, WEBMD HEALTH NEWS 3 (Nov. 2, 2010), <http://www.webmd.com/cancer/news/20101102/hpv-vaccine-costeffective-way-to-prevent-anal-cancer?page=1> (quoting Dr. Jaffer A. Ajani, a professor of medicine at MD Anderson Cancer Center in Houston, Texas, who stated that the vaccine “is a rare cancer-prevention opportunity”).

⁷⁰⁷ News Release, Soc’y of Gynecologic Oncology, FDA Approval of Nonavalent HPV Vaccine Adds New Tool to Eradicate Cervical Cancer (Dec. 10, 2014) (quoting Dr. Richard R. Bakarat, President of the Society of Gynecologic Oncology), *available at* <https://www.sgo.org/newsroom/news-releases/fda-approval-of-nonavalent-hpv-vaccine-adds-new-tool-to-eradicate-cervical-cancer/>.

psychological consequence of HPV and HPV-related cancer is not a worthy outcome to pursue.

b. Emotional and Psychosocial Impact and Stigma of Sexually Transmitted Infections

Emotional and psychosocial benefits will also be realized by preventing initial infection.⁷⁰⁸ All types of STIs are associated with at least some degree of stigma and shame and these attitudes are exacerbated by low awareness and misinformation about these diseases.⁷⁰⁹ Many individuals diagnosed with HPV report feeling anger, depression, isolation, shame, and guilt.⁷¹⁰ When participants in Friedman & Sheppard's study were asked what came to mind when they heard "sexually transmitted disease" or "STD," participants commonly mentioned "promiscuity," "infidelity," "shame," "embarrassment," "guilt," and "divorce."⁷¹¹ At the time the data was collected for this study (2003), however, many participants exhibited a general lack of awareness about HPV specifically, especially males. The vaccine's marketing and public health awareness campaigns about the vaccine have increased awareness of the virus, but awareness varies by gender, race, socioeconomic status, and other demographic characteristics.⁷¹² In a 2009 internet survey, 69% of participants had heard of the vaccine, with women (78.7%)

⁷⁰⁸ See sources cited *supra* notes 573–574.

⁷⁰⁹ Friedman & Sheppard, *supra*, note 573, at 475, 477.

⁷¹⁰ Peggy Clarke et al., *The Psychosocial Impact of Human Papillomavirus Infection: Implications for Health Care Providers*, 7 INT'L J. STD & AIDS 197, 198 (1996).

⁷¹¹ Friedman & Sheppard, *supra*, note 573, at 475.

⁷¹² See, e.g., Peng-jun Lu et al., *Human Papillomavirus Vaccine Initiation and Awareness*, 44 AM. J. PREVENTIVE MED. 331 (2013) (finding that, among other characteristics, being Caucasian and having a higher income and education level increased the likelihood of HPV and HPV vaccine awareness); Rachel A. Reimer et al., *Ethnic and Gender Differences in HPV Knowledge, Awareness and Vaccine Acceptability Among White and Hispanic Men and Women*, 39 J. CMTY. HEALTH 274, 277 (2014) (reporting that white female participants were significantly more likely to have heard of HPV).

significantly more likely than men (57.9%) to have heard about the vaccine.⁷¹³ An individual's source of information, however, is not necessarily reliable or trustworthy, with many hearing about the vaccine through popular media rather than a health care provider.⁷¹⁴ Although not always unreliable, "the news media environment is fragmented, with individuals selecting to receive their news from different sources based, in part, on their own political orientation."⁷¹⁵

Women and men diagnosed with an STI face the difficult prospect of disclosing this information, particularly if they are in an intimate relationship and when considering entering into a new intimate relationship.⁷¹⁶ Clarke and colleagues reported that two-thirds of study participants were concerned their infections would cause them to be rejected by potential sexual partners and nineteen percent had already been rejected by a potential partner.⁷¹⁷ As an STI, HPV is frequently associated with "promiscuity and irresponsibility," and although stigma is experienced by both men and women, there is a double standard when it comes to STIs, with women more often shunned and stigmatized after a diagnosis.⁷¹⁸ Women are more likely to report feeling angry, depressed, and other

⁷¹³ Sarah E. Gollust et al., *Political and News Media Factors Shaping Public Awareness of the HPV Vaccine*, 23 WOMEN'S HEALTH ISSUES e143, e146 (2010). Based on data from the 2013 National Health Interview Survey, among 1,741 men aged 18–26 years of age, 51.8% had heard of HPV and only 34.8% had heard about the vaccine.

⁷¹⁴ *Id.* at e148; Reimer et al., *supra* note 712, at 281 (reporting that the three most common sources of information about HPV were the television, physicians, and various sources of print media).

⁷¹⁵ Gollust et al., *supra* note 713, at e149.

⁷¹⁶ Clarke et al., *supra* note 710, at 198 (finding that 57% of study participants were concerned about being negatively judged by an acquaintance because of their infection).

⁷¹⁷ *Id.*

⁷¹⁸ Emily Shire, *The Silent Shame of HPV*, DAILY BEAST (Aug. 29, 2014), <http://www.thedailybeast.com/articles/2014/08/29/the-silent-shame-of-hpv.html>; *see also* Andrea B. Alexander et al., *Adolescent Male Conceptualization of HPV-Related Diseases Through Use of Projection Drawings*, 52 J. ADOLESCENT HEALTH S22 (2013) (finding, in a study examining how adolescent young men view genital warts, that males 9–21 tended to blame women as the primary

negative emotions in response to an HPV-positive test result.⁷¹⁹ Women are also more likely to express feelings of guilt, shame, and “paying for past behavior” than men.⁷²⁰ Dr.

Adina Nack argues

The root of STD stigma is the gender-based double standard of sexual morality: male social status typically increases as their number of sexual partners increases, whereas female social status typically decreases. As a society, we still place a high value on female virginity/chastity and on male sexual contexts. . . . My research has found that infected women most often used the word ‘dirty’ to describe how they felt after receiving an STD diagnosis. Women have more concerns about this than men because of our society’s exist[ing] double standards.⁷²¹

Research findings support the notion that those diagnosed with STIs and HPV-related cancers face stigma and feel shame and guilt.⁷²² Some HPV-positive individuals

transmitters of HPV). This “double standard” provides an additional argument in favor of vaccinating both males and females, because this could help “reduce the stigma associated with offering a vaccine against a sexually transmitted infection to females only.” Rebecca B. Perkins & Jack A. Clark, *Providers’ Attitudes Toward Human Papillomavirus Vaccination in Young Men: Challenges for Implementation of 2011 Recommendations*, 64 AM. J. MEN’S HEALTH 320, 321 (2012).

⁷¹⁹ Ellen M. Daley et al., *Negative Emotions and Stigma Associated with a Human Papillomavirus Test Result: A Comparison Between Human Papillomavirus-Positive Men and Women*, J. HEALTH PSYCHOL. 7–8 (2013) [hereinafter Daley et al., *Negative Emotions and Stigma Associated with HPV Test Result*].

⁷²⁰ *Id.* at 8.

⁷²¹ *Id.*; see also ADINA NACK, DAMAGED GOODS? WOMEN LIVING WITH INCURABLE STDs (2008).

⁷²² See Stephanie L. Marhefka et al., *HPV-Related Information Sharing and Factors Associated with US Men’s Disclosure of an HPV Test Result to their Female Sexual Partners*, 88 SEXUALLY TRANSMITTED INFECTIONS 171, 171 (2012) (discussing numerous studies suggesting that psychosocial factors such as stigma may affect whether disclosure to a partner occurs); Laura A.V. Marlow et al., *Variation in Blame Attributions Across Different Cancer Types*, 19 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1799, 1801 (2010) (finding that 37% of surveyed women attributed some blame to women diagnosed with cervical cancer); Melissa A. Shepherd & Mary A. Gerend, *The Blame Game: Cervical Cancer, Knowledge of its Link to Human Papillomavirus and Stigma*, 29 PSYCHOL. & HEALTH 94, 105–07 (2013) (finding that when participants in a study were told that a patient’s cervical cancer was caused by HPV, they rated

blame themselves because they feel they could have prevented it and many anticipate stigma and potential social isolation and/or rejection.⁷²³ Researchers in one study, for example, report that participants

Focused almost exclusively on social rejection as a consequence of a positive HPV or abnormal Pap test. They frequently used the words ‘nasty,’ ‘dirty,’ and ‘trifling’ . . . and explained that these words indicated promiscuity and lack of condom use: An 18-year-old with negative test results defined *nasty* as “like trifling, trumpy, and like ho-ish, like you been sleeping around and being unprotected.”⁷²⁴

Personal accounts provide a human narrative to this experience. Many women have commented on the difficulties they faced and the frustration they felt after receiving an HPV diagnosis:

- “Jane” described the diagnosis experience as frustrating because her “gynecologist was vague and nonchalant about how to proceed, both in terms of her health and her dealings with sexual partners.” She was just beginning a new relationship and had not yet been sexually intimate with her new partner. When she asked her gynecologist whether she should discuss the diagnosis with her partner, she said “‘That’s up to you.’ There wasn’t much she said about what she thought I should know. She just said come back in a year.”⁷²⁵

the patient as more dirty, dishonest, and unwise, and reported feeling more moral disgust and “grossed out”); Sarah E. Flynn, Shame, Guilt, and Knowledge of HPV in Women Recently Diagnosed with HPV-Related Cervical Intraepithelial Neoplasia (CIN) (2010) (unpublished PhD dissertation, University of Kentucky) *available at* http://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1009&context=gradschool_diss (finding that women with HPV experienced more shame and guilt compared to women with the Epstein-Barr virus (commonly known as “mono”)).

⁷²³ Jessica A. Kahn et al., *Personal Meaning of Human Papillomavirus and Pap Test Results in Adolescent and Young Adult Women*, 26 HEALTH PSYCHOL. 192, 197 (2007).

⁷²⁴ *Id.* at 197.

⁷²⁵ Shire, *supra* note 718.

- When Robyn told her partner she was diagnosed with HPV, he said “But we used condoms” and then “literally hung up on” her.⁷²⁶
- Erica’s partner accused her of being “irresponsible in her sexual past,” and even when she tried to explain to him that *he* could be a carrier of the virus, he “willfully ignored what [she] said.” Erica said his response made her feel “dirtied.”⁷²⁷
- “My HPV causes serious dysplasia inside my cervix, which causes tumors, carcinoma in situ and many more complications, (including infertility, breakthrough bleeding, and severe pain.) It’s not the pain or the fear that I live with most of all, *it’s the stigma of this sidelined disease*. I have heard time and time again, HPV being marginalized as a strictly sexual disease, *brought on by promiscuity and deviance*.” – Kate Madonna Hines.⁷²⁸
- “I feel like a pariah. The doctor tried to quell my fear by telling me that I was not alone—as I found out, about 50% of all sexually active individuals are infected with HPV. But still, I felt dirty, damaged, and guilty that not only did I have this disease, but that *I brought it upon myself*.” - Anonymous⁷²⁹

Although men appear to experience less HPV-related stigma than women,⁷³⁰ their experiences with HPV and HPV-related cancer stigma and shame should not be

⁷²⁶ *Id.*

⁷²⁷ *Id.*

⁷²⁸ Kate Madonna Hines, *20 Million Mind-Blowing Statistics About HPV and Cancer*, MINNPOST (June 26, 2012), <http://www.minnpost.com/minnesota-blog-cabin/2012/06/20-million-mind-blowing-statistics-about-hpv-and-cancer> (emphasis added).

⁷²⁹ Anonymous, *My Story: Living With an STD*, DAILY MUSE (Feb. 9, 2012), <https://www.themuse.com/advice/my-story-living-with-an-std?ref=search> (emphasis added).

⁷³⁰ Daley et al., *Negative Emotions and Stigma Associated with HPV Test Result*, *supra* note 719, at 7–8.

discounted because HPV is an important concern for men as well.⁷³¹ The vaccine's ability to reduce the risk of HPV-related cancers such as anal, penile, and oropharyngeal cancers⁷³² will help many men avoid the stigma of HPV and these related diseases. In a small study of men diagnosed with HPV-related oropharyngeal cancer, researchers found that a majority experienced feelings of embarrassment and some participants expressed feelings of shame and stigma related to the sexually transmitted nature of HPV.⁷³³ Men reporting shame and stigma also tended to have decreased sexual desire or enjoyment.⁷³⁴ As stated by one participant: "Obviously, the prospect of something being sexually transmitted can be somewhat embarrassing to think about that. That, you know, something I did when I was single 25, 30 years ago came back to haunt me. You know, was all-in-all embarrassing to say the least."⁷³⁵

Anal cancer also carries a heavy degree of stigma, whether HPV-related or not—"It affects the part of the body no one wants to discuss and remains one of the most stigmatized of diseases."⁷³⁶ Although saying the word "breast" in public used to be taboo, discussing breast cancer is no longer stigmatized, as illustrated by the "pink ribbon"

⁷³¹ Joel M. Palefsky, *Human Papillomavirus-Related Disease in Men: Not Just a Woman's Issue*, 46 J. ADOLESCENT HEALTH S12 (2010).

⁷³² Watson et al., *supra* note 85, at 2841.

⁷³³ Shrujal Baxi et al., *Sharing a Diagnosis of HPV-Related Head and Neck Cancer: The Emotions, the Confusion, and What Patients Want to Know*, 35 HEAD & NECK 1534, 1537 (2013).

⁷³⁴ *Id.* at 1537.

⁷³⁵ *Id.*

⁷³⁶ Victoria Colliver, *Anal Cancer Study Offers Hope of Treatment*, SFGATE (Nov. 25, 2013, 2:00 PM), <http://www.sfgate.com/health/article/Anal-cancer-study-offers-hope-of-treatment-4994535.php>.

campaign.⁷³⁷ This success in de-stigmatizing an area of the body and related type of cancer has not spread to anal cancer, which some describe as “the least-talked-about cancer It’s that word no one wants to say.”⁷³⁸ Anal cancer’s association with anal sex increases its “taboo” status because many associate anal sex with homosexuality, despite it being a practice engaged in by individuals of *all* sexual orientations.⁷³⁹ In fact, the average anal cancer patient in the United States is a woman in her early sixties.⁷⁴⁰ Both men and women diagnosed with anal cancer, therefore, face the stigma against anal cancer and its “taboo” nature, making it difficult and embarrassing to discuss and disclose to others.⁷⁴¹

One could argue that breaking down and eradicating the stigma itself is the better option, but that is easier said than done. Because stigma persists (even though the majority of sexually active individuals have HPV) the combination of HPV-related stigma and the negative health consequences of HPV provide a strong case for fighting and preventing the disease in the first place. Vaccine supporters and public health advocates, however, must be vigilant and combat the transfer of stigma from an HPV-*diagnosis* to the *vaccine* itself, with some of the vaccine’s opponents suggesting that only

⁷³⁷ *Id.*; Barron H. Lerner, *Pink Ribbon Fatigue*, N.Y. TIMES WELL BLOG (Oct.11, 2010, 11:00 AM), <http://well.blogs.nytimes.com/2010/10/11/pink-ribbon-fatigue/> (“The pink ribbon has been a spectacular success in terms of bringing recognition and funding to the breast cancer cause.”).

⁷³⁸ Colliver, *supra* note 736 (quoting Richard Goldman of San Francisco, who was diagnosed with anal cancer).

⁷³⁹ SHOBHA S. KRISHNAN, THE HPV VACCINE CONTROVERSY 156 (2008) (arguing that anal sex “is a form of sexual expression that has been practiced not only by homosexuals but also by bisexuals and heterosexuals for centuries”).

⁷⁴⁰ *Anal Cancer: Risk Factors for Anal Cancer*, HPV AND ANAL CANCER FOUND., <http://www.analcancerfoundation.org/learn/anal-cancer/> (last visited Feb. 11, 2015), Surveillance, Epidemiology, and End Results Program, *SEER Stat Fact Sheets: Anal Cancer*, NAT’L CANCER INST., <http://seer.cancer.gov/statfacts/html/anus.html> (last visited Feb. 11, 2015).

⁷⁴¹ See, e.g., Julie Midtgaard et al., *Modesty and Recognition—A Qualitative Study of the Lived Experience of Recovery from Anal Cancer*, 17 SUPPORTIVE CANCER CARE 1213 (2009).

“promiscuous women are at risk for HPV” and therefore in need of the vaccine.⁷⁴² As an increasing number of robust studies conclude that the vaccine has no link to “promiscuous” behavior, the stigma against the vaccine itself should ebb.⁷⁴³

Lowering the age of consent for the HPV vaccine to increase its uptake among young adolescent males and females, those in a position to receive the greatest benefit from the vaccine, is good public policy. Not only is it more financially cost-effective, it has the additional benefits of reducing the emotional and psychosocial consequences of HPV and HPV-related cancer. When prevention rather than treatment is a viable option, prevention should be the path chosen.

IV. LOWERING THE AGE OF CONSENT IS APPROPRIATE AND IMPORTANT FOR INDIVIDUAL AND PUBLIC HEALTH REASONS

To avoid the need to continually amend these statutes if new vaccines are developed to prevent other STIs or communicable diseases (e.g., HIV, herpes, gonorrhea), the statutory language should ideally be broad enough to include vaccines for any STI, or even any infectious/communicable disease. If the broader language proves too controversial and incapable of garnering the necessary legislative and public support, then the language can be tailored to the appropriate specificity to increase its likelihood of enactment.

California’s current law provides a useful model for states to use. The consent law could be included with a state’s existing laws related to a minor’s consent to certain types of health care services, in a statutory section dealing with prevention and control of

⁷⁴² Suellen Hopfer & Jessica R. Clippard, *College Women’s HPV Vaccine Decision Narratives*, 21 QUALITATIVE HEALTH RES., 262, 271 (2011).

⁷⁴³ See sources cited *supra* notes 383–385.

infectious/communicable diseases, or provisions detailing a minor's general ability to consent and contract. California's current law provides a useful model. California Family Code § 6926 states, in its entirety:

- (a) A minor who is 12 years of age or older and who may have come into contact with an infectious, contagious, or communicable disease may consent to medical care related to the diagnosis or treatment of the disease, if the disease or condition is one that is required by law or regulation adopted pursuant to law to be reported to the local health officer, or is a related sexually transmitted disease, as may be determined by the State Public Health Officer.
- (b) A minor who is 12 years of age or older may consent to medical care related to the prevention of a sexually transmitted disease.
- (c) The minor's parents or guardian are not liable for payment for medical care provided pursuant to this section.

However, instead of simply stating that the minor may consent to *preventive* care, the statute should specifically include/mention the right to consent to preventive care, *including but not limited to vaccinations*. In this way, there is no ambiguity or ability to argue the legislature did not intend the term "prevention" or "preventive care/treatment" to exclude vaccinations. Legislators should also feel free to lower the age even further or provide no age, simply stating that "a minor" has the right to consent to such preventive medical care. In fact, this may be ideal because it would allow HCPs to administer the HPV vaccine to a minor patient as young as nine years old⁷⁴⁴ if the HCP believes the minor is at risk for HPV exposure at an earlier age (e.g., at risk of early sexual initiation,

⁷⁴⁴ Gardasil is approved for use in males and females beginning at age nine. *Approved Products: Gardasil*, *supra* note 92.

at risk for sexual abuse). The exact age or language used may vary by state depending on the make-up of a particular legislature and public response and support, but twelve, at the oldest, should be the goal.

To attempt to mitigate opposition, legislators proposing these changes should make sure to stress that parental involvement and consent should be the norm and should be sought whenever possible. The ideal situation is when the adolescent, parent/guardian, and HCP all agree the vaccine is in the adolescent's best interest. This promotes a healthy, honest, and open parent-child relationship, gives the adolescent some degree of input into his or her medical care, and increases the likelihood the adolescent will complete all three doses. The *presumption* in favor of parental involvement and consent, however, should no longer be a barrier to vaccination if the parent opposes the vaccine or if the adolescent does not want to involve or notify her parents about her desire to receive the vaccine. The presumption merely indicates that HCPs should discuss with adolescent patients the possibility of involving parents.

V. CONCLUSION

This thesis has taken an interdisciplinary approach to analyzing and addressing the issue of parental refusal and/or deferral to consent to HPV vaccination for their children. It rests on both public policy arguments and individual rights. Parental consent requirements are a frequent barrier to the vaccine's administration and parents refuse to consent for a variety of reasons, including cost, concerns about safety and effectiveness, and misconceptions about the vaccine's impact on adolescent sexual behavior. There are many reforms that can help increase vaccine uptake. Lowering the age of consent to

allow minors twelve years and older to consent to the vaccine despite parental refusal and/or non-involvement is a statutory change that can occur at the state level and may pave the way for allowing minors to consent to other vaccines for infectious diseases.

This thesis has argued that lowering the age of consent is a good public policy that is medically and ethically sound. Legalizing a lower age of consent clears the path for public health officials, HCPs, school officials, and other relevant parties to implement policies that improve vaccine delivery and ensure adolescents have the opportunity to consider the vaccine. The proposal acknowledges and respects adolescent autonomy, allows adolescent health care providers to act in the best interests of their patients, and promotes the current and future physical, mental, and social well-being of adolescents.