



UC DAVIS

LAW REVIEW

UNIVERSITY OF CALIFORNIA, DAVIS, SCHOOL OF LAW • VOL. 41, No. 5, JUNE 2008

Human Papillomavirus Vaccination, Private Choice, and Public Health

*Sylvia Law**

In 2006 the United States Food and Drug Administration (“FDA”) approved Gardasil, a vaccine that prevents transmission of human papillomavirus (“HPV”), for girls aged nine to twenty-six. HPV is a sexually transmitted disease strongly associated with 4000 deaths due to cervical cancer in the United States each year. This sobering statistic means that Gardasil is one of the most promising medical breakthroughs

* Elizabeth K. Dollard Professor of Law, Medicine and Psychiatry; Co-Director, Arthur Garfield Hays Civil Liberties Program, New York University School of Law. J.D. 1968, New York University School of Law, B.A., 1964, Antioch College. This Article is based on the Brigitte M. Bodenheimer Lecture on Family Law delivered on October 25, 2007, at UC Davis School of Law. Thanks to those who provided helpful comments: Dr. Jon S. Abramson, former chair, Advisory Committee on Immunization Practice; James Colgrove, Columbia University Mailman School of Public Health; Barry Ensminger; Martha Field, Harvard Law School; Lawrence O. Gostin, Georgetown University Law Center; Martin Guggenheim, New York University School of Law; Celine Mizrahi, Center for Reproductive Rights; Dr. Rebecca Rudisell; Barbara Seaman; Cynthia Tracy; and Sophia Yen. Able research assistance was provided by Suzy Kim Lee, New York University Department of Sociology, and Abby R. B. Herzberg, New York University School of Law. Thanks also to the Editors of the UC Davis Law Review. Leslie Jenkins gives me essential support. The Filomen D’Agostino and Max E. Greenberg Faculty Research Fund of New York University contributed financial help.

in recent history. The vaccination is only effective if administered before a person becomes infected with HPV, which means before a girl becomes sexually active.

School-based vaccination mandates are currently the most successful way to achieve widespread childhood vaccination in the United States and are also particularly effective in reducing racial disparities in vaccination levels. Vaccination mandates raise important questions. This Article considers the ethical, political, medical, and constitutional issues raised by vaccination mandates in the context of HPV vaccination and concludes that school-based HPV vaccination mandates should be adopted. To achieve the broadest protection against HPV, the vaccine mandate should be extended to boys, if, as expected, currently pending clinical trials demonstrate that the vaccine is similarly effective for them.

Policies giving parents broad authority to refuse vaccinations for their children seriously undermine the effectiveness of any vaccination campaign. Nonetheless, for practical political reasons, this Article argues that the vaccine mandate should be accompanied by broad parental authority to opt-out.

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INTRODUCTION

Compulsory childhood vaccination against contagious disease is one of the most successful public health interventions of the twentieth century. It has helped control the spread of many deadly epidemic diseases.¹ In 2006, the U.S. Food and Drug Administration (“FDA”) approved a new vaccine, Gardasil, to protect against four strains of the human papillomavirus (“HPV”), a sexually transmitted disease that is a major cause of cervical cancer and other serious illnesses.² Compulsory vaccination raises profound ethical, political, medical, and sometimes constitutional conflicts. This Article argues for compulsory HPV vaccination, finding that the benefits of the vaccine outweigh the costs.

Every year, more than six million people in the United States become infected with HPV.³ In 2004, over 26% of all U.S. females were infected with HPV, with infection rates of over 44% for women ages twenty to twenty-four⁴ and over 80% for women by age fifty.⁵ Infection rates among men are similar.⁶ Ninety percent of HPV

¹ Ctrs. for Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Ten Great Public Health Achievements — United States, 1900-1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 241 (Apr. 2, 1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm> (recognizing control of smallpox, measles, mumps, rubella, diphtheria, polio, and hepatitis B through vaccination).

² Press Release, U.S. Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>; see also Thomas Ginsberg, *Glaxo Asks Cervarix Approval*, PHILA. INQUIRER, May 30, 2007, at C01 (discussing GlaxoSmithKline’s pending approval for its version of HPV vaccine, Ceravix).

³ Ctrs. for Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 MORBIDITY & MORTALITY WKLY. REP. 1,1 (Mar. 23, 2007), available at <http://www.cdc.gov/mmwr/PDF/rr/tr5602.pdf>; see also Deanna A. Pollard, *Sex Torts*, 91 MINN. L. REV. 769, 771, 774-77 (2007) (describing prevalence of HPV and proposing expanded tort remedies).

⁴ Eileen Dunne et al., *Prevalence of HPV Infection Among Females in the United States*, 297 JAMA 813, 813 (2007) (reporting HPV prevalence increases each year from age 14 to 24, followed by gradual decline).

⁵ CTRS. FOR DISEASE CONTROL & PREVENTION (CDC), GENITAL HPV INFECTION FACT SHEET, at 1 (May 2004), available at <http://www.cdc.gov/std/hpv/hpv.pdf>.

⁶ See CTRS. FOR DISEASE CONTROL & PREVENTION (CDC), HPV and Men Fact Sheet

infections produce no symptoms and clear the body within two years.⁷ Cervical cancer is the most common serious disease showing a strong correlation with HPV. Each year nearly 10,000 women in the U.S. are diagnosed with cervical cancer and nearly 4000 die.⁸ HPV is detected in 99% of these cases.⁹ HPV is also associated with other less common fatal cancers and more common, but less dangerous, diseases including genital warts.¹⁰

If administered to people who have not previously contracted HPV, Gardasil is 100% effective in protecting against the four viruses it targets.¹¹ In the United States in 2002, 26% of young women had engaged in vaginal intercourse by age fifteen and 70% by age eighteen.¹² In a study of four common sexually transmitted diseases, the Centers for Disease Control and Prevention ("CDC") estimate that 18% of teenage girls have HPV.¹³ Given this prevalence, the vaccine is far more likely to be effective if administered before a person becomes sexually active. In 2006, the federal Advisory Committee on Immunization Practices ("ACIP") of the CDC recommended that girls age eleven or

(Dec. 2007), <http://www.cdc.gov/std/hpv/STDFact-HPV-and-men.htm>.

⁷ Ctrs. for Disease Control & Prevention, *supra* note 3, at 4; Gloria Y.F. Ho et al., *Natural History of Cervicovaginal Papillomavirus Infection in Young Women*, 338 *NEW ENG. J. MED.* 423, 425 (1998), available at <http://content.nejm.org/cgi/reprint/338/7/423.pdf>.

⁸ Ctrs. for Disease Control & Prevention, *supra* note 3, at 1. See generally Mona Saraiya et al., *Cervical Cancer Incidence in a Pre-Vaccine Era in the United States, 1998-2002*, 109 *OBSTETRICS & GYNECOLOGY* 370 (2007) (analyzing regional differences in cervical cancer incidence in United States).

⁹ Ctrs. for Disease Control & Prevention, *supra* note 3, at 2.

¹⁰ See sources cited *infra* notes 23-24.

¹¹ Ctrs. for Disease Control & Prevention, *supra* note 3, at 8-11. There are over 100 types of HPV; Gardasil only protects against four of them — types 6, 11, 16 and 18. *Id.* at 8. HPV types 6 and 11 (genital warts) are low risk and their prevalence is low. *Id.* at 6. Types 16 and 18 are high risk; the prevalence rate of virus 16 is 1.5%, and the prevalence rate of virus 18 is 0.8%. *Id.* at 4. One core difficulty is Gardasil, like any vaccine, does not protect against viruses with which a person is already infected. *Id.* at 16.

¹² William D. Mosher et al., *Sexual Behavior and Selected Health Measures: Men and Women 15-44 Years of Age, United States, 2002*, *ADVANCE DATA FROM VITAL & HEALTH* (U.S. Dep't of Health & Human Servs., Hyattsville, Md.), Sept. 15, 2005, at 22 tbl.16, available at <http://www.cdc.gov/nchs/data/ad/ad362.pdf>.

¹³ Lawrence K. Altman, *Sex Infections Found in Quarter of Teenage Girls*, *N.Y. TIMES*, Mar. 12, 2008, at A1 (describing results of CDC study estimating that one in four girls aged 14 to 19 has at least one sexually transmitted disease and noting racial disparities).

twelve routinely receive the vaccine.¹⁴ The FDA has not approved the vaccine for boys, but Merck is now testing Gardasil on them.¹⁵

Part I addresses personal considerations in deciding whether to be vaccinated and discusses whether children should be vaccinated against HPV before becoming sexually active. After evaluating scientific research, Part I concludes that, except for children with particular medical problems, vaccination is wise. Part II places the issue in a social context. In the twenty-first-century United States, state mandates, enforced through compulsory school attendance requirements, are the most likely means of achieving a high level of vaccination and assuring that vaccination extends beyond girls from privileged families. Part II further examines the strengths and weaknesses of “no shots, no school” policies, both generally and in the specific context of HPV, and concludes that HPV vaccination should be required as a condition of mandatory school attendance. Part III considers whether and when the law should allow parents to refuse vaccinations for their children, and concludes that, at the present time, state laws should allow broad parental authority to refuse a mandatory HPV vaccination.

I. AFTER EVALUATING THE MEDICAL EVIDENCE, WOULD A
REASONABLE YOUNG PERSON CHOOSE TO BE VACCINATED AGAINST
HPV?

This part considers the medical evidence that would influence a reasonable person deciding whether to seek HPV vaccination, including the diseases prevented by the vaccine, risks of the vaccine, opinions of medical experts, and individual attitudes toward medical intervention. Part I concludes that, on balance, the vaccine is advisable.¹⁶

The largest factor motivating people to seek HPV vaccination is that it protects against the significant risk of cervical cancer.¹⁷ Since the 1950s, Pap smear tests have substantially reduced the risks of contracting cervical cancer.¹⁸ However, cervical cancer is still

¹⁴ Ctrs. for Disease Control & Prevention, *supra* note 3, at 16.

¹⁵ *Id.* at 17. The exclusion of boys raises complex issues discussed *infra* notes 166-71.

¹⁶ This part refers to all people, even though the FDA has only approved the vaccine for girls. Ctrs. for Disease Control & Prevention, *supra* note 3, at 17; see discussion *infra* notes 120-27 (discussing parental decision making).

¹⁷ Ctrs. for Disease Control & Prevention, *supra* note 3, at 1.

¹⁸ *Id.* at 5 (reporting that cervical cancer incidence rates have decreased approximately 75% and death rates approximately 70% since 1950s, largely because of

common and often fatal.¹⁹ More than fifty million Pap smears are performed annually in the United States, and about 5% of them are abnormal.²⁰ An abnormal Pap smear typically requires further costly surgical diagnostic testing.²¹ HPV is associated with precancerous lesions that lead to abnormal Pap smears. Vaccination against HPV reduces traumatic events of post-Pap smear surgical tests by preventing the transmission of HPV diseases.²² While women should still receive Pap smears after they have been vaccinated, their chances of irregular Pap smears are reduced after vaccination. In addition to cervical cancer and precancerous lesions, HPV infection is also strongly associated with many other cancers and sexually transmitted diseases.²³ Cervical cancers, other more rare forms of cancer, and invasive, costly tests resulting from abnormal Pap smears are serious

Pap testing); David S. Guzick, *Efficacy of Screening for Cervical Cancer: A Review*, 68 AM. J. PUB. HEALTH 125, 125 (1978) (reporting cervical cancer rates in United States dropped from 44 cases per 100,000 women in 1947, when regular Pap testing began, to 8.8 per 100,000 in 1970); Nelson D. Holmquist, *Revisiting the Effect of the Pap Test on Cervical Cancer*, 90 AM. J. PUB. HEALTH 620, 622 (2000) (confirming that early identification of cervical cancer through Pap tests results in better prognosis).

¹⁹ See Ctrs. for Disease Control & Prevention, *supra* note 3, at 1.

²⁰ Judith M.E. Walsh, *Cervical Cancer: Developments in Screening and Evaluation of the Abnormal Pap Smear*, 169 W.J. MED. 304, 304 (1998) (reporting 90% of cervical displasias are associated with HPV).

²¹ Anna Bennetts et al., *PEAPS-Q: A Questionnaire to Measure the Psychosocial Effects of Having an Abnormal Pap Smear*, 48 J. CLINICAL EPIDEMIOLOGY 1235, 1240-41 (1995) (reporting results of research on women's distress from abnormal Pap smear results); Harrell W. Chesson et al., *The Estimated Direct Medical Costs of Sexually Transmitted Diseases Among American Youth, 2000*, 36 PERSP. SEXUAL & REPROD. HEALTH 11, 13 (2004) (estimating \$3 billion per year in treatment costs for HPV, mostly for follow-up care from abnormal Pap tests); *cf.* Gideon Fait et al., *Contribution of Human Papillomavirus Testing by Hybrid Capture in the Triage of Women with Repeated Abnormal Pap Smears Before Colonoscopy Referral*, 79 GYNECOLOGIC ONCOLOGY 177, 177 (2000) (reporting highly significant association between positive test for high-risk HPV types and precancerous cervical abnormalities); Walsh, *supra* note 20, at 304 (reporting that it costs \$6 billion each year to evaluate colposcopically and treat these abnormalities).

²² Walsh, *supra* note 20, at 304.

²³ Gypsyamber D'Souza, *Case-Control Study of Human Papillomavirus and Oropharyngeal Cancer*, 356 NEW ENG. J. MED. 1944, 1952-53 (2007) (concluding that HPV-16, against which Gardasil protects, is strongly associated with oropharyngeal cancer with or without risk factors of alcohol or tobacco use). HPV is also associated with vaginal, vulvar, and penile cancer. Ctrs. for Disease Control & Prevention, *supra* note 3, at 6. Their connection to HPV is not well understood. *Id.* Anal cancer, which is rare but affects both men and women, is associated with HPV in 90% of those cases. *Id.* HPV types 6 and 11 cause 90% of genital warts. *Id.* These warts may aid the entry of other STDs, including HIV. *Id.* Gardasil protects against both HPV types 6 and 11. *Id.*

harms that HPV vaccination can prevent. In short, the HPV vaccination will prevent more unnecessary deaths and traumas than many commonly mandated vaccines.²⁴

When making a decision about the HPV vaccine, a reasonable person likely wants to know the risks associated with the immunization as found in clinical trials. Under FDA supervision, Merck studied the risks of the HPV vaccine during a five-year clinical trial involving almost 12,000 participants.²⁵ The evidence from these trials suggests that, in the short term, the HPV vaccination does not cause serious adverse side effects.²⁶ One out of every 10,000 women

²⁴ In its worst year, death rates from polio were less than those from cervical cancer. Ctrs. for Disease Control & Prevention, *supra* note 3, at 1 (estimating 3700 deaths from cervical cancer in 2007); Harold M. Schmeck, Jr., *Dr. Jonas Salk, Whose Vaccine Turned Tide on Polio, Dies at 80*, N.Y. TIMES, June 24, 1995, at 1 (reporting over 3000 polio deaths at peak of U.S. epidemic in 1952). Death rates from tetanus are much lower than those from cervical cancer. Ctrs. for Disease Control & Prevention, *supra* note 3, at 1; Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 40 MORBIDITY & MORTALITY WKLY. REP. 1, 1 (Aug. 8, 1991), available at <http://www.cdc.gov/MMWR/preview/mmwrhtml/00041645.htm> (reporting 560 cases of tetanus in 1947, when national reporting began). Mumps causes fewer deaths per year than cervical cancer. Ctrs. for Disease Control & Prevention, *supra* note 3, at 1 (estimating 3700 deaths from cervical cancer in 2007). The National Network for Immunization Information suggests that, prior to vaccination, there were about 200,000 cases of mumps and about 20 to 30 deaths per year. Nat'l Network for Immunization Info., Vaccine Information (Sept. 25, 2006), http://www.immunizationinfo.org/vaccineInfo/vaccine_detail.cfv?id=23#historydata.

²⁵ Ctrs. for Disease Control & Prevention, *supra* note 3, at 12-13. In 2007, results from three additional clinical trials confirmed that Gardasil is highly effective in preventing the lesions associated with cervical cancer and genital warts. Elmar A. Joura et al., *Efficacy of a Quadrivalent Prophylactic Human Papillomavirus (Types 6, 11, 16, and 18) L1 Virus-Like-Particle Vaccine Against High-Grade Vulval and Vaginal Lesions: A Combined Analysis of Three Randomized Clinical Trials*, 369 LANCET 1693 (2007). The trials also show that Cervarix, an alternative bivalent vaccine that protects against HPV types 16 and 18, is 90% effective against viruses that cause cancer, but does not protect against genital warts. Maurie Markman, *Human Papillomavirus Vaccines to Prevent Cervical Cancer*, 369 LANCET 1837, 1837-38 (2007); see Kevin A. Ault, *Effect of Prophylactic Human Papillomavirus L1 Virus-Like-Particle Vaccine on Risk of Cervical Intraepithelial Neoplasia Grade 2, Grade 3, and Adenocarcinoma in Situ: A Combined Analysis of Four Randomized Clinical Trials*, 369 LANCET 1861, 1865-67 (2007).

²⁶ Ctrs. for Disease Control & Prevention, *supra* note 3, at 13-14, 16-17; The FUTURE II Study Group, *Quadrivalent Vaccine Against Human Pappilomavirus to Prevent High-Grade Cervical Lesions*, 356 NEW ENG. J. MED. 1915, 1924 tbl.4 (2007). Pain at the injection site is the most common side effect, reported by 83.9% of those injected, as opposed to 48.3% of those in a control group injected with saline solution. Ctrs. for Disease Control & Prevention, *supra* note 3, at 13 tbl.7; see The FUTURE II

in the study experienced serious adverse side effects within fifteen days of injection; however, the proportion of women experiencing serious effects was similar when compared to a placebo.²⁷

While the evidence supporting the efficacy and safety of the vaccine is positive, it is also thin. As noted, the initial clinical trials involved a population of less than 12,000 participants for only five years.²⁸ For a rare disease, this would be a large and long clinical trial, but for a vaccine proposed for half the population, against a condition that does not manifest for decades, the clinical trial is reasonably short. It is not yet known whether or how often booster shots will be needed to maintain the vaccine's effectiveness,²⁹ nor do we know whether vaccination against some forms of HPV will make other forms of the virus more dangerous.³⁰

In addition to questioning the depth of the evidence supporting the vaccine's effectiveness, some vaccine opponents argue that it is unsafe. They rely primarily on data available from the 1989 National Childhood Vaccine Injury Act's Vaccine Adverse Event Reporting System ("VAERS"). The Act requires that all physicians report adverse events following vaccination to the CDC and the FDA to make that information available to the public.³¹ Judicial Watch, a conservative³² "public interest group that investigates and prosecutes government corruption," analyzed adverse reactions to Gardasil reported to

Study Group, *supra*. Gardasil is more painful than a standard shot. Fewer than 5% of girls vaccinated experienced a slightly elevated temperature within 15 days of vaccination. Ctrs. for Disease Control & Prevention, *supra* note 3, at 13 tbl.9.

²⁷ Ctrs. for Disease Control & Prevention, *supra* note 3, at 14.

²⁸ *Id.* at 12-13.

²⁹ George F. Sawaya & Karen Smith-McCune, *HPV Vaccination — More Answers, More Questions*, 356 NEW ENG. J. MED. 1991, 1992 (2007).

³⁰ *Id.* at 1992.

³¹ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3775-78 (1986) (codified at 42 U.S.C. §§ 300aa-1 to 34 (1986)). The Act provides reimbursement for a wide range of medical and rehabilitative care for those injured by any vaccine designated by the CDC for routine administration to children and prohibits most punitive damages unless gross negligence is shown to the Secretary of Health and Human Services. *See id.* at 3767-68. The Act also delegates the responsibility for developing vaccine warnings to and relieves manufacturers of liability if they convey the government-issued warnings. 42 U.S.C. §§ 300aa-1, 300aa-22 (2000). For a discussion of the Act, see JAMES COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 216-17 (2006); Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 355-64 (2001).

³² *See* Paul Blustein & Toni Locy, *To Gadfly of the Right, Clinton Administration Is Unsafe at Any Speed*, WASH. POST, Nov. 17, 1996, at A17.

VAERS.³³ As of May 2007, physicians have reported 1637 adverse vaccination reactions, including 371 serious reactions and three deaths.³⁴ However, neither the VAERS Report nor Judicial Watch provides a comparison between the adverse reactions of Gardasil and the outcomes on a similar population of girls who did not receive the vaccination.³⁵ In this way, the data is less reliable than the FDA supervised clinical trials involving Gardasil.

In addition to the medical evidence, many reasonable people considering vaccination are influenced by the recommendations of experts and professional organizations. In 2006, the relevant federal agencies, including the FDA, CDC, and ACIP, recommended that all girls be vaccinated at age eleven or twelve.³⁶ The ACIP guidelines have been endorsed by several professional medical associations including the American Medical Association (“AMA”),³⁷ American College of Obstetricians and Gynecologists,³⁸ and American Academy of Pediatricians.³⁹

In May 2007, the prestigious New England Journal of Medicine published three original articles,⁴⁰ two perspective articles,⁴¹ two

³³ Press Release, Judicial Watch, Judicial Watch Uncovers Three Deaths Relating to HPV Vaccine (May 23, 2007), available at <http://www.judicialwatch.org/6299.shtml>.

³⁴ *Id.*; see also Press Release, Nat'l. Vaccine Info. Ctr., Analysis Shows Greater Risk of GBS Reports When HPV Vaccine Is Given with Meningococcal and Other Vaccines (Aug. 15, 2007), available at <http://www.nvic.org/PressReleases/PR081507HPV.htm> (reporting greater risk of Guillain-Barré Syndrome (“GBS”) with vaccination but not comparing naturally occurring incidence).

³⁵ Compare Press Release, *supra* note 33 (reporting three deaths related to HPV vaccine), with Ctrs. for Disease Control & Prevention, *supra* note 3, at 15-17 tbls.7-9 (reporting vaccine groups and placebo groups experience similar rates of serious adverse side effects).

³⁶ Ctrs. for Disease Control & Prevention, *supra* note 3, at 15; see also Press Release, *supra* note 2.

³⁷ Ctrs. for Disease Control & Prevention, *Recommended Immunization Schedules for Persons Aged 0-18 Years — United States 2007*, 297 JAMA 691, 691-94 (2007). The AMA gave its highest award to the doctors who discovered the vaccine. Press Release, Am. Med. Ass'n, AMA Honors Inventors of HPV Vaccine with Top Government Service Award (Feb. 13, 2007), available at <http://www.ama-assn.org/ama/pub/category/17315.html>.

³⁸ Committee on Adolescent Health Care and The ACOG Working Group on Immunization, *Human Papillomavirus Vaccination*, 108 OBSTETRICS & GYNECOLOGY 699 (2006).

³⁹ Comm. on Infectious Diseases, Am. Acad. of Pediatrics, *Recommended Immunization Schedules for Children & Adolescents — United States, 2007*, 119 PEDIATRICS 207, 207 (2007).

⁴⁰ The FUTURE II Study Group, *supra* note 26 (first original article); Suzanne M. Garland et al., *Quadrivalent Vaccine Against Human Papillomavirus to Prevent*

editorials,⁴² a letter to the editor,⁴³ and an audio interview on the subject of HPV. While noting the limited available evidence, all of the articles generally supported vaccination. An editorial accompanying the articles concluded:

On the one hand, the vaccine has high efficacy against certain HPV types that cause life-threatening disease, and it appears to be safe; delaying vaccination may mean that many women will miss an opportunity for long-lasting protection. On the other hand, a cautious approach may be warranted in light of important unanswered questions about overall vaccine effectiveness, duration of protection, and adverse effects that may emerge over time.⁴⁴

In 2006, another organization, Legal Momentum (formerly the National Organization for Women Legal Defense Fund), announced a campaign to make HPV vaccination compulsory in every state, with a broad exemption for parents who object on conscientious, medical, or

Anogenital Diseases, 356 NEW ENG. J. MED. 1928 (2007) (second original article describing results of double-blind, placebo-controlled HPV vaccine and concluding that highly effective vaccine will reduce overall incidence of cervical and anogenital disease associated with four types of HPV if administered to young women); Gypsyamber D'Souza et al., *Case-Control Study of Human Papillomavirus and Oropharyngeal Cancer*, 356 NEW ENG. J. MED. 1944 (2007) (third original article).

⁴¹ R. Alta Charo, *Politics, Parents, and Prophylaxis — Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 1905 (2007) (first perspective article discussing political landscape of individual state HPV mandate proposals and suggesting that debate over mandates should focus on public health and financing rather than sexual politics); Jan M. Agosti & Sue J. Goldie, *Introducing HPV Vaccine in Developing Countries — Key Challenges and Issues*, 356 NEW ENG. J. MED. 1908 (2007) (second perspective article describing enormous impact HPV vaccine could have on global incidence of cervical cancer and identifying challenges to vaccination financing and delivery in developing countries).

⁴² Lindsey R. Baden et al., *Human Papillomavirus Vaccine — Opportunity and Challenge*, 356 NEW ENG. J. MED. 1990 (2007) (first editorial noting potential of HPV vaccine to reduce global incidence of cervical cancer and recognizing need for further research on potential adverse effects and long-term consequences); Sawaya & Smith-McCune, *supra* note 29, at 1993 (second editorial acknowledging positive potential of HPV vaccine while recognizing that long-term effectiveness, duration of protection, and adverse consequences are still unknown).

⁴³ Alexandra M. Stewart, *Mandating HPV Vaccination — Private Rights, Public Good*, 356 NEW ENG. J. MED. 1998 (2007) (letter to editor describing judicial precedent for compulsory vaccination programs and identifying objections to such mandates).

⁴⁴ Sawaya & Smith-McCune, *supra* note 29, at 1993; *see also* John Carreyrou & Keith Winstein, *Medical Journal Questions Efficacy of HPV Vaccine*, WALL ST. J., May 10, 2007, at D3 (citing Sawaya and Smith-McCune editorial as condemnation of mandates).

religious grounds.⁴⁵ From the other side of the political spectrum, two conservative organizations — Focus on the Family and the Family Research Council — announced support for “widespread (universal) availability of HPV vaccines,” while opposing mandatory vaccinations for entry to public school.⁴⁶ Although the question of mandates is discussed in Part II, such broad general support for HPV vaccination is likely to influence a reasonable person’s decision on the vaccination.

Individual vaccination decisions do not, however, turn solely on scientific evidence or expert recommendations. Individual characteristics and attitudes also matter. For example, some individuals may take a “wait and see” approach, forgoing a decision on vaccination until the evidence of the vaccination’s effectiveness grows. This approach is not without merit; the Public Citizen Health Research Group generally advises doctors and patients to avoid “using newly approved drugs unless they are in the small minority of such drugs with a significant therapeutic benefit.”⁴⁷ Analysis of newly approved drugs shows that 20% are withdrawn or subject to FDA warnings within twenty-five years; half of these warnings occurred within seven years of introduction.⁴⁸ However, even though the respected Public Citizen Health Research Group generally advises avoiding new drugs for seven years,⁴⁹ the group supports Gardasil as one of the exceptional new drugs that should be used without delay. The group notes that “cervical cancer takes the lives of some 3700 American women each year. Preventing these deaths is obviously an end worth pursuing.”⁵⁰ Unless there are alternative means of avoiding HPV and cancer, the cost of “wait and see” is death for many women and a painful struggle with cancer for many more.

⁴⁵ Legal Momentum, HPV Vaccine: A Call for Mandatory Vaccination, <http://www.legalmomentum.org/site/DocServer/hpv.pdf?docID=385> (last visited Feb. 13, 2008).

⁴⁶ Focus on the Family, Focus on the Family Position Statement: Human Papillomavirus Vaccines, <http://www.family.org/socialissues/A000000357.cfm> (last visited Feb. 13, 2008); see Family Research Council, Family Research Council Statement Regarding HPV Vaccines (Feb. 21, 2006), <http://www.frc.org/get.cfm?i=LH06B03>.

⁴⁷ Public Citizen, Protecting Yourself and Your Family from Preventable Drug-Induced Injury, http://www.worstpills.org/public/page.cfm?op_id=45#do_not_use (last visited Mar. 25, 2008).

⁴⁸ Nicholas J. Cavuto et al., *Pharmacies and Prevention of Potentially Fatal Drug Interactions*, 275 J. AM. MED. ASSN. 1086, 1086 (1996) (reporting on new FDA approval chemical entities later withdrawn or subject to warnings).

⁴⁹ See Public Citizen, *supra* note 47.

⁵⁰ Q & A on the Human Papilloma Virus Vaccine Gardasil, HEALTH LETTER (Pub. Citizen Health Research Group), July 2007, at 1.

Since Gardasil was approved in June 2006, millions of people have received it.⁵¹ As time passes, valuable information will be reported to VAERS, allowing a more informed decision about the risks and benefits of Gardasil. Nonetheless, the costs of waiting for evidence to gather are high. It will take decades to know whether a girl who receives Gardasil in 2008 will suffer adverse side effects when she is older. Similarly, because it takes decades for cervical cancer to develop, direct evidence of the effect of HPV vaccination in reducing cervical cancer will not be immediately available. However, if Gardasil proves to be safe and effective in the long term, “wait and see” might mean that thousands of women will die unnecessarily from cervical cancer in the next twenty or thirty years.

One of the nation’s leading proponents of natural and alternative healing, Dr. Andrew Weil, also supports Gardasil: “This is a big public health step forward. More than half of all men and women pick up HPV within a year of becoming sexually active. The vaccine won’t work for women who already are infected with HPV, which is why it is so important to immunize young girls before they become sexually active.”⁵²

On balance, the answers to whether a reasonable person would receive the vaccine are not clear. The most powerful argument against the vaccination is that the evidence is thin. But the evidence will only become thick in decades, not years or months. Both the risks of cervical cancer and the unrealistic alternative of avoiding sex for decades seem a high price to pay for better evidence about possible adverse side effects of the vaccine. Ample evidence supports HPV vaccination as a reasonable choice.

⁵¹ Merck 2007 Annual Review: Driving Growth with Our Commitment to Vaccines, <http://www.merck.com/finance/annualreport/ar2007/vaccines.html> (last visited April 8, 2008) (reporting 7 million girls have received at least their first dose of Gardasil).

⁵² Weil is a leader in the alternative health movement and appeared on the cover of *Time* magazine in 1997 and 2005. See Sanjay Gupta, *Andrew Weil: The Guru of Self-Healing*, *TIME*, Apr. 18, 2005, at 109; *Time’s 25 Most Influential Americans*, *TIME*, Apr. 21, 1997, at 61; see also Seth Schiesel, *For Cover Subject of Time Magazine, A Time Warner Deal*, *N.Y. TIMES*, May 12, 1997, at D8. *Time* also named him one of the 25 most influential Americans in 1997 and one of the 100 most influential people in the world in 2005. See Gupta, *supra*; Schiesel, *supra*. Weil asserts that, in general, “the benefits of vaccines outweigh the risks.” Andrew Weil, *A Shot in the Dark?*, *AARP MAG.*, Sept./Oct. 2007, at 30.

II. SHOULD A STATE MANDATE VACCINATIONS AGAINST INFECTIOUS DISEASES, SUCH AS HPV?

Within months of the FDA's approval of the Gardasil vaccination, twenty-four state legislatures considered laws requiring the HPV vaccination for school admission.⁵³ In May 2007, Virginia became the first state to mandate HPV vaccination for school attendance.⁵⁴ Part II considers whether mandating the HPV vaccine is the correct response in light of the numerous objections to a mandate.

Part II.A discusses general issues common to any mandatory vaccination. It explores the claim that it is preferable to avoid mandates and encourage vaccination through education and voluntary programs. Other developed nations have achieved high levels of vaccination through such programs. Part II.A explores why the United States has come to rely on state vaccination mandates enforced through compulsory school attendance requirements, rather than voluntary programs. It considers the claim that mandatory vaccinations threaten constitutionally protected interests in individual autonomy, physical integrity, and parental authority. Part II.A concludes that mandates are both constitutional and preferable to a voluntary vaccination system.

Part II.B focuses on specific issues related to making HPV vaccination mandatory. It describes the groups who have opposed mandating HPV and considers their major arguments. Finally, Part II.C addresses how adding the HPV vaccine to "no shots, no school" policies can effectively reduce deaths from cervical cancer and the racial disparities that exist among those suffering from the disease.

A. While Organized and Funded Voluntary Vaccination Programs Are Theoretically Preferable to School-Based Mandates, in Recent Years, Only School-Based Mandates Have Effectively Achieved High Levels of Immunization in the United States

1. Based on U.S. Experiences, Mandatory Vaccination Programs Are More Successful than Voluntary Programs

The best way to encourage vaccination against HPV is through an organized health care system, which assures that people have access to affordable, quality health care. However, in the United States, many

⁵³ National Conference of State Legislatures, HPV Vaccine, <http://www.ncsl.org/programs/health/HPVvaccine.htm> (last visited Feb. 13, 2008).

⁵⁴ *Id.*

people do not have health insurance, a regular source of medical care, or the means to pay for even the most urgent medical needs, much less vaccines.⁵⁵ This section addresses the challenges that a lack of financing and access pose to both voluntary and mandatory vaccination programs. It first explores the organization of vaccination programs in the United States and then tackles the issue of how to finance vaccines. This section concludes that a “no shots, no school” policy is the only effective way to widely distribute vaccines in the United States.

Professor James Colgrove, a leading scholar of vaccination policy, observed that “throughout the middle of the twentieth century, health officials relied very little on coercion.”⁵⁶ Public health officials respected principles of liberty and autonomy, believing that persuasion was likely to be more effective than coercion because coercion triggers resistance. In 1927, the New York State Health Commissioner said, “Persuasion is a slow process. Its results are seldom spectacular but they are certain and durable, accomplishing far more among average human beings than attempts at legal compulsion.”⁵⁷

Similarly, the European countries with the highest levels of immunization — Sweden, Norway, Denmark, the Netherlands, and the United Kingdom — have achieved those levels without compulsion.⁵⁸ Mandates are not needed in Europe because all children have a regular source of primary health care, including organized vaccine services.⁵⁹ But even when people have routine access to primary care, organization matters. In the related context of routine Pap smears, European experience demonstrates that whether

⁵⁵ See KAISER COMM'N ON MEDICAID & THE UNINSURED, *THE UNINSURED: A PRIMER*, 6 (2007), available at <http://www.kff.org/uninsured/upload/7451-03.pdf> (finding over 46 million Americans — 18% of population — lack health insurance); Robin M. Weineck et al., *Racial and Ethnic Difference in Access to and Use of Health Care Services, 1977-1996*, 57 *MED. CARE RES. & REV.* 36, 42 (2000) (finding approximately 17% of Americans had no usual source of care in 1996 and among Hispanic and African Americans, 30% and 20%, respectively); Robin M. Weineck & Nancy A. Krauss, *Racial/Ethnic Differences in Children's Access to Care*, 90 *AM. J. PUB. HEALTH* 1771, 1772 (2000) (finding approximately 8.7% of all children in 1996 had no usual source of medical care and among Hispanic and African American children, 17.2% and 12.5%, respectively).

⁵⁶ COLGROVE, *supra* note 31, at 10.

⁵⁷ Mattias Nicoll, *The Age of Public Health*, 27 *N.Y. ST. J. MED.* 114, 116 (1927).

⁵⁸ Daniel A. Salmon et al., *Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, and Future*, 367 *LANCET* 436, 440 (2006).

⁵⁹ *Id.* at 436.

women receive recommended tests is significantly influenced by whether public health officials organize a screening or whether the screening is “opportunistic,” meaning it is left to the discretion of individual patients and doctors.⁶⁰ Organized programs are far more effective than opportunistic testing.

The critical issue may not be whether a vaccine is mandatory or voluntary, but rather whether there is an organized effort to assure wide availability. As recently as the 1940s and 1950s, voluntary U.S. vaccination campaigns against polio and smallpox succeeded because there were large public and private commitments to publicize and make vaccinations available.⁶¹ In recent decades, the United States has not seen such organized, voluntary, and widespread public health campaigns.⁶² Instead, the United States has relied primarily on school-based mandates to promote vaccination. School-based vaccination requirements are a relatively recent development in U.S. history. From 1968 to 1981, the percentage of states requiring at least one vaccination for school attendance went from 50% to 100%.⁶³

The effectiveness of school vaccination mandates is illustrated by a natural experiment that took place from 1970 to 1971 in Texarkana.⁶⁴

⁶⁰ Marc Arbyn, *Cervical Cancer Prevention in Europe*, 64 ENTRE NOUS, EUR. MAG. SEXUAL & REPROD. HEALTH 10, 10 (2007), available at <http://www.euro.who.int/document/ens/en64.pdf> (reporting nine countries with organized HPV screening programs have high rates of HPV screening while in countries dependent on opportunistic screening, screen women too often or not at all).

⁶¹ COLGROVE, *supra* note 31, at 10. In 1938, polio’s most famous victim, President Franklin D. Roosevelt, helped to create the National Foundation for Infantile Paralysis and a new philanthropic model based on small contributions from large numbers of people, resulting in the March of Dimes. *Id.* at 114-17. These groups worked with local and federal officials, first promoting research and then organizing mass vaccination campaigns. *Id.* at 114-49. Although by the 1960s, rates of vaccination had increased and the incidence of the disease declined, polio became concentrated among the poor and racial minorities. *Id.* at 132. With the infusion of federal funds during the Kennedy Administration, polio was largely eradicated. *Id.* at 145.

In another example, smallpox vaccination had waned in New York City until 1947, when a tourist brought the disease to the city, infecting several people. *Id.* at 75. In response to requests from public health officials, Mayor William O’Dwyer requested a special appropriation of half a million dollars to purchase and distribute the vaccine. *Id.* at 76. Over three weeks, “New York City witnessed one of the most extraordinary mobilizations of the population in its history. Each day, hundreds of thousands of people waited, sometimes for hours in the rain, in long lines that snaked around blocks.” *Id.* at 76. In a month, 6.35 million people, 80% of the population, were vaccinated. *Id.* at 76.

⁶² See *id.* at 114-49.

⁶³ *Id.* at 177.

⁶⁴ *Id.*

The town of Texarkana is located on the border of Texas, where measles vaccination was not required, and Arkansas, where it was. When an epidemic broke out, the rate of infection was twelve times higher in Texas than in neighboring Arkansas.⁶⁵ Soon after this epidemic, Texas mandated vaccination for school attendance, and the mandate withstood legal challenges ending when the Texas Supreme Court upheld the law in 1973.⁶⁶

Experience shows that, in the United States, high levels of childhood immunization are achieved only through vigorous enforcement of “no shots, no school” rules.⁶⁷ In the 1970s, levels of immunization remained low because school officials failed to enforce the rules; consequently, preventable diseases re-emerged.⁶⁸ Immunization rates rose in the 1970s and 1980s because state and local health officials pressured school authorities to enforce the rules, threatening school officials with fines and other sanctions.⁶⁹ Children are also more likely to receive vaccinations when mandates are enforced not only for entry into public school, but also for day care, college, or as an aspect of approved home-schooling.⁷⁰

If organized voluntary programs are more respectful than mandates, and are effective internationally, why has the United States come to rely upon school-based vaccination mandates? There are two basic answers. First, the United States does not have a comprehensive, organized health care service. Second, the United States does not have universal health insurance, or even universal coverage for the costs of vaccinations. While a school-based vaccination mandate does not automatically produce an organized program to provide and finance vaccination services, this section argues that in the United States mandatory programs, rather than those that are voluntary or opportunistic, are more likely to effectively address the critical issues of cost and access in this century.

⁶⁵ *Id.*

⁶⁶ TEX. EDUC. CODE ANN. § 38.001 (Vernon 2003); *Itz v. Penick*, 493 S.W.2d 506 (Tex. 1973).

⁶⁷ COLGROVE, *supra* note 31, at 200-08.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*; Saad B. Omer et al., *Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence*, 296 JAMA 1757, 1757 (2006) (reporting that, between 2000 and 2004, states permitting parents to refuse vaccination for personal, nonreligious reasons have lower levels of immunization, as do states that make it easy to claim exemption).

The cost and access problems associated with voluntary vaccination programs are particularly problematic for eleven- to fourteen-year-olds, the group for whom Gardasil is most beneficial. These problems exist because many girls in that age group do not have a regular source of medical care.⁷¹ By contrast, almost all infants receive medical care and vaccinations because most infants are born in hospitals with standards and professional norms requiring treatment including vaccinations.⁷² Dr. Jon S. Abramson, Chair of the ACIP when Gardasil received FDA approval for girls,⁷³ observed that, as a practical matter, universal vaccination can be achieved for newborns without a formal state mandate.⁷⁴ At the other end of childhood, when young people become sexually active, there are incentives to seek regular medical care to prevent pregnancy and sexually transmitted diseases.⁷⁵ Family planning clinics serve this purpose, providing counseling about HPV and vaccination. As such, family planning clinics constitute a major source of health care information and services to low-income and minority women, precisely those who are at highest risk for cervical cancer.⁷⁶ However, many middle school children — eleven- to fourteen-year-olds for whom Gardasil is most likely to be helpful — are too young for family planning clinics and thus do not have regular visits with a health care provider.⁷⁷ In sum, a voluntary program for

⁷¹ *Supra* note 55; See Matthew M. Davis et al., *Physician Attitudes and Preferences About Combined Tdap Vaccines for Adolescents*, 31 AM. J. PREVENTIVE MED. 176, 176 (2006).

⁷² Joyce A Martin et al., *Births: Final Data for 2005*, 56 NAT'L VITAL STAT. REP. 1, 18, 70 tbl.27 (2007), available at http://www.cdc.gov/nchs/data/nvsr/nvsr56/nvsr56_06.pdf (reporting 99% of 2005 births were in hospitals).

⁷³ Ctrs. for Disease Control & Prevention, *supra* note 3, at 16.

⁷⁴ Telephone Interview with Dr. Jon S. Abramson, Chair, Advisory Comm. on Immunization Practice, in Wash., D.C. (Aug. 14, 2007).

⁷⁵ In 2002, one-third of all women 15 to 24 who obtained any reproductive health services did so at a family planning clinic. Rachael Benson Gold, *Challenges and Opportunities for U.S. Family Planning Clinics in Providing the HPV Vaccine*, 10 GUTTMACHER POL'Y REV. 8, 11 (2007). For many of these young women, a periodic family planning visit may be their only contact with a medical care professional. *Id.*

⁷⁶ *Id.* at 8.

⁷⁷ See Jonathan D. Klein et al., *Prior Health Care Experiences of Adolescents Who Enroll in SCHIP*, 17 J. HEALTH CARE FOR THE POOR & UNDERSERVED 789, 796, 797 tbl.4 (2006) (reporting 19% of all adolescents lacked usual source of care in year before SCHIP enrollment; among Hispanic and black adolescents, approximately 20% and 25% respectively lacked usual source of care); M. Diane McKee & Jason Fletcher, *Primary Care for Urban Adolescent Girls from Ethnically Diverse Populations: Foregone Care and Access to Confidential Care*, 17 J. HEALTH CARE POOR & UNDERSERVED, 759, 763, 765-66 tbl.2 (2006) (finding approximately 20% of adolescents lacked usual source of care).

eleven- to fourteen-year-olds will only reach those young women who affirmatively seek vaccination and are able to identify a willing health care provider, tasks that are particularly unlikely to be performed by that age group.

Because the United States lacks universal health care, a vaccination mandate necessarily involves funding considerations. The HPV vaccine is the most expensive childhood vaccine recommended by the CDC,⁷⁸ costing \$360 to immunize one child.⁷⁹ The problem of vaccine costs is not confined to HPV vaccinations. Between 1987 and 2003, the price paid by the CDC for the total package of recommended vaccinations rose from \$33.70 to \$436, both because the number of recommended vaccines increased and because the price of individual vaccines went up.⁸⁰ Between 1995 and 2007, the cost to fully vaccinate a child in the public sector rose from \$155 to \$1170.⁸¹

A small majority of girls and women in the United States are covered by private insurance.⁸² Private insurers typically follow ACIP guidelines and cover recommended vaccines.⁸³ In 2002, private sources — health insurance and out-of-pocket payments — financed 43% of the costs of childhood vaccinations.⁸⁴ However, even people with private insurance that includes coverage for vaccinations confront financial barriers because “[c]o-payments and deductibles can make

⁷⁸ See ASS'N OF ST. & TERRITORIAL HEALTH OFFICIALS, COST TO IMMUNIZE ONE CHILD IN PUBLIC SECTOR, available at <http://www.astho.org/pubs/2007HillCosttoimmunize1.pdf> (citing CDC data).

⁷⁹ See Kevin Outterson, *Patient Buy-Outs for Global Disease Innovations for Low- and Middle-Income Counties*, 32 AM. J. LAW & MED. 159, 166 (2006); ASS'N OF ST. & TERRITORIAL HEALTH OFFICIALS, *supra* note 78 (estimating federal government's contract price at \$290.25).

⁸⁰ Alan R. Hinman et al., *Financing Immunizations in the United States*, 38 CLINICAL INFECTIOUS DISEASES 1440, 1441 (2004) (noting that CDC's purchase price was substantially lower than drug companies' catalog price, e.g., \$33.70 versus \$115.99 in 1987 and \$436.87 to \$437.52 versus \$704.69 to \$739.20 in 2003).

⁸¹ Grace M. Lee et al., *Gaps in Vaccine Financing for Underinsured Children in the United States*, 298 JAMA 638, 638 (2007).

⁸² THE HENRY J. KAISER FAMILY FOUND., WOMEN'S HEALTH POLICY FACTS: FACT SHEET, HPV VACCINE: IMPLEMENTATION AND FINANCING POLICY 1 (2007), available at <http://www.kff.org/womenshealth/upload/7602.pdf>. In 2004, 58% of girls 9 to 18 were covered by employer-sponsored health insurance, and an additional 5% were covered by individual insurance. *Id.* at 1 tbl.1. Among women 19 to 26, 46% were covered by employer-sponsored insurance, and an additional 10% were covered by individual policies. *Id.*

⁸³ *Id.* at 1.

⁸⁴ Hinman et al., *supra* note 80, at 1440.

vaccination prohibitively expensive.”⁸⁵ Primary care doctors, who must make decisions about whether to stock and store vaccinations, are currently uncertain of whether and how many patients will seek the HPV vaccine. “Given the economic realities, some medical practices have chosen not to stock the vaccine until the price goes down or demand can be more reliably predicted.”⁸⁶ Some women who actively seek the vaccine, and are able to pay out-of-pocket, find that physicians are reluctant to provide it.⁸⁷ However, if the HPV vaccine were mandatory, it is likely that demand would become more certain, increasing the likelihood primary care doctors would stock the vaccine.

Unfortunately, private health insurance coverage for vaccinations is decreasing rapidly. Between 2003 and 2006, the proportion of employer-sponsored plans that excluded coverage for vaccination increased from 5% to 20%.⁸⁸ In 2006, only 34% of states required insurers to follow current ACIP or American Academy of Pediatrics recommendations for children and adolescents, while 49% of states had no rules requiring private insurance plans to cover particular services.⁸⁹ Sharp federal restrictions on a state’s authority to regulate employment-based insurance are a substantial barrier to state insurance mandates.⁹⁰ In response to the shrinking private insurance coverage for vaccinations, the federal Vaccines for Children (“VFC”) program became the most important single source of vaccination funding, paying for 41% of all children’s vaccinations in 2002.⁹¹

⁸⁵ Rebecca Gudeman, *High Cost of HPV Vaccine Limits Use in Surprising Way: The Problem with Private Insurance*, 28 YOUTH L. NEWS 1, 2 (2007), available at http://www.youthlaw.org/fileadmin/ncyl/youthlaw/publications/yln/2007/issue_2/YLN_APR_JUN_Article_1.pdf.

⁸⁶ *Id.* at 5.

⁸⁷ Julia Scirrotto, *Sex, Lies, and the HPV Vaccine*, MARIE CLAIRE, Feb. 2008, available at <http://www.marieclaire.com/life/healthy/health-tips/hpv-vaccine-sex-lies> (noting 26-year-old woman with private doctor and private insurance could only get vaccine by buying it herself and bringing it to doctor).

⁸⁸ Comm. on Child Health Fin., Am. Acad. of Pediatrics, *High Deductible Health Plans and the New Risks of Consumer-Driven Health Insurance Products*, 119 PEDIATRICS 622, 622 (2007) (reporting on changes in health insurance coverage); see Lee et al., *supra* note 81, at 642 (documenting unavailability of vaccines to uninsured children).

⁸⁹ Lee et al., *supra* note 81, at 641.

⁹⁰ Sylvia A. Law, *Do We Still Need a Federal Patients’ Bill of Rights?*, 3 YALE J. HEALTH POL’Y L. & ETHICS 1, 1 (2002).

⁹¹ Lee et al., *supra* note 81, at 641. This federally funded program pays for ACIP-approved vaccines for children under age 19 who receive care at a federally qualified health center and are Medicaid-eligible, uninsured, American Indians, Alaska Natives or those who have insurance that excludes vaccinations. Hinman et al., *supra* note 80, at 1442.

For a growing number of children, vaccinations are not covered by either private insurance or the VFC program. Children who have insurance that excludes coverage for vaccinations may obtain VFC funded vaccines only at federally qualified health centers, which are not available to many children.⁹² Between 2004 and 2006, states introduced new limits on publicly funded vaccines for underinsured children as a result of rising health care costs and new restrictions on the use of state and federal funds.⁹³

In 2007, while many states considered vaccination mandates,⁹⁴ other states, including New Hampshire, South Dakota, and Washington, launched voluntary programs to make the vaccine available free to eleven- to eighteen-year-old-girls.⁹⁵ In 2007, New Hampshire spent 28% of its immunization budget on HPV vaccines, half of which was funded by the federal government and half by private insurers.⁹⁶

Despite the enthusiasm and financial resources, many New Hampshire girls seeking vaccination through the public program confront a four-month wait.⁹⁷ Girls with private insurance or the ability to pay out-of-pocket receive the vaccine more quickly.⁹⁸ Some insurance companies deny coverage to girls who are eligible for a free vaccine under the state program.⁹⁹ Confronted with a shortage of the vaccine, New Hampshire doctors have “devised an elaborate triage system.”¹⁰⁰ In New Hampshire, the triage system favors girls who are sexually active, older, or have had an abortion.¹⁰¹ Given that the vaccine is not effective in sexually active girls infected with HPV,¹⁰² this makes no sense. In the state of Washington, the triage makes more sense, favoring girls who are eleven or twelve. South Dakota has

⁹² Ctrs. for Disease Control & Prevention, VFC: For Parents, <http://www.cdc.gov/vaccines/programs/vfc/parents/default.htm#eligible> (last visited Feb. 15, 2008).

⁹³ Lee et al., *supra* note 81, at 641.

⁹⁴ Nat'l Conference of St. Legislatures, *supra* note 53.

⁹⁵ Pam Belluck, *In New Hampshire, for One State, Soft Sell Eases Vaccine Fears*, N.Y. TIMES, May 12, 2007, at A1. Greg Moore, a spokesman for the Health and Human Services Department said, “I suspect that we’re not seeing a significant controversy because there was never a discussion about whether to make this mandatory.” *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Supra* notes 11-14 and accompanying text.

more vaccines than girls requesting it,¹⁰³ but there is no reason to believe that most girls are being vaccinated.

Perhaps one reason why states are having trouble achieving high levels of vaccination through voluntary programs is that it is not a priority among local health officials. For example, a local New Hampshire health official commented on the ease of running a voluntary HPV program when compared to running flu shot programs stating, “[w]e usually have to bust our hump every September to convince people to get their flu shots.”¹⁰⁴ Implicit in this statement is that the HPV program is easy because local officials commit less effort to HPV vaccinations than they commit to encourage flu vaccines. While flu vaccinations are not mandatory, a judgment has been made that public health officials should work hard to get flu vaccines to vulnerable people.

2. Mandatory HPV Vaccinations Do Not Violate the Constitution

Bedrock principles of U.S. constitutional and common law affirm that a competent adult has the “right to determine what shall be done with his own body,”¹⁰⁵ and parents may make medical decisions for their minor children.¹⁰⁶ Mandatory vaccinations are a major exception to these principles. All states require vaccinations for children entering school and for newborns.¹⁰⁷ State-mandated school immunization requirements have played a major role in achieving and maintaining low rates of vaccine-preventable diseases in the United States.¹⁰⁸

Given our strong legal and cultural commitments to individual and parental choice in relation to medical care, why do we make an exception for vaccinations? When smallpox was epidemic and caused massive death and disability, a general consensus supported laws mandating universal use of vaccinations.¹⁰⁹ Through the twentieth

¹⁰³ Belluck, *supra* note 95.

¹⁰⁴ *Id.*

¹⁰⁵ *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.).

¹⁰⁶ *See, e.g., Parham v. J.R.*, 442 U.S. 584, 602-03 (1979); *see also* Elizabeth J. Sher, Note, *Choosing for Children: Adjudicating Medical Care Disputes Between Parents and the State*, 58 N.Y.U. L. REV. 157, 163-66 (1983) (discussing varying ways state and federal courts approach issue of parental right to make medical decisions for their children).

¹⁰⁷ James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L.J. 831, 833 (2002).

¹⁰⁸ *See supra* notes 63-70 and accompanying text.

¹⁰⁹ COLGROVE, *supra* note 31, at 75-80.

century, as other vaccinations were developed and proved safe and effective, mandates expanded.¹¹⁰ Support for mandatory vaccination rests on both public health and paternalistic values. The public health justification for mandates reflects an ethical appreciation that no individual needs to be vaccinated against an infectious disease if everyone else is vaccinated. Nonetheless, it is broadly understood to be unfair to allow exceptions for “free riders” absent special and compelling circumstances.¹¹¹ Further, epidemiological research shows that near universal vaccination can eradicate deadly disease, but that even relatively minor exceptions can cause the disease to re-emerge.¹¹² In addition, paternalistic reasons — a desire to protect as many individuals as possible from deadly diseases — also support mandatory vaccination. In the twenty-first century, the question of mandatory vaccination must be situated in the context of “a broader social movement for patients’ rights and a rejection of medical paternalism, in a political climate in which the judgment of government and scientific elites is met with increasing cynicism and mistrust.”¹¹³ However, even in this context, significant public health considerations still justify vaccine mandates.

The states’ power to mandate vaccinations is not constitutionally controversial. In 1905 the Supreme Court considered a constitutional challenge to a Massachusetts rule requiring smallpox vaccinations when necessary for public health or safety.¹¹⁴ Plaintiff Henning Jacobson challenged the law, asserting basic rights of bodily integrity and personal autonomy, noting his prior bad experiences with vaccination.¹¹⁵ Justice John Marshall Harlan, writing for the Court, rejected his claims finding:

[T]he liberty secured by the Constitution of the United States . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its

¹¹⁰ Salmon et al., *supra* note 58, at 436.

¹¹¹ COLGROVE, *supra* note 31, at 3-4, 12-13.

¹¹² *Id.* at 12-13, 174-80. The concrete issues of herd immunity in relation to HPV are discussed *infra*; see text accompanying *infra* notes 166-71.

¹¹³ COLGROVE, *supra* note 31, at 187.

¹¹⁴ Jacobson v. Massachusetts, 197 U.S. 11, 37-39 (1905) (two Justices dissenting without opinion).

¹¹⁵ *Id.* at 37.

members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.

In dicta, Justice Harlan also suggested that vaccination mandates must be based on the “necessity of the case” and may not be exercised in “an arbitrary, unreasonable manner” or “go so far beyond what was reasonably required for the safety of the public.”¹¹⁶ The Court acknowledged that requiring a person to be immunized with knowledge that the vaccination would pose a special risk of harm to the particular person would be “cruel and inhuman.”¹¹⁷ Whether a medical necessity exemption to vaccination requirements is constitutionally required has never been tested because all states provide them.¹¹⁸ At the time of *Jacobson*, many respectable doctors questioned the wisdom of the smallpox vaccine, indicating that medical support for a vaccine need not be universal for a mandate to pass constitutional muster.¹¹⁹

In 1922, the Court extended *Jacobson* to children to rebuff parents’ claims that the Constitution protects their right to refuse vaccinations for their children. The Court affirmed the broad authority of school and public health authorities to determine the manner and types of vaccinations required.¹²⁰ Even if state legislatures have broad authority to mandate vaccines that prevent the spread of infectious diseases, claims of parental authority may be more powerful when the state demands vaccination against diseases that are not infectious, such as tetanus.¹²¹ However, in the case of the HPV vaccine, the mandate can be justified on both public health and paternalist grounds; people infected with HPV are personally at risk of various diseases and, unlike tetanus, can easily transmit the virus and risk of disease to others.

¹¹⁶ *Id.* at 28.

¹¹⁷ *Id.* at 38-39.

¹¹⁸ See Hodge & Gostin, *supra* note 107, at 856-58.

¹¹⁹ *Jacobson*, 197 U.S. at 34-35.

¹²⁰ *Zucht v. King*, 260 U.S. 174, 176-77 (1922).

¹²¹ Email from Martin Guggenheim, Fiorello LaGuardia Professor of Clinical Law, N.Y. Univ. Sch. of Law, to Sylvia A. Law, Elizabeth K. Dollard Professor of Law, Medicine & Psychiatry, N.Y.U. Sch. of Law (Sept. 18, 2007, 15:22 EST) (on file with author).

Jacobson has been widely followed in both state and federal constitutional interpretation and is rarely challenged.¹²² In response to September 11 and the subsequent anthrax attacks, the CDC released a model state law that authorized misdemeanor charges and quarantine for people who refused recommended vaccinations.¹²³ The proposal sparked criticism, with some suggesting *Jacobson* was no longer good law. Professor George Annas asserted, “[T]oday, almost 100 years after *Jacobson*, both medicine and constitutional law are radically different. We now take constitutional rights much more seriously, including the right of a competent adult to refuse any medical treatment, even life-saving treatment.”¹²⁴ To make this argument, Annas relied primarily on the Supreme Court’s 1990 decision in *Cruzan v. Director, Missouri Department of Health*.¹²⁵ In that case, five members of the Court upheld a state law providing that the parents of a woman in a persistent vegetative state could not remove her feeding tube unless they were able to present “clear and convincing evidence” that she would want the tube removed.¹²⁶ The question whether the state may constitutionally compel vaccination seems far removed from the issue of whether the state may impose a demanding showing of proof to remove life support for a person in a persistent vegetative state.¹²⁷ Specifically, infectious diseases create public health concerns that were not present in *Cruzan*. Moreover, the fact that HPV is such a highly infectious disease more directly implicates the valid concerns addressed by the *Jacobson* Court a century ago.

In summary, our state and federal constitutions give state authorities broad discretion to determine whether vaccines are required. In the case of HPV, delivering medical care to preteens presents particular challenges because many do not have a source of regular medical care

¹²² Hodge & Gostin, *supra* note 107, at 863-67 (summarizing cases).

¹²³ COLGROVE, *supra* note 31, at 242-43.

¹²⁴ George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 NEW ENG. J. MED. 1337, 1340 (2002); *see also* Wendy K. Mariner et al., *Jacobson v. Massachusetts: It’s Not Your Great-Great-Grandfather’s Public Health Law*, 95 AM. J. PUB. HEALTH 581, 581 (2005).

¹²⁵ 497 U.S. 261, 286-87 (1990).

¹²⁶ *Id.*

¹²⁷ *See* James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of Jacobson v. Massachusetts*, 95 AM. J. PUB. HEALTH 571, 571 (2005) (arguing *Jacobson* remains good law and noting courts uphold compulsory measures where threat to community is tenuous, such as laws requiring use of motorcycle helmets); Lawrence Gostin, *Jacobson v. Massachusetts at 100: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 576 (2005) (arguing *Jacobson* remains good law).

or insurance that covers vaccines. These challenges are particularly acute for people who have low incomes or are racially or culturally vulnerable. Achieving high levels of vaccination requires an organized and well-funded effort. Given the failures of voluntary vaccination programs in Texarkana and New Hampshire, states should require HPV vaccines through school attendance requirements.

B. Objections to Adding the HPV Vaccine to the List of Mandatory Childhood Vaccinations Do Not Withstand Scrutiny

This section focuses on HPV and examines specific objections to making the vaccination mandatory. It first describes the major groups that have raised concerns about the vaccination. It then considers and responds to the major objections raised.

Opposition to mandatory HPV vaccinations generally comes from sexual conservatives, some feminists and people of color, a lively antivaccination movement, and some public health authorities. For sexual conservatives, HPV is not a problem because of a belief that sex can and should be avoided until one is in a monogamous marriage with a desire to have children.¹²⁸ Some feminists question HPV vaccination mandates,¹²⁹ remembering times when the medical establishment rushed to promote insufficiently tested innovations that proved seriously harmful to women.¹³⁰ Similarly, some communities

¹²⁸ See *HPV Mandate Stirs Protest*, EDUC. REP., Mar. 2007, available at <http://www.eagleforum.org/educate/2007/mar07/HPV-mandate.html>; Phyllis Schlafly, *Experimenting on Teen Girls*, EAGLE FORUM, Mar. 7, 2007, <http://www.eagleforum.org/column/2007/mar07/07-03-07.html>. See generally CRISTINA PAGE, *HOW THE PRO-CHOICE MOVEMENT SAVED AMERICA: FREEDOM, POLITICS, AND THE WAR ON SEX* (2007) (showing right to life movement's vision of family opposes not only abortion, but also contraception, sex education, and all forms of sex not tied to marriage and open to procreation).

¹²⁹ For an excellent four-part series criticizing Gardasil and the process by which it has been promoted from a feminist perspective, see *Profit Knows No Borders, Selling Gardasil to the Rest of the World*, <http://www.prwatch.org/node/6263> (July 18, 2007); *Setting the Stage*, <http://www.prwatch.org/node/6186> (June 26, 2007); *Judith Siers-Poisson, Research, Develop, and Sell, Sell, Sell*, <http://www.prwatch.org/node/6208> (June 30, 2007); and *Women in Government, Merck's Trojan Horse*, <http://www.prwatch.org/node/6232> (July 10, 2007).

¹³⁰ In the 1960s, early versions of the contraceptive pill caused serious and unnecessary harm to women. See, e.g., *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657-58 (1st Cir. 1981) (discussing adequacy of Ortho-Novum 2mg warnings); BARBARA SEAMAN, *THE DOCTOR'S CASE AGAINST THE PILL* (1969) (documenting that early versions of pill were unnecessarily dangerous to women).

In the 1960s and 1970s, physicians prescribed Benedictine for morning sickness to a quarter of pregnant U.S. women until it was discovered that it caused serious birth

of color question HPV vaccine mandates¹³¹ because of past grievous harms committed by medical and public health experts targeting racial minorities.¹³²

One argument against the HPV vaccine mandate is that, unlike infectious diseases transmitted through the air or through casual contact, HPV is transmitted through sexual contact that can be avoided. Sharing this view against mandates are the conservative Family Research Council,¹³³ Dr. Jon S. Abramson,¹³⁴ and some

defects. Sylvia A. Law, *Tort Liability and the Availability of Contraceptive Drugs and Devices in the United States*, 23 N.Y.U. REV. L. & SOC. CHANGE 339, 368-72 (1997). In 1970, the Dalkon Corporation marketed its Dalkon Shield, an intrauterine contraceptive device ("IUD"), with little testing, resulting in needless death and infertility. *Id.* at 362-68. Contraceptive pills and IUDs are now very safe; some commentators say this is in part because of the challenges to the earlier, dangerous products. *See id.* at 381, 384-85.

¹³¹ See Karen Houppert, *Who's Afraid of Gardasil?*, NATION, Mar. 26, 2007, at 20 (describing Washington D.C. African American newspaper as strongly opposed to HPV vaccination mandates); Courtland Milloy, Op-Ed, *District's HPV Proposal Tinged with Ugly Assumptions*, WASH. POST, Jan. 10, 2007, at B01 (challenging proposed HPV vaccination mandate on grounds that it was based on racist assumptions about sexual activity of African American girls, paternalism towards their parents, and recalling past racist medical campaigns); Courtland Milloy, *Force Is Not the Only Way to Administer a Vaccine*, WASH. POST, Jan. 24, 2007, at B01 (advocating voluntary program like that adopted in New Hampshire). For a discussion of the New Hampshire program, see *supra* notes 95-104 and accompanying text.

¹³² From 1932 to 1972, the United States Public Health Service conducted a study of 399 black men with the goal of tracking the course of syphilis in the human body. Vanessa N. Gamble, *Under the Shadow of Tuskegee: African Americans and Health Care*, 87 AM. J. PUB. HEALTH 1773, 1773 (1997). None of the men with syphilis were told they had it, and no treatment was offered. *Id.* It is considered one of the worst ethical failures in public health, and President Bill Clinton issued a formal apology in 1997. *Id.* As a result, some African American groups believe that HIV/AIDS is a government-created conspiracy and form of genocide. Stephen B. Thomas & Sandra C. Quinn, *The Tuskegee Syphilis Study, 1932-1972: Implications for HIV Education and AIDS Risk Education Programs in the Black Community*, 81 AM. J. PUB. HEALTH 1498, 1498-99 (1991) (describing Tuskegee Study and describing these theories); see Darryl Fears, *Study: Many Blacks Cite AIDS Conspiracy*, WASH. POST, Jan. 25, 2005, at A02 (reporting results of survey of African American beliefs about origin of AIDS). As another example of targeting particular groups, poor women and women of color were subject to various forms of coerced sterilization through the twentieth century. *See generally* Johanna Schoen, *Between Choice and Coercion: Women and the Politics of Sterilization in North Carolina, 1929-1975*, 13 J. WOMEN'S HIST. 132 (2001) (discussing history of forced sterilization of poor women and women of color in North Carolina).

¹³³ Family Research Council, *supra* note 46. The Eagle Forum argues that a mandate is "unnecessary, inadvisable, and an assault on parental rights." HPV Mandate Stirs Protest, *supra* note 128. Phyllis Schlafly of the Eagle Forum notes that the vaccine is not necessary for "good girls who don't engage in premarital sex and don't need the vaccine. At the same time, girls who receive the vaccine will be given a

feminists. This argument underestimates the prevalence of sexual conduct among teens,¹³⁵ the unfortunate fact that not all sex is voluntary, and the fact that the vaccine is effective only if administered before acquiring the virus.

Also, vaccination requirements “do not exist solely to prevent the transmission of disease in school or during childhood. Instead, they further society’s strong interest in ensuring that people are protected from disease throughout their lives and are a highly efficient means of eradicating disease in the larger community.”¹³⁶ For example, every state requires that school children be immunized against rubella, even though the disease is typically mild in children. Children are immunized because of the need to protect pregnant women from the devastating effects that the disease can have on a developing fetus.¹³⁷ Similarly, every state requires vaccination against tetanus,¹³⁸ even though it is not contagious. Most states require vaccination against hepatitis B,¹³⁹ even though it is most often transmitted through sexual contact.

Others oppose mandating the HPV vaccine because they believe drug companies in general, and Merck in particular, cannot be trusted. Merck is one of the seven largest pharmaceutical companies in the world and holds the exclusive right to market the HPV vaccine in the United States.¹⁴⁰ Merck has a history of aggressive marketing.¹⁴¹ In

false sense of security that will be even more costly to them than the high-priced vaccine is to the public.” Schlafly, *supra* note 128.

¹³⁴ Telephone Interview with Dr. Jon S. Abramson, *supra* note 74.

¹³⁵ J. Dennis Fortenberry, *The Limits of Abstinence-Only in Preventing Sexually Transmitted Infections*, 36 J. ADOLESCENT HEALTH 269, 269 (2005); Mosher et al., *supra* note 12.

¹³⁶ Cynthia Dailard, *Achieving Universal Vaccination Against Cervical Cancer in the United States: The Need and the Means*, 9 GUTTMACHER POL’Y REV. 12, 14 (2006).

¹³⁷ *Id.*; see Hodge & Gostin, *supra* note 107, at 869-73.

¹³⁸ Hodge & Gostin, *supra* note 107, at 869-73.

¹³⁹ *Id.* (reporting 31 states mandate hepatitis B vaccine for school children); Charles Marwick & Mike Mitka, *Debate Revived on Hepatitis B Vaccine Value*, 281 JAMA 15, 16 (1999).

¹⁴⁰ See Donald G. McNeil, *How a Vaccine Search Ended in Triumph*, N.Y. TIMES, Aug. 29, 2006, at F1.

¹⁴¹ In 1999, the FDA approved Merck’s request to market rofecoxib (Vioxx). In 2004, after more than 80 million patients had taken this arthritis medication and annual sales had topped \$2.5 billion, Merck withdrew the drug because it caused heart attacks and strokes. Evidence in support of the drug had not been subject to peer review prior to approval and, in 2001, the professional FDA Arthritis Advisory Committee warned about the dangers of the drug and urgently called for further testing. Merck declined to do the testing but rather intensified its advertising and

2005, Merck began its award-winning campaign¹⁴² marketing the HPV vaccine even before the FDA approved the drug.¹⁴³ Critics regard the Merck campaign as exaggerating the problems associated with HPV in order to create a market, or more cynically, telling people that there is a problem when there isn't.¹⁴⁴ Alternatively, the Merck campaign can be seen as public education program to inform people of a problem of which they were not aware.¹⁴⁵

In addition to this massive public relations campaign, Merck launched a lobbying effort to encourage state legislatures to make Gardasil vaccinations mandatory. In its efforts to make Gardasil mandatory throughout the U.S., Merck lobbied decision makers in

promotional "educational" campaign. Eric J. Topol, *Failing the Public Health — Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707, 1707-08 (2004). Whether Merck's actions in relation to Vioxx were illegal or negligent is now being litigated. Associated Press, *Judge Rejects Merck's View on F.D.A. Issues*, N.Y. TIMES, July 4, 2007, at C2 (discussing district court's rejection of Merck argument that FDA approval provides drug company absolute immunity as "entirely unpersuasive"). In November 2007, Merck settled 27,000 lawsuits by people who claim that they or family members suffered injury or died after taking the drug. It may be the largest settlement in civil litigation. Alex Berenson, *Merck Agrees to Settle Vioxx Suits for \$4.85 Billion*, N.Y. TIMES, Nov. 9, 2007, at A1.

¹⁴² In February 2007, *Pharmaceutical Executive Magazine* named Gardasil the brand of the year. Siers-Poisson, *supra* note 129. Merck received many awards at the Pharmaceutical Research and Manufacturers of America ("PhRMA") May 2007 advertising awards ceremony. *Id.*

¹⁴³ Merck partnered with organizations that it helped to create — the Cancer Research and Prevention Foundation (CRPF) and a celebrity charity, Step Up Women's Network. With Merck's help, these groups created a campaign called "Make the Connection," publicizing the connection between HPV and cervical cancer through celebrity events and the popular media. *Id.* In 2006, the campaign transformed into "Make the Commitment," which urged women to discuss the connection between HPV and cervical cancer with their doctors. *Id.* When the FDA approved Gardasil in 2006, Merck launched a direct-to-consumer advertising campaign, "One Less," consisting of television, print, and online ads in which attractive girls urge others to be one less statistic, one less death from cervical cancer. *Id.* Later in 2007, Merck and its allies launched the "Tell Someone" campaign, urging women and girls to get out the word on HPV and cervical cancer. *Id.*

¹⁴⁴ See Siers-Poisson, *supra* note 129.

¹⁴⁵ Of Americans polled in the late 1990s, only 8% of men and 13% of women were able to identify HPV as a common STD when asked to name STDs of which they had heard. Kaiser Family Found., *The Tip of the Iceberg: How Big Is the STD Epidemic in the U.S.?*, 4 (Dec. 2, 1998), <http://www.kff.org/womenshealth/upload/the-tip-of-the-iceberg-how-big-is-the-STD-epidemic-in-the-u-s-q-a.pdf>. In 2005 only 40% of women aged 18 to 75 had heard of HPV and, of that group, less than half knew of its association with cervical cancer. Jasmine A. Tiro et al., *What Do Women in the U.S. Know About Human Papillomavirus and Cervical Cancer?*, 16 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 288, 289-90 (2007).

fifty states for its vaccine.¹⁴⁶ It is reasonable to criticize Merck's aggressive marketing and lobbying strategies. Professor Lawrence Gostin argued that "since the manufacturer stands to profit from widespread vaccine administration, it is inappropriate for the company to finance efforts to persuade states and public officials to make HPV vaccinations mandatory Private wealth should never trump public health."¹⁴⁷ However, Merck's behavior is typical of the U.S. pharmaceutical industry as a whole.

In 2002, drug companies spent almost twice as much on marketing, including lobbying and advertising, as they did on research and development.¹⁴⁸ But should these grave problems, endemic to the drug industry as a whole, lead to the rejection of any new drug developed by the U.S. pharmaceutical industry? Dr. Sydney Wolff,

¹⁴⁶ Six months after the FDA approved Gardasil, Texas Governor Rick Perry issued an executive order requiring that sixth grade girls receive the vaccination as a condition of admission to school starting in September 2008. Dan Frosch, *Texas House Rejects Order By Governor on Vaccines*, N.Y. TIMES, Mar. 14, 2007, at A14. The Texas legislature quickly reversed the Governor by a veto proof vote of 135 to 2. Ralph Blumenthal, *Texas Legislators Block Shots for Girls Against Cancer Virus*, N.Y. TIMES, Apr. 26, 2007, at A16. The legislators resented the fact that they were not consulted, hearings not held, and the issues not debated. *Id.* The Governor did not consult with his Republican colleagues who presided over the Texas House and Senate. Harvey Kronberg, editor of the legislative website Quorum Report, said: "This kind of imperiousness offended his base." *Id.* The legislature was also suspicious of Perry, who received \$6,000 from Merck for his reelection campaign. Women in Government, *supra* note 129.

Some commentators identify one group, Women in Government ("WIG") as particularly influential in Merck's campaign in the states. Women in Government, *supra* note 129. Founded in 1985, WIG is a nonprofit, nonpartisan organization of women state legislators. Women in Government, <http://www.womeningovernment.org> (last visited Mar. 26, 2008). The organization focuses on a broad range of women's issues, including Medicare and higher education policy. WIG receives funds from the Merck Foundation as well as over 60 corporate and professional organizations, including dozens of drug companies. Women in Government, Current Sponsors, http://www.womeningovernment.org/home/support_sponsors.asp (last visited Mar. 24, 2008). In Texas, Perry had family connections to the organization; Perry's 2007 chief of staff's mother-in-law, Texas Republican State Representative Dianne White Deliai, was a state director for Women in Government. His wife, Anita, a nurse by training, addressed a WIG conference on cervical cancer in Atlanta in 2005. Women in Government, *supra* note 129. Some critics see WIG as a tool of Merck or of the drug industry more generally. *Id.*

¹⁴⁷ Lawrence O. Gostin & Catherine D. DeAngelis, Editorial, *Mandatory HPV Vaccination: Public Health vs. Private Wealth*, 297 JAMA 1921, 1922 (2007).

¹⁴⁸ MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 37-51, 115-73 (2004); Steven S. Hall, 'The Truth About the Drug Companies' and 'Powerful Medicines': *The Drug Lords*, N.Y. TIMES, Nov. 14, 2004, § 7, at 8.

head of the respected Public Citizen Health Research Group, concluded that “just because self-interested corporate behavior is at the root of an initiative does not prove that the initiative is not worthwhile. Cervical cancer takes the lives of some 3700 American women each year. Preventing these deaths and the much more common costs of treating suspected cervical cancer is obviously an end worth pursuing.”¹⁴⁹ Indeed, critics of a Gardasil mandate may no longer tout Merck’s lobbying efforts as a basis for their argument because on February 20, 2007, Merck announced that it was suspending its campaign to persuade state governments to make Gardasil mandatory.¹⁵⁰ It seems that Merck decided that its aggressive lobbying campaign was counterproductive.

Merck is not the only organization that opponents to vaccine mandates criticize. The FDA, which approved Gardasil on a fast track basis,¹⁵¹ has also been subject of intense criticism in recent years.¹⁵² One journalist noted, “Safety and speed are the yin and yang of drug regulation These goals can be incompatible.”¹⁵³ In response to the 1980s HIV crisis, Congress was persuaded that the FDA process was too slow in approving life-saving drugs. Thus, in 1992, major reforms reduced the time of the drug-approval process by requiring drug companies to make contributions to finance the expedited process.¹⁵⁴ As the FDA has become more dependent upon pharmaceutical industry funding, the industry has insisted that its funds be used to expedite approval and not to monitor post-approval safety.¹⁵⁵ FDA leadership and scientific staff are regularly subjected to pressures from the industry to approve profitable drugs and ignore evidence of adverse side effects.¹⁵⁶ The FDA’s failure to conduct

¹⁴⁹ Q & A on the Human Papilloma Virus Vaccine Gardasil, *supra* note 50, at 1.

¹⁵⁰ Adam Sonfield, *Merck Backs Off Campaign to Make Cervical Cancer Vaccination School Entry Requirement for Preteen Girls*, 10 GUTTMACHER POL’Y REV. 23, 23 (2007).

¹⁵¹ Press Release, *supra* note 2.

¹⁵² COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYSTEM, NAT’L ACAD. OF SCIENCES, *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 4* (2007) [hereinafter *FUTURE OF DRUG SAFETY*] (reporting perception of crisis that has compromised credibility of FDA and pharmaceutical industry).

¹⁵³ Gardiner Harris, *Potentially Incompatible Goals at F.D.A.*, N.Y. TIMES, June 11, 2007, at A14 (reporting that informed observers believe that FDA does too little to assure drug safety).

¹⁵⁴ ANGELL, *supra* note 148, at 208.

¹⁵⁵ See *FUTURE OF DRUG SAFETY*, *supra* note 152, at 7.

¹⁵⁶ In 2002, for example, the industry vetoed one respected candidate for the FDA’s top job because, in the words of Senator Bill Frist, “he put too much emphasis on safety.” Hall, *supra* note 148, at 8; see also Gardiner Harris, *FDA Approves Broader*

follow-up testing and warn consumers of adverse reactions to approved drugs is particularly problematic.¹⁵⁷ While Congress has considered reforms, it has not acted, primarily because of influential opposition from the drug industry and the complexity of reform.¹⁵⁸

If the FDA is not to be trusted, how can parents, patients, and state lawmakers considering mandates rely on its assurance that Gardasil is safe and effective? Perhaps the debate about Gardasil will jumpstart a serious focus on much needed reform of federal pharmaceutical regulation. In the meantime, Dr. Wolff, a longtime critic of the FDA, suggested that we have no choice but to trust the FDA. While the fact that new drug studies are funded and conducted by the companies promoting the drugs “should always make one skeptical of the results reported, one cannot simply dismiss studies solely on the basis of who is their sponsor. To do so would lead to refusing to take almost all drugs.”¹⁵⁹ In addition, many in the medical, scientific, public health, and feminist communities continue to seek evidence about safety and efficacy.¹⁶⁰ In the case of the HPV vaccine, the costs of rejecting the vaccine mean that significant numbers of women will die of preventable cancer.

Yet another argument against requiring girls to be vaccinated against HPV is that if half the relevant infectious population (boys) is exempt from the mandate, there is no hope of achieving a high level of immunity. Individual girls might sensibly choose to be vaccinated but one important justification for mandatory vaccination is to achieve

Access to Next-Day Pill, N.Y. TIMES, Aug. 26, 2006, at A1 (noting that three years after scientific community recommended morning-after pill for over-the-counter distribution, FDA finally agreed, but only made it available without prescription to women over 18); Harris, *supra* note 153 (reporting FDA scientists who were pushed out after seeking stronger warning for known drug dangers). Political influence with medical and scientific regulation is not limited to the FDA. Gardiner Harris, *Surgeon General Sees 4-Year Term as Compromised*, N.Y. TIMES, July 11, 2007, at A1 (reporting that Surgeon General in Bush Administration was subject to greater political pressures than prior surgeons general).

¹⁵⁷ FUTURE OF DRUG SAFETY, *supra* note 152, at 11-14; Gardiner Harris, *At F.D.A., Strong Drug Ties and Less Monitoring*, N.Y. TIMES, Dec. 6, 2006, at A1 (documenting that FDA is too underfunded to do follow up on drugs in market).

¹⁵⁸ Diedtra Henderson, *Panel: FDA Needs More Power, Funds*, BOSTON GLOBE, Sept. 23, 2006, at B5 (describing congressional action).

¹⁵⁹ Q & A on the Human Papilloma Virus Vaccine Gardasil, *supra* note 50, at 3.

¹⁶⁰ The VAERS reporting system will allow researchers to monitor short-term adverse effects. *Supra* notes 31-35. Medical researchers will continue to investigate how long the protection of the vaccine lasts. *Supra* note 42. Data on the key question of reduction of cervical cancer incidence will not be available for many years. *Id.*

herd immunity¹⁶¹ by which an entire community is protected against a contagion because a sufficiently large percentage of the group is immune.¹⁶² While the question of what portion of the population must be vaccinated to achieve herd immunity remains controversial and varies among diseases and populations, studies over the years put the number at between 75% and 90% of the population.¹⁶³ Given that the HPV vaccine has only been approved for women and girls and mandated only as to them, it is currently impossible to achieve herd immunity, at least until the vaccine is approved for boys. If the vaccine is approved for boys, the argument for a mandate would be bolstered by the increased potential to completely eradicate HPV.

The benefits of herd immunity beg the question of why boys have been excluded from the Gardasil approval process. The most obvious answer is that they are not at risk of contracting cervical cancer. However, boys can become infected with HPV,¹⁶⁴ transmit the virus to others, and suffer from diseases other than cervical cancer, which are also associated with the HPV strains Gardasil protects against.¹⁶⁵ Preliminary studies suggest that the HPV vaccine has similar protective effects for boys,¹⁶⁶ though the FDA has not yet approved the vaccine for them.

The lack of Gardasil's approval for boys is disconcerting. In the twenty-first century, state and federal policies rarely differentiate explicitly on the basis of gender. Under the Equal Protection Clause, government gender classifications are unconstitutional unless they are supported by an "exceedingly persuasive justification."¹⁶⁷ What "exceedingly persuasive justification" supports these gender-based policies?

One response is that Merck only sought to have the vaccine approved for girls, and as a private company, Merck is entitled to engage in gender discrimination. But, public agencies are not

¹⁶¹ See COLGROVE, *supra* note 31, at 75-80. The other justification for mandatory vaccination is paternalistic, protecting individuals against serious diseases, whether or not infectious.

¹⁶² *Id.* at 3-4, 158-59, 169.

¹⁶³ *Id.*

¹⁶⁴ See Eileen F. Dunne et al., *Prevalence of HPV Infection Among Men: A Systematic Review of the Literature*, 194 J. INFECTIOUS DISEASES 1044, 1044 (2006).

¹⁶⁵ *Supra* note 11.

¹⁶⁶ Stan L. Block et al., *Comparison of the Immunogenicity and Reactogenicity of a Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16 and 18) L1 Virus-Like Particle Vaccine in Male and Female Adolescents and Young Adult Women*, 118 PEDIATRICS 2135, 2143 (2006).

¹⁶⁷ *United States v. Virginia*, 518 U.S. 515, 531, 534 (1996).

ordinarily authorized to engage in invidious gender discrimination because a private actor asks them to do so.¹⁶⁸ Merck could assert that it only tested the vaccine on girls because only women suffer the devastating consequences of cervical cancer. Because both private and public actors are constitutionally entitled to address problems “one step at a time,”¹⁶⁹ Merck decided to first address the area where its vaccine could prevent the most deaths, more specifically, deaths among women from cervical cancer. Furthermore, when Merck first sought FDA approval to undertake clinical trials of Gardasil, common sense may have supported taking one step at a time to recruit test subjects directly affected by the virus, namely women.

Despite these responses, gender-based classifications remain the subject of more demanding scrutiny than ordinary social and economic regulation.¹⁷⁰ More important, as the evidence that the vaccine is safe and effective grows, the justifications for limiting testing and mandates to girls decreases.¹⁷¹ This Article does not fully explore the claim that the gender-targeted research and mandate of the HPV vaccine is unconstitutional. It does, however, suggest that it is

¹⁶⁸ Merck’s choice to test and market only to females does not wholly immunize public agencies from claims of gender discrimination. The FDA’s response, “we just do what our customers ask,” may be similar to the airlines’ claims in the 1970s that they could only hire attractive young women as flight attendants because that was what the customers preferred. Courts have held that customer preference does not justify sex discrimination on the part of an actor prohibited from discriminating on the basis of sex. See *Diaz v. Pan Am. World Airways, Inc.*, 442 F.2d 385, 388-89 (5th Cir. 1971); *Wilson v. Sw. Airlines Co.*, 517 F. Supp. 292, 298 (N.D. Tex. 1981).

¹⁶⁹ *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955). In the constitutional terms applicable to public actors, “[i]t is no requirement of equal protection that all evils of the same genus be eradicated or none at all.” *Ry. Express Agency v. New York*, 336 U.S. 106, 110 (1949).

Evils in the same field may be of different dimensions and proportions, requiring different remedies. Or so the legislature may think. Or the reform may take one step at a time, addressing itself to the phase of the problem which seems most acute. . . . The prohibition of [equal protection] goes no further than invidious discrimination.

Williamson, 348 U.S. at 489 (citation omitted).

¹⁷⁰ Biology does not justify the gender-based distinction. Men are as capable as women of acquiring HPV. See *supra* note 164. Like women, HPV exposes men to increased risk of cancer. See *supra* note 23. Real differences do not automatically justify sex-based classifications. *Craig v. Boren*, 429 U.S. 190, 200 (1976) (holding difference in drinking ages unconstitutional even though evidence showed men are more likely than women to drink and drive).

¹⁷¹ See Jan Hoffman, *Vaccinating Boys for Girls’ Sake*, N.Y. TIMES, Feb. 24, 2008, at ST1 (observing responsible men want HPV immunization).

worth considering whether the public conversation about the HPV vaccine would be different if the vaccine prevented 3700 premature deaths and much larger numbers of traumatic medical interventions among men every year. Even if gender discrimination is not a valid legal claim, the gendered focus of the HPV vaccine should inform our thinking.

C. *The Case for Mandatory HPV Vaccination*

It is difficult for politicians to think about consequences beyond the next election, or for business people to think about the bottom line beyond a short horizon. Obviously, it is even more difficult to think about consequences twenty or thirty years out. The women who will die of cervical cancer in my lifetime had no opportunity to avoid HPV. Why should we worry about the unnecessary, premature deaths of our grandchildren or great-grandchildren? Although the answer seems obvious, it is difficult to translate into either political or market terms.

Generally, there are two reasons why states should add HPV vaccination to the list of mandatory school vaccinations. First, as noted earlier in Part II.A, young people are far more likely to receive timely vaccination prior to contracting the virus if vaccination is mandatory. If not vaccinated now, thousands of women will die unnecessarily from cervical cancer in twenty or thirty years, and thousands more will undergo costly and traumatic testing that the vaccine may prevent. Second, the positive impact of making a vaccine mandatory is greatest for low-income people and racial minorities. Disproportionately large numbers of those women who suffer and die unnecessarily will be women of color who may be saved by the vaccine.¹⁷²

In the twenty-first century, it is well-documented that African Americans and other people of color receive less adequate medical care than white people.¹⁷³ This results partly because people of color are more likely to be poor and uninsured.¹⁷⁴ In addition, when researchers control for wealth, insurance, education, medical conditions, test results, and all other factors, people of color

¹⁷² *Infra* notes 173-79.

¹⁷³ See RONALD D. SMEDLEY ET AL., *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* 29 (2002); *id.* at 39-79 (finding sizeable racial and ethnic disparities in health care, even after adjusting for socioeconomic differences and other facts relating to health care access).

¹⁷⁴ RAND ROSENBLATT ET AL., *LAW AND THE AMERICAN HEALTH CARE SYSTEM*, 108-11 (1999).

systematically receive medical care that is inferior to that provided to white people.¹⁷⁵ It is therefore not surprising that there are marked racial and ethnic disparities in immunization levels among adults.¹⁷⁶ African American women are 50% more likely to experience cervical cancer than white women, and African American mortality rates from cervical cancer are more than twice as high.¹⁷⁷ African Americans are not the only affected minority; Hispanic women have the highest levels of cervical cancer in the nation.¹⁷⁸ This pattern of health disparity, which negatively affects people of color, does not exist with respect to childhood immunization,¹⁷⁹ thus illustrating that school-based mandates are a particularly effective way to address racial disparities that are otherwise pervasive in health care.

III. THREE APPROACHES TO ANSWERING THE QUESTION OF WHETHER, WHEN, AND HOW STATES SHOULD MANDATE HPV VACCINATION

One way in which states seek to balance the conflict between the public interest in encouraging vaccination against communicable diseases and individual interests in autonomy and physical integrity is to allow exemptions for individuals or for parents on behalf of their children. Every state exempts people who have a medical condition that makes them particularly susceptible to a vaccination's risks. All

¹⁷⁵ See, e.g., June Elchner & Bruce C. Vladeck, *Medicare as a Catalyst for Reducing Health Disparities*, 24 HEALTH AFF. 165 (2005) (detailing racial disparities and missed opportunities to use Medicare to address them); Arnold M. Epstein, *Health Care in America — Still Too Separate, Not Yet Equal*, 351 NEW ENG. J. MED. 603 (2004) (detailing that 22% of doctors serve 80% of black patients); Marsha Lillie-Blanton & Caya B. Lewis, *Policy Challenges and Opportunities in Closing the Racial/Ethnic Divide in Health Care* (Kaiser Family Found.), Mar. 2005, at 1, available at <http://www.kff.org/minorityhealth/upload/Policy-Challenges-and-Opportunities-in-Closing-the-Racial-Ethnic-Divide-in-Health-Care-Issue-Brief.pdf> (documenting ignorance of race-based health care disparities among public and physicians).

¹⁷⁶ CR Stein et al., *Racial/ethnic Disparities in Influenza and Pneumococcal Vaccination Levels Among Persons Age ≥ 65 Years — United States, 1989-2001*, 52 MORBIDITY & MORTALITY WKLY. REP. 958, 958 (2003).

¹⁷⁷ See, e.g., Ctrs. for Disease Control & Prevention, *Cervical Cancer, Compare by Race and Ethnicity*, <http://www.cdc.gov/cancer/cervical/statistics/race.htm> (last visited May 1, 2008).

¹⁷⁸ Gold, *supra* note 75, at 11.

¹⁷⁹ Press Release, Ctrs. for Disease Control & Prevention, *Racial Disparities in Childhood Immunization Coverage Rates Closing* (Sept. 14, 2006), available at <http://www.cdc.gov/od/oc/media/pressrel/r060914.htm> (reporting that for first time in past 10 years, rates for full series of recommended vaccines did not vary significantly by race and ethnicity).

but two states allow exemptions for religious reasons and about half the states exempt those who object for reasons of conscience.¹⁸⁰

The conflicts between public health and individual autonomy are even more complex when considering mandatory vaccination of children. Traditionally, parents make medical decisions for children. For Gardasil to be legitimately accepted as a mandatory vaccine for children, both individual autonomy claims and claims that parents should be able to decide what is best for their children need to be addressed. This part describes the complex landscape of parental consent to medical treatment and vaccination. It considers three approaches addressing parental choice in mandatory HPV vaccination for their children. First, states could mandate the vaccination and allow broad parental opt-out. Second, states might reject an HPV vaccine mandate because it is better to have no mandate at all than have a politically acceptable mandate with a broad parental opt-out. Third, states may mandate vaccination without parental opt-out, except for medical reasons.

In the United States, no government has any general power “to standardize its children.”¹⁸¹ This right to a “private realm of family life which the state cannot enter”¹⁸² was made with an explicit recognition that family cultures differ.¹⁸³ The tradition of respect for family autonomy has remained strong in U.S. culture and constitutional law,¹⁸⁴ despite the original assumption that autonomy was based in part on the view that the man was the family decision maker and women and children were his property.¹⁸⁵

¹⁸⁰ Hodge & Gostin, *supra* note 107, at 874 n.23.

¹⁸¹ Parental control over the medical treatment of children is one aspect of the fundamental U.S. cultural and constitutional assumption that “[t]he child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and prepare him for additional obligations.” *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925) (holding law requiring children to attend public schools unconstitutional).

¹⁸² *Meyer v. Nebraska*, 262 U.S. 390, 401 (1923) (holding that state may not prohibit students from learning foreign language).

¹⁸³ The Supreme Court noted that in Plato’s vision of the ideal commonwealth, measures for the collective training and education of children “have been deliberately approved by men of great genius.” *Id.* at 401.

¹⁸⁴ *See, e.g., Moore v. City of E. Cleveland*, 431 U.S. 494, 494 (1977) (holding that Fourteenth Amendment protects right of grandmother and grandchildren to live together despite single-family zoning law). *But see Dandridge v. Williams*, 397 U.S. 471, 488 (1970) (holding that state may deny additional welfare when more than four children live in family).

¹⁸⁵ The type of family formerly venerated by English and U.S. law was controlled by men and regarded both women and children as a form of property. Sylvia A. Law,

In protecting parents' authority to make medical decisions for their children, the common law draws a sharp distinction between procedures required to save the life of a child and those that are required or recommended to improve conditions that may be serious but not life threatening. In cases involving life-threatening injuries or conditions, courts can override parents' objections, including religious objections, to permit procedures to save a child's life.¹⁸⁶ A vaccine that protects against cervical cancer could be seen as a form of life-saving treatment. To do so, however, would require a liberal interpretation of existing principle because the risk of contracting cancer by HPV is statistical and remote.

In addition to the principle that parents cannot deny their children life-saving treatments, there are numerous other exceptions to the rule that parents are entitled to make medical choices for their children. While state rules vary, most states allow children to consent to medical treatment without parental involvement in a number of situations.¹⁸⁷ The principle seems to be that the decision-making autonomy of older minors is respected "when the treatment is relatively low risk, and when denying access may cause the minor (or the public at large) to suffer permanent harm."¹⁸⁸

The patchwork of exceptions for older minors, and the principles underlying it, do little to resolve questions about HPV vaccinations and vaccinations more generally for teens or preteens. Perhaps consent to the HPV vaccine could be regarded as treatment for a sexually transmitted disease, allowed in all states without parental consent.¹⁸⁹ But this also seems a stretch given that the vaccine prevents rather than treats already acquired sexual transmitted diseases.

The Founders on Families, 39 U. FLA. L. REV. 583, 589-91 (1987); Lawrence Schlam & Joseph P. Wood, *Informed Consent to the Medical Treatment of Minors: Law and Practice*, 10 HEALTH MATRIX 141, 141 (2000).

¹⁸⁶ James G. Dwyer, *Parents' Religion and Children's Welfare: Debunking the Doctrine of Parents' Rights*, 82 CAL. L. REV. 1371, 1397-99 (1994); Elizabeth J. Sher, *Choosing for Children: Adjudicating Medical Care Disputes Between Parents and the State*, 58 N.Y.U. L. REV. 157, 161 (1983).

¹⁸⁷ Kimberly M. Mutcherson, *Whose Body Is It Anyway?: An Updated Model of Health Care Decision-Making Rights for Adolescents*, 14 CORNELL J.L. & PUB. POL'Y 251, 263-67 (2004) (describing law on parental decision-making for children and noting that parental involvement is not required when children seek contraceptives; treatment for substance abuse, sexually transmitted diseases, prenatal care, or mental illness; or in emergencies); see also Rhonda Gay Hartman, *Coming of Age: Devising Legislation for Adolescent Medical Decision-Making*, 28 AM. J. L. & MED. 409, 416-27 (2002).

¹⁸⁸ Mutcherson, *supra* note 187, at 270.

¹⁸⁹ *Id.* at 264.

Under the Constitution, states are free to mandate vaccinations without making allowance for religious or conscientious objections by parents.¹⁹⁰ In the 1944 case of *Prince v. Massachusetts*, the Supreme Court considered the claims of a Jehovah's Witness convicted of violating child labor laws after taking her nine-year-old niece and ward with her to distribute religious literature on the streets of their town. In denying her First and Fourteenth Amendment challenges to the child labor laws, Justice Wiley Rutledge famously wrote: "Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."¹⁹¹ Distributing literature on a public street is unlikely to make a martyr of a nine-year-old, but the Court held that state legislatures are entitled to enforce child labor laws over the religious objections of the parents. By contrast, denying a HPV vaccine to young women may lead to increased deaths from cervical cancer,¹⁹² particularly among minority women.¹⁹³ If a state can enforce labor laws against a parent's religious beliefs, it should also be able to enforce a life-saving vaccine to protect children despite a parent's objections.

While states are not constitutionally required to provide exemptions for the parents of children who object to vaccination on religious grounds, states are free to do so and most have provided such exemptions.¹⁹⁴ Lower courts are divided on whether a state may limit exemptions to parents who object on religious grounds, rather than other forms of deep moral objections.¹⁹⁵

¹⁹⁰ Because states typically allow exemption from mandatory vaccination requirements for parents with religious objections, there are few legal decisions addressing whether such exemptions are constitutionally required. Hodge & Gostin, *supra* note 107, at 859. Nonetheless, "requesting a person to submit to vaccination against his religious beliefs is generally viewed as constitutional." *Id.* For example, the Mississippi Supreme Court found that when mandatory school vaccination requirements "conflict with the religious beliefs of a parent, however sincerely entertained, the interests of the school children must prevail." *Brown v. Stone*, 378 So. 2d 218, 223 (Miss. 1979).

¹⁹¹ *Prince v. Massachusetts*, 321 U.S. 158, 170 (1944).

¹⁹² *See supra* notes 7-13.

¹⁹³ *See supra* note 13.

¹⁹⁴ *See* Hodge & Gostin, *supra* note 107, at 859.

¹⁹⁵ *See* *McCartney v. Austin*, 293 N.Y.S.2d 188, 192-93, 200 (1968) (rejecting claims based on "deep moral convictions" by chiropractors and Catholics seeking exemption under New York law for adherents of "recognized" or "established" religions). *Compare* *Kleid v. Bd. of Educ.*, 406 F. Supp. 902, 907 (W.D. Ky. 1976) (holding that exemption for members of established religion does not violate

As a practical matter, the availability of exemptions affects the level of vaccination. When exemptions are broad and freely given, diseases that can be prevented through vaccination re-emerge.¹⁹⁶ Even if exceptions are narrowly drawn, many school authorities rubberstamp requests for exemption, and vaccine opponents offer Internet services that easily enable people to qualify for exemptions.¹⁹⁷ In some states, exemption from vaccination requirements on the basis of personal belief is so freely available that “it is easier to claim this exemption than to complete the school immunization form that requires a health care clinician to obtain the child’s medical record and transcribe the dates of vaccine administration.”¹⁹⁸

One approach is to mandate HPV vaccine with broad parental opt-out provisions. The organization Legal Momentum supports this approach and finds that such provisions “are vital to preserving individual decision making.”¹⁹⁹ A mandate, even with a broad opt-out provision, helps to command the attention of public health and education officials to organize programs to provide vaccinations to all girls whose parents do not object.²⁰⁰ Under a mandatory vaccination program, it is more likely that vaccines will be offered to racial

Establishment Clause), with *Dalli v. Bd. of Educ.*, 267 N.E.2d 219, 223 (Mass. 1971) (holding equal protection prohibits states from granting exemptions to objectors from recognized church or religious denomination while denying it to others with sincere religious objections), and *Brown v. Stone*, 378 So. 2d 218, 233 (Miss. 1979) (finding religious exemption violates Equal Protection Clause because it “discriminate[s] against the great majority of children whose parents have no such religious convictions”). *Contra Sherr v. Northport-E. Northport Union Free School Dist.*, 672 F. Supp. 81, 97 (E.D.N.Y. 1987) (upholding exemption for parents with “sincere religious beliefs,” but holding that requirement that they be “bona fide members of a recognized religious organization” violated Establishment Clause).

¹⁹⁶ COLGROVE, *supra* note 31, at 174-80; Omer et al., *supra* note 70, at 1758; Daniel A. Salmon et al., *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles*, 281 JAMA 47, 47 (1999) (reporting exemptors were 35 times more likely than vaccinated persons to contract measles).

¹⁹⁷ Donald G. McNeil Jr., *Worship Optional: Joining a Church to Avoid Vaccines*, N.Y. TIMES, Jan. 14, 2003, at F1 (“A lot of states call their exemptions religious, but anyone who wants it, gets it.” (quoting Daniel A. Salmon of Johns Hopkins University School of Public Health)); see also Jennifer S. Rota et al., *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*, 91 AM. J. PUB. HEALTH 645, 645 (2001) (reporting that most states routinely grant medical exemptions that last forever once granted).

¹⁹⁸ Omer et al., *supra* note 70, at 1758.

¹⁹⁹ Legal Momentum, *supra* note 45 (“We encourage states to make opt-out provisions accessible for parents who object to vaccination.”).

²⁰⁰ *Supra* notes 67-70 (discussing how mandates increase vaccination levels).

minorities, the uninsured, and low-income children.²⁰¹ Vaccination levels are likely to be higher under a mandatory program; lives will be saved, and other serious harms avoided.²⁰²

At the same time, a broad parental opt-out allows a political safety valve for parents with strong feelings. The broad opt-out allows Legal Momentum to criticize conservative groups for taking “stealth positions [which] assert that parents should have a ‘choice’ about vaccination rather than having states mandate it. Using the smokescreen of parental choice, vaccination opponents are playing politics with public health.”²⁰³

Another approach is to reject HPV mandates because of the practical political reality that such mandates will likely include broad parental opt-outs. Lawrence Gostin, an influential public health scholar and a strong supporter of mandates, opposes mandates for Gardasil.²⁰⁴ The heart of Gostin’s argument is that it is more important to preserve other mandatory vaccinations that limit the sweep of parental opt-outs than it is to add mandates that offer broad exemptions. “The use of compulsion [for HPV vaccination], therefore, could have the unintended consequence of heightening parental and public apprehensions about childhood vaccinations. It also does not help to offer generous religious and conscientious exemptions for HPV vaccinations because legislators may extend these to other childhood vaccinations, which would be detrimental to the public’s health.”²⁰⁵ Dr. Jon. S. Abramson, former Chair of the Advisory Committee on Immunization Practice of the CDC, takes a similar position, advocating for HPV vaccination, but opposing an HPV vaccine mandate.²⁰⁶

²⁰¹ *Supra* note 178-79 (discussing racial and economic disparities in relation to mandatory vaccinations).

²⁰² *Supra* text accompanying notes 8-10 (discussing HPV’s harms).

²⁰³ Legal Momentum, *supra* note 45; see also Ross D. Silverman, *No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure Public Health Protection*, 12 ANNALS HEALTH L. 277, 294 (2003) (suggesting law should require parents to meet with health professional to discuss risks and benefits of immunization and exemption and to renew their exemptions from time to time).

²⁰⁴ Gostin & DeAngelis, *supra* note 147, at 1922.

²⁰⁵ *Id.* at 1923.

²⁰⁶ Telephone Interview with Dr. Jon S. Abramson, *supra* note 74. Dr. Neal Halsey, Director of the Institute for Vaccine Safety at the Johns Hopkins Bloomberg School of Public Health, commenting on the speed with which Gardasil moved from approval to mandate in 2007, said, “For many of us in public health who have been involved in immunization and state laws, it’s been too quick. You want the demand to come from the public who realize the potential benefits from the vaccine, not to be imposed upon them.” Gold, *supra* note 75, at 10-11.

A third approach is to mandate HPV vaccination and to limit parents' authority to opt-out of vaccinations for their children, except for medical reasons. Proponents of this approach argue the choice of whether to mandate a vaccine should be social, and mandates should have few exceptions. Children should not be denied the protection of vaccination because of their parents' religious, conscientious, scientific, or political beliefs. Opposition from parents, or other concerned citizens, should be an essential factor in determining whether to make a vaccination mandatory. But when the state decides to make the vaccine mandatory, individual exceptions should not be allowed because it is difficult to distinguish between parents who have religious, conscientious, or scientific objections and those who are simply free riders. In addition, herd immunity can be achieved only through a broad mandate for boys and girls with a narrow parental exemption.²⁰⁷ Further, a process scrutinizing the legitimacy of parents' decisions to withhold vaccination would be cumbersome and costly. Professor Martin Guggenheim observed, "If the bases for the mandatory vaccine are great enough to prevail in the first place, it is problematic to permit the uncertainties to resurface when discussing the parents' objection as applied to their child."²⁰⁸

CONCLUSION

Approximately 10,000 women in the United States are diagnosed with cervical cancer each year. Of those, nearly 4000 die. HPV is strongly associated with these deaths as well as other harmful diseases, and Gardasil prevents transmission of HPV. The prevalence of sexual activity and HPV infection rates in the United States, combined with the public health and scientific evidence demonstrating the effectiveness of Gardasil, support routine HPV vaccination for girls between the ages of eleven and fourteen. In the absence of a universal health care financing and delivery system in the United States, school-based mandates are currently the only mechanism with the potential to achieve widespread vaccination. In addition, such mandates have the benefit of proven effectiveness in reducing racial disparities in childhood vaccination levels.

²⁰⁷ See *supra* notes 161-66.

²⁰⁸ Email from Martin Guggenheim, *supra* note 121. Professor Guggenheim is a strong, informed, sophisticated advocate of parents' rights. See generally MARTIN GUGGENHEIM, WHAT'S WRONG WITH CHILDREN'S RIGHTS (2005) (discussing children's rights, especially those antagonistic to parents' rights).

Although public health principles support vaccination mandates with narrow medical exemptions, opposition to HPV vaccination mandates with broad parental opt-out are the next best choice. While there is valid concern among some public health advocates that broad parental opt-out provisions for HPV vaccination might threaten continued success of other important school-based vaccine mandates, the risk of such danger materializing is uncertain and speculative. In contrast, the health risks of HPV infection are certain and preventable, and school-based mandates should be adopted.