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MANDATING HPV VACCINATIONS IN THE UNITED STATES

Anthony D. Pegion

Andrew Zacher

INTRODUCTION

Like many jurisdictions throughout the United States, the New York State Legislature currently has proposals to mandate immunization against the human papillomavirus (HPV).¹ One such proposal, New York State Assembly Bill A699, is broad in scope and “[p]rovides for the immunization of all children born after January 1, 1996, with the Human Papillomavirus [vaccine].” As stated in the bill, the proposed legislation would be read with New York State’s existing mandatory vaccination statute and thus, if passed, would require all female students in the State of New York to be vaccinated with the HPV vaccine in order to attend school.²

New York’s existing vaccination statute allows parents to exempt their children from mandatory immunizations based upon medical or religious grounds.³ The exemption is authorized through an informed consent procedure.⁴ However, unlike 21 other states, New York’s vaccination statute does not allow for exemptions based upon philosophical or other personal grounds.⁵ In a 2002 decision, a Federal District Court in Arkansas overturned a similarly worded statute, finding

1. S.B. 98, 2011 Gen. Assemb., Reg. Sess. (N.Y. 2011)., “[e]ncourag[ing], through the provision of written educational materials and consultation, the voluntary vaccination against human papillomavirus (HPV) for school-aged children by their parents or guardians”; *see also* Assemb. B. A699, 2011 Gen. Assemb., 234th Sess. (N.Y. 2011), mandating the Human Papillomavirus vaccination for all children born after 1996.

2. Assemb. B. A699, 2011 Gen. Assemb., 234th Sess. (N.Y. 2011), N.Y. PUB. HEALTH LAW § 2164 (2007). While the text of the bill reads “all children,” the only HPV vaccination approved by the FDA can only be administered to females; therefore the law would only be applicable to female students.

3. *Id.* at § 2164(6).

4. *Id.*

5. *See Id.* at § 2164. Twenty-one States allow parents to exempt their children from mandatory vaccination based upon ethical or philosophical grounds. *See* ARK. CODE ANN. § 6-18-702(d)(4)(B); ARIZ. REV. STAT. § 15-873(A)(1); CAL. HEALTH & SAFETY CODE § 120325(b); C.R.S. 25-4-903(2)(b); IDAHO CODE ANN § 39-4802; IND. CODE § 20-17.2-6-11; LA. REV. STAT. § 17:170(A); ME. REV. STAT. tit. 20A § 6355(3); MICH. COMP. LAWS § 333.9215(2); MIN. STAT. § 121A.15; NEB. REV. STAT. § 79-221(2); N.D. CENT. CODE § 23-07-17.1(3); N.M. STAT. ANN § 24-5-3(A)(3); OHIO REV. CODE § 3313.67; OKLA. STAT. tit. 70 § 1210.191; PA. CONS. STAT. 28 § 23.84(b); UTAH CODE ANN. 1953 § 53A-11-302(3)(b)(ii); TEX. EDUC. CODE ANN. § 38.001(c)(1)(B); VT. STAT. ANN. Tit. 18, § 1122(a)(3); WASH. REV. CODE § 28A.210.090; WIS. STAT. § 252.04(3).

that the religious exemption clause in that State's mandatory vaccination statute unconstitutional under the First Amendment's Establishment and Free Exercise Clauses.⁶ In light of this decision, the Arkansas Legislature amended the State's mandatory vaccination statute to include a provision that gives parents the ability to exempt their children from vaccination based upon any philosophical, personal, religious or medical ground.⁷

Given the unique nature of this particular virus, this article argues that Assembly Bill A699 should be amended to include a provision that would allow parents to exempt their children, specifically from immunization against HPV, through informed written consent based upon philosophical or personal grounds in addition to medical or religious grounds.⁸ Moreover, by analyzing the legal, moral, and ethical basis for state mandated vaccinations, this article argues that the legislation proposed in Assembly Bill A699, if properly amended to include additional language allowing for parents to exempt their children based on philosophical or personal beliefs, is not only as beneficial as other state mandated vaccines, but also as necessary.

This article will begin by providing background about HPV and the recently developed vaccine. Next, the constitutional basis for state mandated vaccinations, as well as an examination of the law in other jurisdictions will be discussed. By analyzing both the religious and economic aspects of the proposed legislation, this article will conclude by addressing the inherent moral and ethical arguments it encounters. This article will focus on New York's legislative proposals to argue that mandatory HPV laws should provide parents the ability to exempt their children from being vaccinated based upon philosophical or personal grounds. New York's mandatory HPV vaccination proposal should only be enacted with this amendment.

HPV BACKGROUND

To better understand the controversies surrounding the HPV vaccination, it is essential to examine both the impact and the severity of this virus. The Centers for Disease Control (CDC) has classified HPV as the most common sexually transmitted disease.⁹ According to the New York State Department of Health, "[i]t is estimated that 20 million people

6. See *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002).

7. *Id.* at § 6-18-702(d)(4)(B).

8. Assemb. B. A699, 2011 Gen. Assemb., 234th Sess. (N.Y. 2011).

9. *Human Papillomavirus Virus (HPV)*, CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), <http://www.cdc.gov/hpv/WhatIsHPV.html>.

in the U.S. are currently infected with HPV, and over 6 million new HPV infections are diagnosed each year.”¹⁰ It is predicted that somewhere between 50-80% of sexually active men and women will acquire the HPV infection at some point in their lives.¹¹

According to the CDC, HPV is most often contracted during vaginal and anal sex, but may also be passed through other sexual activities including oral sex and genital-to-genital contact.¹² What makes HPV especially troubling, in addition to its prevalence, is that the virus can be passed on even if the infected partner has no signs or symptoms.¹³ According to the CDC, “[m]ost infected persons do not realize they are infected or that they are passing the virus on to a sex partner.”¹⁴

Unfortunately, this virus can also have severe consequences. According to the New York State Department of Health:

Research has shown that 99.7% of cervical cancers are caused by HPV infection. There are 120 different types of HPV of which 35 are linked to infection of the genital tract. Genital HPV types are divided into low-risk and high-risk types based on their potential to cause cervical and other lower genital tract cancers.¹⁵

Similarly, the American Cancer Society recently noted that roughly “500,000 pre-cancerous cell changes of the cervix, vagina, and vulva are diagnosed each year in the United States,” half of which are related to two of the high risk strands of HPV.¹⁶ In 2007, the American Cancer Society predicted that there would be approximately “11,150 new cases of invasive cervical cancer in the United States . . . of which an estimated 3,670 women [would] die.”¹⁷

Gardasil, created by the American pharmaceutical company Merck Corporation (Merck), was the first vaccine developed to prevent cervical

10. *Questions and Answers about Human Papillomavirus (HPV) Vaccine*, NEW YORK STATE DEPARTMENT OF HEALTH, http://www.health.state.ny.us/prevention/immunization/human_papillomavirus.

11. *Id.* (“Based on national estimates, 80% of sexually active men and women will acquire HPV infection at some point in their lives.”); CDC, *supra* note 7 (“At least 50% of sexually active people will have genital HPV at some time in their lives.”).

12. *Genital HPV Infection CDC Fact Sheet*, CDC, <http://www.cdc.gov/std/HPV/STDFact-HPV.htm#howget>.

13. *Id.*

14. *Id.*

15. NEW YORK STATE DEPARTMENT OF HEALTH, *supra* note 10.

16. *Human Papillomavirus (HPV), Cancer, and HPV Vaccine, Frequently Asked Questions*, AMERICAN CANCER SOCIETY, http://www.cancer.org/docroot/CRI/content/CRI_2_6x_FAQ_HPV_Vaccines.asp.

17. Katherine A. Fortune, *Medical Miracle Or Unnecessary Exercise? The Legal Implications Of Mandatory Childhood Vaccination For HPV*, 85 UDTMLR 203, 205 (2008).

cancer caused by the high-risk HPV Types 16 and 18, which account for 70% of cervical cancer.¹⁸ Studies conducted on more than 20,000 women have shown that the vaccine reduces the rate at which young women between 16 and 23 years of age contract the virus by 90-100%.¹⁹ However, in order to have any efficacy, the vaccine must be given prior to contracting the virus; this emphasizes the importance of vaccinating young women prior to sexual activity.²⁰

LEGAL BACKGROUND

Historically, compulsory vaccination laws have been upheld based on the state police powers.²¹ However, these mandates have often been challenged on constitutional grounds.²² As a result, several common exceptions to mandatory vaccination laws allow parents to opt out of vaccination programs; these exceptions generally include medical, religious, and philosophical objections, or personal grounds.²³ This section details the judicial precedents that have allowed mandatory vaccination statutes to be upheld based on the police powers. Additionally, this section describes the constitutional bases that provide parents the ability to choose not to have their children vaccinated.

Police Powers

Pursuant to the police power, which is derived from the 10th Amendment of the Constitution, States have the authority to enact laws that are reasonably related to the health, safety, morals and general welfare of the public.²⁴ The Supreme Court has interpreted the police power to include the authority to mandate vaccinations.²⁵ Mandatory vaccines

18. Carrie A. Roll, *The Human Papillomavirus Vaccine: Should It Be Mandatory Or Voluntary*, 10 J. HEALTH CARE L. & POL'Y 421, 424-25 (2007).

19. *See id.* at 425.

20. *See id.*

21. *See Jacobson v. Mass.*, 197 U.S. 11 (1905); *see also Adams v. Milwaukee*, 228 U.S. 572 (1913).

22. *See Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 887 (Ark. 1951); *see also McCartney v. Austin*, 293 N.Y.S. 2d 188, 200 (1968)

23. *See* ARK. CODE ANN. § 6-18-702(d)(4)(B); ARIZ. REV. STAT. § 15-873(A)(1); CAL. HEALTH & SAFETY CODE § 120325(b); C.R.S. 25-4-903(2)(b); IDAHO CODE ANN § 39-4802; IND. CODE § 20-17.2-6-11; LA. REV. STAT. § 17:170(A); ME. REV. STAT. tit. 20A § 6355(3); MICH. COMP. LAWS § 333.9215(2); MIN. STAT. § 121A.15; NEB. REV. STAT. § 79-221(2); N.D. CENT. CODE § 23-07-17.1(3); N.M. STAT. ANN § 24-5-3(A)(3); OHIO REV. CODE § 3313.67; OKLA. STAT. tit. 70 § 1210.191; PA. CONS. STAT. 28 § 23.84(b); UTAH CODE ANN, 1953 § 53A-11-302(3)(b)(ii); TEX. EDUC. CODE ANN. § 38.001(c)(1)(B); VT. STAT. ANN. Tit. 18, § 1122(a)(3); WASH. REV. CODE § 28A.210.090; WIS. STAT. § 252.04(3).

24. *Lochner v. N.Y.*, 198 U.S. 45, 53 (1905) (*citing* U.S. CONST. AMEND. X).

25. *Jacobson v. Mass.*, 197 U.S. 11 (1905).

forschool entrance has been widely accepted and judicially sanctioned.²⁶

One of the first cases in American jurisprudence that dealt with a vaccination statute dates back to 1830.²⁷ New York City enacted its own local vaccination ordinance for smallpox in 1862.²⁸ In 1905, the issue finally reached the Supreme Court in *Jacobson v. Massachusetts*, where the Court upheld a Massachusetts statute that fined citizens who refused to receive smallpox vaccinations because the vaccination was deemed necessary for public health and safety.²⁹ In *Jacobson*, the Court relied on the state's police power to uphold the law, specifically finding that although the limits of a state's police power are not distinctly defined, it is within the state police power to enact laws to protect public health and safety.³⁰ Based on this finding, the Court upheld a Massachusetts statute because it was deemed necessary for the public health or safety.³¹ The Court did, however, stress that its holding was not intended to allow the police power to be used in an arbitrary or oppressive way.³² The Court definitively held that it is constitutional for a state to mandate vaccines so long as certain criteria are satisfied.³³

According to *Jacobson*, first the law must be enacted to "safeguard the public health and the public safety."³⁴ Second, there must be a "reasonable relationship between the public health intervention and the achievement of a legitimate public health objective."³⁵ Specifically, the method adopted must bear a "substantial relation to those objects," and

26. See *id.*; see also *Adams v. Milwaukee*, 228 U.S. 572, 581-82 (1913) (The Supreme Court reaffirmed *Jacobson's* holding that states may delegate the power to order vaccinations to local municipalities for the enforcement of public health regulations.); *Zucht v. King*, 260 U.S. 174, 176 (1922) (holding that vaccination laws do not discriminate against schoolchildren to the exclusion of others similarly situated, i.e., children not enrolled in school); *Prince v. Mass.*, 321 U.S. 158 (1944) (The Court held generally that the right to practice religion does not include the liberty to jeopardize the well being of minors.); *Seubold v. Fort Smith Special Sch. Dist.*, 237 S.W.2d 884, 887 (Ark. 1951) (Mandatory school vaccination does not deprive individuals of liberty and property interests without due process of law.); *McCartney v. Austin*, 293 N.Y.S. 2d 188, 200 (1968) (New York vaccination law does not interfere with freedom to worship because Roman Catholic faith does not proscribe vaccination.).

27. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 857-58 (2001-02) (citing *Hazen v. Strong*, 2 Vt. 427 (1830)).

28. See *id.* at 851 (citing Letter from Lewis A. Sayre to the Hon. Geo. Opdyke, Mayor of the City of New York, President of the Board of Commissioners of Health 5 (Feb. 27, 1862) (on file with author)).

29. *Id.* at 27.

30. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 25 (1905).

31. *Id.* at 27.

32. *Id.* at 38.

33. See *Jacobson*, 197 U.S. at 11.

34. *Id.* at 25.

35. Tracy Solomon Dowling, *Mandating a Human Papillomavirus Vaccine: An Investigation into Whether Such Legislation is Constitutional and Prudent*, 34 AM. J.L. & MED. 65, 68 (2008).

not simply “a plain, palpable invasion of rights.”³⁶ Lastly, it is required that the “measure itself not pose a health risk to the subject.”³⁷

In 1922 the Supreme Court extended the *Jacobson* ruling in *Zucht v. King*.³⁸ In that decision, the Court expanded the state’s police power by upholding a San Antonio city ordinance that required compulsory vaccination before a child could attend the city’s public schools.³⁹ The Court reasoned that *Jacobson*, and other Supreme Court decisions such as *Laurel Hill Cemetery v. San Francisco*, had given the states the power to “delegate to a municipality [the] authority to determine under what conditions health regulations shall become operative.”⁴⁰

Currently, all 50 states and Washington, D.C., have laws mandating vaccines for children to attend school.⁴¹ Like most jurisdictions, New York’s vaccination statute is based on the CDC’s Vaccine Recommendation Schedule.⁴² Currently, the recommendation schedule includes the HPV vaccination, which the New York State Legislature is now considering.⁴³

Constitutional Challenges

Commonly included in mandatory vaccination statutes are four possible exemptions, which are medical, religious, and philosophical objections, or personal grounds.⁴⁴ However, in accordance with *Jacobson*, all mandatory vaccination statutes provide some medical exemption that allows parents to exempt their children from vaccination in the event that the child would be harmed.⁴⁵ However, states vary on granting exemptions based upon either religious, philosophical or personal grounds.

For instance, New York’s vaccination statute provides an exemption

36. *Jacobson*, 197 U.S. at 31.

37. Dowling, *supra* note 29.

38. *Zucht v. King*, 260 U.S. 174, 176 (1922) (citing *Laurel Hill Cemetery v. San Francisco*, 216 U.S. 358 (1899)).

39. *See id.* at 175.

40. *Id.* at 176 (stating, “[Jacobson] and others had also settled that a State may, consistently with the Federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative.”)

41. *See Fortune*, *supra* note 17, at 206; *see, e.g.*, N.Y. PUB. HEALTH § 2164(2); ARK. CODE § 6-18-702(d).

42. *See* N.Y. PUB. HEALTH LAW § 2164; *Recommended Immunization Schedule For Persons Aged 7 Through 18 Years, CENTERS FOR DISEASE CONTROL*, <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/7-18yrs-schedule-pr.pdf>.

43. *Id.*

44. *See* James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 833 (2002) (discussing the various exemptions to state vaccination laws.).

45. *See Roll*, *supra* note 18 at 430.

based upon on religious grounds, but does not allow for exemptions on philosophical grounds.⁴⁶ The religious exemption in New York's statute states that the mandate "shall not apply to children whose parent, parents, or guardian hold genuine and sincere religious beliefs which are contrary to the practices herein required, and no certificate shall be required as a prerequisite to such children being admitted or received into school or attending school."⁴⁷

In regard to the HPV vaccination in particular, the major constitutional challenges include First Amendment Freedom of Religion and Fourteenth Amendment Due Process and Equal Protection. One way to ensure the constitutionality of a mandatory HPV vaccination statute is to provide a clause which allows parents to exempt their daughters from receiving the vaccine on philosophical or personal grounds in addition to medical or religious.

First Amendment Freedom of Religion

The Free Exercise Clause of the First Amendment, which is sacrosanct in American jurisprudence, states that "Congress shall make no law respecting an establishment of religion."⁴⁸ Although it has been held constitutional to request that all children become vaccinated, all but two states, Mississippi and West Virginia, allow parents to exempt their children from vaccination based upon religious objections.⁴⁹ As mentioned previously, New York's vaccination statute includes such a provision.

It is well settled that the Supreme Court has recognized that the Free Exercise clause grants individuals certain protections from state interference with their religious practices or beliefs.⁵⁰ However, these protections are not absolute. In the landmark decision addressing the First Amendment right of Free Exercise, *Prince v. Massachusetts*, the Supreme Court held that, "the family itself is not beyond regulation in the public interest, as against a claim of religious liberty[] [a]nd neither rights of religion nor rights of parenthood are beyond limitation."⁵¹ Furthermore, in *dictum*, the Court explicitly stated that parents "cannot claim freedom from

46. See N.Y. PUB. HEALTH LAW § 2164.

47. PUB. HEALTH § 2164(9).

48. U.S. CONST. AMEND. I.

49. See Hodge, *supra* note 24, at 874; MISS. CODE § 41-23-37; W. VA. CODE § 16-3-4.

50. See, e.g., *Emp't Div. v. Smith*, 494 U.S. 872 (1990); *Wis. v. Yoder*, 406 U.S. 205 (1971); *Sherbert v. Verner*, 374 U.S. 376 (1963); *Torcaso v. Watkins*, 367 U.S. 488 (1961).

51. *Prince*, 321 U.S. at 166-67 (*citing* *Reynolds v. U.S.*, 98 U.S. 145 (1878); *Davis v. Beason*, 133 U.S. 333 (1890)).

compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.”⁵²

However, in *Wisconsin v. Yoder*, a case also decided under the Free Exercise Clause, the Supreme Court held that a state’s interest in mandatory education was not so compelling that “the established religious practices of the Amish must give way.”⁵³ The Court further held:

[A] State’s interest in universal education, however highly we rank it, is not totally free from a balancing process when it impinges on fundamental rights and interests, such as those specifically protected by the Free Exercise Clause of the First Amendment, and the traditional interest of parents with respect to the religious upbringing of their children.⁵⁴

The Court’s decisions in *Prince* and *Yoder* demonstrate that while First Amendment religious freedom is a fundamental right, it is capable of being restrained depending upon the particular circumstances.

More recently, the Supreme Court’s interpretation of the Free Exercise Clause has narrowed.⁵⁵ The Supreme Court has held that cases similar to *Yoder* such as *Employment Div., Dept. of Human Resources of Oregon v. Smith*, in which the Court is dealing with religious freedom and parental child rearing rights, are in fact a hybrid between First Amendment religious rights and Fourteenth Amendment Due Process rights, which triggers strict scrutiny.⁵⁶

However, in *Boone v. Boozman*, a Federal District Court in Arkansas made a compelling argument in rejecting the plaintiff’s contention that a hybrid theory of rights should have been employed, and thus triggering strict scrutiny in deciding whether or not to vaccinate her daughter. In that case, plaintiff opposed vaccinating her daughter on religious grounds despite not being a member of any specific church.⁵⁷ The plaintiff contended that:

[S]he was a deeply religious person and felt strongly that [her daughter] should not have to “defile” her body by injecting it

52. *Id.* at 166 -67.

53. *Yoder*, 406 U.S. at 221.

54. *Id.* at 214.

55. *See Emp’t Div.*, 494 U.S. at 882.

56. *See id.*

57. *Id.* at 944.

with the Hepatitis B vaccine.” She stated that her beliefs came from revelations she received on a regular basis from God, and what she perceived to be her personal relationship with God.⁵⁸

Despite her objections, the Arkansas School District informed the plaintiff that her daughter could no longer attend school because she did not have the required Hepatitis B vaccine. The district refused to grant an exemption based upon her personal religious convictions.⁵⁹ In its decision, the Court recognized that under a hybrid rights theory, “the Court may apply strict scrutiny to neutral laws of general applicability because a Free Exercise claim is conjoined with other constitutional protections such as . . . the right of parents to direct the education of their children.”⁶⁰

In its analysis, the Court detailed the relevant Supreme Court cases decided under a hybrid rights theory, like *Yoder*, and ultimately held:

The key characteristic of these cases is that they relate to educational instruction. Plaintiff’s desire that her daughter not be immunized has no relation to her directing her daughter’s education, other than it may limit where and how she receives that education. A parent’s constitutional right to direct the education of her child is not implicated under the facts of this case, and thus plaintiff cannot proceed under a “hybrid rights” theory.⁶¹

Furthermore, in *Boozman* the Court noted that the Supreme Court frowned upon extending strict scrutiny with regard to mandatory vaccination laws, and therefore refused to extend it in this case.⁶² The Court noted that the Supreme Court frowned upon extending strict scrutiny with regard to mandatory vaccination laws, and therefore refused to extend it in this case.⁶³ Nevertheless, the First Amendment analysis does not end there. Regardless of the strength that the Supreme Court currently gives to the Free Exercise Clause standing alone against mandatory vaccination statutes, the fact remains that all but two states have chosen to include religious exemption provisions in their statutes.⁶⁴ By providing religious exemptions, states have created an entirely new constitutional issue with

58. *Id.*

59. *Id.* at 942.

60. *Id.* at 953 (citing *Emp’t Div.*, 494 U.S. at 881-82).

61. *Id.* at 955.

62. *Id.* at 953 (citing *Emp’t Div.*, 494 U.S. at 888-89).

63. *See id.*

64. *See Hodge, supra* note 24, at 874; Miss. Code § 41-23-37; W. Va. Code § 16-3-4.

regard to how religion is defined under the statute.

The Court in *Boozman* further held that the Arkansas mandatory vaccination statute's provision providing for a religious exemption was facially unconstitutional.⁶⁵ The now repealed statute read in pertinent part:

The provisions of this section shall not apply if the parents or legal guardian of that child object thereto on the grounds that immunization conflicts with the religious tenets and practices of a recognized church or religious denomination of which the parent or guardian is an adherent or member.⁶⁶

First, the Court held that the statute violated the Establishment Clause of the First Amendment because it only provided exemptions for those who adhere to "the commands of a particular religious organization," and not for those who opposed immunization on grounds of "personal religious beliefs."⁶⁷ Second, the Court held that the statute violated the Free Exercise Clause of the First Amendment because when "the State elects to accommodate religion on a particular issue like immunization, it is simply not constitutionally permissible for it to indulge the free exercise rights of some individuals and inhibit the free exercise rights of others on an arbitrary basis."⁶⁸ In its ruling, the Court held that it was "difficult to imagine how the State would have a compelling interest in limiting the religious exemption to some religious sects and individuals over others."⁶⁹

In light of this decision, it is difficult to imagine that New York's vaccination statute would not be subject to the same scrutiny if ever challenged. New York's religious exemption provision states in pertinent part:

This section shall not apply to children whose parent, parents, or guardian hold *genuine and sincere religious beliefs* which are contrary to the practices herein required, and no certificate shall be required as a prerequisite to such children being admitted or received into school or attending school.⁷⁰

65. See *Boozman*, 217 F. Supp. 2d at 952.

66. *Id.* at 942 (quoting ARK. CODE § 6-18-702(d)(2) (Repl.1999) (emphasis added)).

67. *Id.* at 947.

68. *Id.* at 951.

69. *Id.* at 951; see also *Thomas v. Rev. Bd.*, 450 U.S. 707, 714 (1981) ("religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection"); *Cooper v. Gen. Dynamics*, 533 F.2d 163, 166 n.4 (5th Cir. 1976) ("federal courts are powerless to evaluate the logic or validity of religious beliefs which are sincerely held").

70. N.Y. PUB. HEALTH LAW § 2164(2) (emphasis added).

Statutory exemptions that are specifically grounded upon religious belief, but then limited to “recognized church or religious denomination” or to “genuine and sincere religious beliefs” seem to be contrary to the very basic principles of the free exercise of religion and facially unconstitutional.⁷¹

Due Process

With regard to the Due Process Clause, the Supreme Court has held that individuals are afforded a “heightened protection against government interference with certain fundamental rights and liberty interests.”⁷² Specifically, in *Pierce v. Society of Sisters*, the Supreme Court held that parents and guardians have a liberty interest under the Due Process Clause “to direct the upbringing and education of children under their control.”⁷³ The Court held:

[R]ights guaranteed by the Constitution may not be abridged by legislation which has no reasonable relation to some purpose within the competency of the state. The fundamental theory of liberty upon which all governments in this Union repose excludes any general power of the state to standardize its children by forcing them to accept instruction from public teachers only. The 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.⁷⁴

Numerous states have recognized the fundamental rights of parents to include the right to exempt their children from mandatory vaccinations.⁷⁵ In addition to religious grounds, many states have statutorily extended this right to allow parents to exempt their children from being vaccinated based upon philosophical grounds.⁷⁶ Unfortunately, New York’s mandatory vaccination statute does not extend this right to parents.⁷⁷

71. ARK. CODE § 6-18-702(d)(2) (Repl. 1999); N.Y. PUB. HEALTH § 2164(2).

72. *Wash. v. Glucksberg*, 521 U.S. 702, 719 (1997).

73. *Pierce v. Society of Sisters*, 268 U.S. 510, 534-35 (1925) (*aff’d* *m. Troxel v. Granville*, 530 U.S. 57, 65 (2000)); *see also* *Meyer v. Neb.*, 262 U.S. 390 (1923) (overturning a state statute that attempted restrict teachers from teaching any language other than English because the Court found that there was a liberty interest in a parents right to direct the instruction of their children which included the teaching of a foreign language).

74. *Society of Sisters*, 268 U.S. at 535.

75. *See* Roll, *supra* note 18, at 431.

76. *Id.*

77. N.Y. PUB. HEALTH § 2164.

However, arguing whether or not the New York vaccination statute should be amended to include the right for all parents to exempt their children from mandatory vaccinations based upon philosophical grounds is beyond the scope of this particular article. Nevertheless, given the unique nature of HPV, New York should include a provision for nonreligious, philosophical exemptions in any proposed HPV vaccination law. As will be discussed below, other jurisdictions that have adopted similar HPV vaccination mandates have included a provision for a philosophical exemption even when the general vaccination statute includes no such provision.⁷⁸

Equal Protection

Pursuant to the Fourteenth Amendment's Equal Protection Clause, a state may not deny individuals equal protection of the law.⁷⁹ Moreover, the Equal Protection Clause "prohibits the government from intentionally discriminating against members of a protected class."⁸⁰ Although the mandatory vaccination statutes we have addressed thus far have been gender neutral, there is an apparent discriminatory impact because no male HPV vaccination exists. Therefore, it can be argued that mandating the HPV vaccination solely for young girls and not boys is tantamount to sex-based discrimination, and thus a direct violation of the Equal Protection Clause.

In the landmark decision regarding sex-based discrimination, *United States v. Virginia*, the Supreme Court held that intermediate scrutiny applies when conducting a constitutional analysis on sex-based discrimination.⁸¹ Under intermediate scrutiny, the state must demonstrate that there is an "important governmental objective[]" and that the discriminatory means employed are substantially related to the achievement of those objectives.^{82 83} Intermediate scrutiny is not as stringent as strict scrutiny, which requires that there to be a "compelling government interest," that the statute be narrowly tailored, and that the state employ the least restrictive means to accomplish their objective.⁸⁴

78. See VA. CODE § 32.1-46; D.C. CODE § 7-1651.04(b)(1)(B)(iii).

79. U.S. CONST. AMEND. XIV.

80. Lindsay Heinz, "Please, Don't Shoot My Daughter!" Is There Legal Support For State-Compelled HPV Vaccination Laws? Why Ethical, Moral and Religious Opposition To These Laws May Be Jumping The Gun, 56 U. KAN. L. REV. 913, 922 (2008) (citing Hodge, *supra* note 24, at 861).

81. See *U.S. v. Va.*, 518 U.S. 515 (1996).

82. *Id.* at 524.

83. *Id.*

84. *Gratz v. Bollinger*, 539 U.S. 244, 270 (2003).

The Supreme Court has held that a state violates equal protection when it denies women “simply because they are women.”⁸⁵ Furthermore, in another influential sex-based discrimination case, *Frontiero v. Richardson*, the Supreme Court held that “statutory distinctions between the sexes often have the effect of invidiously relegating the entire class of females to inferior legal status without regard to the actual capabilities of its individual members.”⁸⁶ Under intermediate scrutiny, the Court has held that laws that rely on archaic gender stereotypes are presumed invalid state interests.⁸⁷

In this instance, the state’s mandatory vaccination statute would not be based upon an archaic gender stereotype, nor would it deny women anything simply because they are women. This situation is most closely analogous to the one presented in another landmark Supreme Court decision, *City of Cleburne, Tex. v. Cleburne Living Center*. In that case, the lower courts had held that the city’s zoning ordinance, which required a special use permit for group homes for the mentally retarded, violated the equal protection clause because the mentally retarded were a quasi-suspect class.⁸⁸ However, the Supreme Court upheld the statute, holding that it was enacted to protect, not discriminate against, a group of people that are “different from other persons” and thus the State’s interest in “providing for them [was] plainly a legitimate one.”⁸⁹ To that end, state statutes targeting the vaccination of all female students would most likely pass intermediate scrutiny with regard to Equal Protection because the statute is aimed at achieving an “important government objective,” protecting women against cervical cancer.

Furthermore, those seeking to challenge HPV vaccination statutes would have an additional burden to overcome because the statutes are written in gender neutral language. When statutes do not explicitly draw gender distinctions in their text courts are reluctant to automatically apply the intermediate scrutiny test.⁹⁰ Instead, the burden is on the party bringing the challenge to first prove that the intent of the statute was to discriminate based on gender, regardless of the discriminatory impact.⁹¹

85. Va., 518 U.S. at 516.

86. *Frontiero v. Richardson*, 411 U.S. 677, 687-88 (1973).

87. See Va., 518 U.S. at 550.

88. See *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 435 (1985).

89. *Id.* at 432-33.

90. Niji Jain, *Engendering Fairness in Domestic Violence Arrests: Improving Police*, 60 EMORY L.J. 1011, 1027 (2011).

91. See *id.* (stating, “[w]hile classifications that are overtly or explicitly based on gender will automatically receive intermediate scrutiny, intermediate scrutiny is harder to invoke when the classification is neutral on its face but has an adverse impact on one gender. In these instances, a court will only

Therefore, in order to get a court to apply intermediate scrutiny, a challenger of a facially neutral HPV vaccination statute would have to prove that the statute has a discriminatory impact on females, and, furthermore, that the intent of the statute was to discriminate.

RECENT IMPLEMENTATION OF HPV VACCINATION LAWS

Over forty-one states and the District of Columbia have introduced legislation to require, fund, or educate the public about the availability of the HPV vaccine.⁹² Twenty-four of those states and the District of Columbia have introduced legislation that would mandate the vaccine for young girls for school attendance.⁹³ However, the proposed mandates, including those that have already passed, vary with regard to exceptions. These variations are based upon the language of the bills and the jurisdictions existing law.⁹⁴ This section highlights some of the various HPV vaccination statutes that have been enacted throughout the United States.

Texas

The first state to mandate the HPV vaccine for young girls in order to be admitted to school was Texas. This was done in 2007 through an Executive Order from the Governor Rick Perry.⁹⁵ The order included a provision that provided a mechanism for parents to opt-out of the mandate. Specifically, the opt-out provision “allow[ed] parents to submit a request for a conscientious objection affidavit form via the Internet while maintaining privacy safeguards under current law.”⁹⁶ However, “[l]egislators in Texas passed H.B. 1098 to override the executive order and the governor withheld his veto.”⁹⁷ Currently, statutory law states in pertinent part:

Immunization against human papillomavirus is not required for a person’s admission to any elementary or secondary school;

apply intermediate scrutiny if the plaintiff can demonstrate that the intent behind the policy was to discriminate against the gender that is disproportionately affected. Otherwise, even in the face of an extremely disparate impact on one gender, a facially neutral classification will receive rational basis review”).

92. *HPV Vaccine*, NATIONAL CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/default.aspx?tabid=14381#2009>.

93. *Id.*

94. *Id.*

95. Texas Exec. Order No. RP65 (Feb. 2, 2007), at <http://governor.state.tx.us/news/executive-order/3455/>.

96. *Id.*

97. NATIONAL CONFERENCE OF STATE LEGISLATURES, *supra* note 83.

however, by using existing resources, the Health and Human Services Commission shall provide educational material about the human papillomavirus vaccine that is unbiased, medically and scientifically accurate, and peer reviewed, available to parents or legal guardians at the appropriate time in the immunization schedule by the appropriate school. This subsection preempts any contrary executive order issued by the governor.⁹⁸

The current law, therefore, does not mandate HPV vaccinations despite Governor Perry's attempt to do so. Instead, the law broadly requires education materials about the HPV vaccine to be provided to parents and legal guardians.

Washington, D.C.

After a Congressional review in 2007, proposed legislation mandating the HPV vaccine in Washington, D.C. was enacted into law.⁹⁹ The District's current mandatory vaccination statute only allows exemptions on medical or religious grounds.¹⁰⁰ However, the District's HPV statute includes a specific exemption provision, which states in pertinent part:

The parent or legal guardian, in his or her discretion, has elected to opt out of the HPV vaccination program, for any reason, by signing a form prepared by the Department of Health that states the parent or legal guardian has been informed of the HPV vaccination requirement and has elected not to participate.¹⁰¹

It should be noted that the District's statute requires parents and legal guardians to sign a waiver in order to obtain exemption. The only other jurisdiction to currently mandate the HPV vaccine, Virginia, has a much more liberal exemption policy.

Virginia

In addition to the District of Columbia, Virginia is the only other jurisdiction to have mandated the HPV vaccine among the 20 states that

98. TEX. EDUC. CODE ANN. § 38.001(b-1).

99. NATIONAL CONFERENCE OF STATE LEGISLATURES, *supra* note 83.

100. D.C. CODE § 38-506(1)(2).

101. D.C. CODE § 7-1651.04(b)(1)(B)(iii).

have considered it thus far.¹⁰² Similar to D.C., the mandatory vaccination statute of Virginia only allows for medical or religious exemptions, and the Virginia legislature included a specific exemption provision with regard to HPV.¹⁰³ The Virginia statute provides:

Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent's or guardian's sole discretion, may elect for the parent's or guardian's child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.¹⁰⁴

The Virginia exemption policy with regard to the HPV vaccine is quite liberal; it allows parents or guardians simply to choose not to have their child vaccinated without having to sign a waiver of informed consent.¹⁰⁵ The statute does, however, require parents or guardians to review materials describing the link between HPV and cervical cancer before allowing them to opt-out of the mandatory vaccination requirement.

MORAL AND ETHICAL CONSIDERATIONS

The prospect of mandatory HPV vaccinations raises many moral and ethical concerns. A small number of pharmaceutical companies are poised to make immense profits from compulsory HPV vaccinations laws. Given the lobbying power of this industry, the issue of whether it is ethically permissible to enact a law that will provide a few private sector companies such a windfall arises. Additionally, mandating HPV vaccinations raises religious and moral concerns because the disease is contracted through sexual contact. This section provides a discussion of the ethical and moral concerns associated with HPV vaccinations.

Ethics and Economics

The pharmaceutical industry has been one of the most profitable and fastest growing sectors of the global economy in recent decades. Only a small number of powerful companies control the industry's ever growing influence over both the private and public sectors. Whether these

102. Yamiche Alcindor, *Schools Urging Girls To Get HPV Vaccine; Gardasil Optional for D.C., Va. Sixth-Graders*, WASH. POST (Aug. 21, 2009).

103. See VA. CODE § 32.1-46.

104. VA. CODE § 32.1-46(D)(3).

105. Alcindor, *supra* note 93.

companies' products are absolutely necessary in every instance is subject debate.

Currently, only two pharmaceutical companies worldwide, Merck and the United Kingdom's GlaxoSmithKline (GSK), produce the HPV vaccination.¹⁰⁶ However, despite the existence of multiple producers of the vaccine, there is "no apparent competition on price."¹⁰⁷ In addition to this lack of price competition, the HPV vaccination is the highest priced vaccination in human history.¹⁰⁸ In 2009, both Merck and GSK were ranked in Fortune Magazine's Global 500, among the world's 500 largest corporations.¹⁰⁹ Inevitably, this begs the question "as to whether this type of compulsory vaccination is truly a public health issue, or one motivated by the staggering profits Merck is poised to earn through widespread implementation."¹¹⁰

In addition, Merck's Gardasil only underwent a short six month review process by the Food and Drug Administration (FDA) before receiving approval.¹¹¹ In total there were only "four studies on 21,000 women for vaccine efficiency and 11,000 women . . . for vaccine safety."¹¹² "[T]he long-term effects of the HPV vaccine are unknown, and widespread vaccination might reveal a rare adverse reaction not previously seen."¹¹³ Nevertheless, Merck is poised to generate billions of dollars in revenue if the HPV vaccination mandates are enacted nationwide.¹¹⁴

Although mandating the vaccine could be greatly beneficial, there is reason to be wary of statutorily sanctioning insurance providers. According to the Centers for Disease Control and Prevention, most insurers cover the cost of the vaccine.¹¹⁵ Such sanctions will ultimately require the American public to hand over billions of dollars to two

106. Kevin Outterson, *Foreword--Will HPV Vaccines Prevent Cervical Cancers Among Poor Women Of Color?: Global Health Policy At The Intersection Of Human Rights And Intellectual Property Law*, 35 AM. J.L. & MED. 247, 247 (2009) (noting, that "[t]hrough an accident of patent litigation, we have two brand name manufacturers (Merck and GlaxoSmithKline)").

107. *Id.*

108. *Id.* at 247.

109. Global 500, CNN MONEY, http://money.cnn.com/magazines/fortune/global500/2009/full_list/index.html.

110. Fortune, *supra* note 18, at 220, 226.

111. See Dowling, *supra* note 29, at 72.

112. *Id.*

113. Roll, *supra* note 18, at 427.

114. See Fortune, *supra* note 17, at 214.

115. *HPV Information for Young Women*, CDC, <http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-young-women.htm> (stating that while some insurance companies may cover the vaccine, others may not - most large insurance plans usually cover the costs of recommended vaccines); see also, National Conference of State, *supra* note 83 (stating that at least 15 States have already introduced or passed legislation that would require the HPV vaccine to be covered by medical insurance providers).

pharmaceutical companies. It is essential that state HPV statutes be drafted with two goals in mind. First, the legislation should lead to the widespread vaccination of individuals to ensure the health and safety of society. Second, by including an "opt out clause" legislation could achieve this goal without mandating the transfer of billions of dollars to two private companies by forcing millions of people to obtain their product.

Religion and Morality

Those who oppose mandatory HPV vaccinations based on religious or morality grounds have distinguished this vaccine from vaccines mandated by states in the past. Unlike measles or smallpox, which are transmitted by air or casual contact, and therefore required vaccination statutes because of their highly contagious nature, HPV is primarily transmitted by sexual contact.¹¹⁶ Many oppose mandatory vaccinations because the disease is transmitted through lifestyle choices and specific behavior.¹¹⁷

Moral opposition stems from many parents feeling that the government does not have the right to impose mandates that relate to morality and child-rearing . . . this opposition has centered on the fear that a vaccination aimed at prevention of a sexually transmitted disease will condone premarital sex and will stray from an abstinence-only approach.¹¹⁸

It should be noted that New York's mandatory vaccination statute already includes a provision that allows parents to exempt their children from receiving a vaccine on grounds of religious reservation.¹¹⁹ This exemption is inherently suspect in light of the *Boozen* decision.¹²⁰ Thus, it is unclear from the rigidity of the current language of New York's statute how courts would regard a religious exemption from a vaccine ultimately aimed at preventing cancer not the sexually transmitted virus itself.

As discussed above, in order to best avoid this problem, New York's mandatory HPV vaccination bill should adopt a provision that would allow parents to exempt their daughters based on philosophical grounds in addition to religious. This would provide an outlet for parents to opt out of the vaccination based on moral opposition to a vaccine that protects against a sexually transmitted virus. Moreover, such an opt

116. See Roll, *supra* note 18, at 431 (citing Richard K. Zimmerman, *Ethical Analysis of HPV Vaccine Policy Options*, 24 VACCINE 4812, 4815 (2006)).

117. *Id.*

118. Fortune, *supra* note 17 at 205.

119. N.Y. PUB. HEALTH § 2164(9).

120. *Id.*

out would address any First Amendment religious rights or Fourteenth Amendment due process parental child rearing rights with regard to teaching abstinence only sex education.

CONCLUSION

“From a medical standpoint, the vaccine is an incredibly important milestone, largely supported by the medical community.”¹²¹ However, because of the numerous reasons discussed above any mandates that New York adopts with regard to the HPV vaccine should require a provision that grants parents the ability to exempt their daughters from vaccination for any reason, so long as informed written waiver is provided. Of the limited number of jurisdictions that have passed mandates on HPV vaccination, all have recognized the need to provide parents with the ability to exempt their daughters from receiving the vaccine for not only medical or religious reasons, but also for philosophical or personal reservations.¹²² Nevertheless, a properly amended bill, parallel to the measure passed in Washington, D.C., would be greatly beneficial to the state of New York. While many parents may choose to exempt their daughters from vaccination, any progress that this statute could make in eliminating this detrimental virus is undoubtedly a step in the right direction. Hopefully, over time the vaccine will prove to be both safe and effective and parents will universally choose to vaccinate their daughters and thus ultimately eliminate prevalence of the virus among the population of the United States. But it is that choice that is essential in this equation.

121. Fortune, *supra* note 17, at 220, 226.

122. See VA. CODE § 32.1-46(D)(3); D.C. Code § 7-1651.04(b)(1)(B)(iii).

