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EDUCATION Elementary and Secondary Education: Amend Part 3 of Article 16 of Chapter 2 of Title 20 of the Official Code of Georgia Annotated, Relating to Student Health in Elementary and Secondary Education, so as to Require Immunization Against the Human Papillomavirus for Female Students Entering the Sith Grade; Provide for a Beginning Date for Certain Requirements; Provide for a Sunset for Certain Requirements; Provide for Related Matters; Repeal Conflicting Law; and for Other Purposes

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EDUCATION

Elementary and Secondary Education: Amend Part 3 of Article 16 of Chapter 2 of Title 20 of the Official Code of Georgia Annotated, Relating to Student Health in Elementary and Secondary Education, so as to Require Immunization Against the Human Papillomavirus for Female Students Entering the Sixth Grade; Provide for a Beginning Date for Certain Requirements; Provide for a Sunset for Certain Requirements; Provide for Related Matters; Repeal Conflicting Law; and for Other Purposes

CODE SECTION:	O.C.G.A. § 20-2-771(c) (amended)
BILL NUMBER:	SB 155
SUMMARY:	The bill would have required all female students entering sixth grade to be vaccinated against the human papillomavirus. Exceptions were provided for children whose parents objected on religious grounds. The bill would have also suspended the vaccination requirement in cases of insufficient supplies of the human papillomavirus vaccine. The bill would have left unchanged requirements that schools keep records of the immunizations and report to the Department of Human Resources annually.
EFFECTIVE DATE:	N/A

History

Human Papillomavirus (HPV) currently infects a total of about 20 million people in the United States, and about 6.2 million Americans

(men and women) get a new genital HPV infection each year.¹ The Centers for Disease Control and Prevention (CDC) believes that 50% or more of sexually active men and women are likely to acquire genital HPV infections during their lifetimes.² Current statistics also indicate that, by age fifty, “at least eighty percent of women will have acquired a genital HPV infection.”³ Although most HPV-infected individuals do not exhibit any symptoms associated with the infection, in some individuals the infection may cause visible genital warts, pre-cancerous changes in the genital or anal area, and, in some cases, genital or anal cancer.⁴ Statistics show that of the total cases of cervical cancer, 90% to 100% are associated with HPV.⁵ Moreover, the rates of infection with HPV and mortality from associated cervical cancer are highest in women of Hispanic descent and in African American women.⁶ However, the rates of new infections and deaths from cervical cancer have decreased steadily across all ethnic and racial groups in the recent past.⁷

In a recent report, the CDC explained that, “[a]pproximately 10 of the 30 identified genital HPV types can lead, in rare cases, to development of cervical cancer” and that “persistent infection [longer than 2 years] with ‘high-risk’ types of HPV is the main risk factor for cervical cancer.”⁸ CDC data also shows that although regular Pap Tests, followed by medical observation and treatment if necessary, can help prevent the onset of life-threatening conditions such as cervical cancer, some women do not receive regular Pap Tests.⁹ The American Cancer Society estimates that 11,070 women will be diagnosed with cervical cancer in 2008.¹⁰

1. See Ctrs. for Disease Control & Prevention, STD Facts—Human Papillomavirus (HPV), <http://www.cdc.gov/std/HPV/STDFact-HPV.htm> (last visited Mar. 26, 2008) [hereinafter STD Facts].

2. *Id.*

3. See *id.*; see also Cal. Med. Assoc. (CMA) Found., Facts and Statistics, <http://www.calmedfoundation.org/projects/HPV/FactsStats.aspx> (last visited Mar. 26, 2008) [hereinafter CMA Foundation].

4. STD Facts, *supra* note 1.

5. CMA Foundation, *supra* note 3.

6. See *id.*

7. See Ctrs. for Disease Control & Prevention, Cervical Cancer Statistics, <http://www.cdc.gov/cancer/cervical/statistics> (last visited Mar. 26, 2008) [hereinafter Cervical Cancer Statistics].

8. STD Facts, *supra* note 1.

9. See *id.*

10. *Id.*

On June 8, 2006, the Food and Drug Administration (FDA) approved Gardasil, a recombinant DNA vaccine which is “the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) Types 6, 11, 16 and 18” for use in females ages nine to twenty-six.¹¹ The vaccine is manufactured by Merck & Co., Inc.¹² GlaxoSmithKline is currently expecting its own vaccine, Cervarix, intended to target HPV strains 16 and 18, to receive FDA approval.¹³ Merck’s vaccine, Gardasil, can be administered as three injections during a six month period.¹⁴ Vaccination with Gardasil may “prevent most cases of cervical cancer due to the HPV types 6, 11, 16 and 18.”¹⁵ However, as the FDA has explained, because “Gardasil does not protect against less common HPV types not included in the vaccine, . . . routine and regular pap screening remain critically important to detect precancerous changes in the cervix to allow treatment before cervical cancer develops.”¹⁶ Ideally, these screenings should begin no later than at age twenty-one and should initially be performed every year or every two years, depending on the type of test used.¹⁷ Moreover, women already infected with HPV before immunization would not receive any protective health benefits from post-infection vaccination, a fact which highlights the importance of vaccination before any potential exposure to the HPV virus.¹⁸

To determine the efficacy of the vaccine, three multinational and one U.S.-based study were performed on 21,000 female subjects between the ages sixteen and twenty-six.¹⁹ The international clinical

11. Press Release, U. S. Food and 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> [hereinafter FDA Press Release].

12. *Id.*

13. See Nat’l Conference of State Legislatures, HPV Vaccine, <https://www.ncsl.org/programs/health/HPVvaccine.htm> (last visited Mar. 26, 2008) [hereinafter State Legislatures].

14. See FDA Press Release, *supra* note 11.

15. *Id.*

16. *Id.*

17. See Am. Cancer Soc’y, Guidelines for the Early Detection of Cancer, http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp (last visited Mar. 26, 2008).

18. FDA Press Release, *supra* note 11.

19. *Id.*

studies indicated that in previously uninfected women, the vaccine was almost 100% effective in the prevention of cervical, vaginal, and vulvar precancerous lesions, as well as genital warts, for a period of up to four years.²⁰ Three additional studies were performed, one on younger females, ages sixteen to twenty-six, in order to determine the efficacy of the vaccine in this age group, and two which tested the immune response of girls age nine to fifteen.²¹ The studies showed a stronger response in the nine- to fifteen-year-old age group than in the sixteen- to twenty-six-year-old group; the FDA found this result sufficiently significant to extend the results of the efficacy study on the sixteen-twenty six year-old group to the younger group.²² However, ethical and logistical considerations prevented a complete effectiveness study on the nine- to fifteen-year-old group.²³ Furthermore, safety studies were conducted on a group of approximately 11,000 individuals.²⁴ The worst side effects to the vaccine in this study were “mild or moderate local reactions, such as pain or tenderness at the site of injection.”²⁵ The drug producer Merck further agreed that, after the licensing of the vaccine, it would perform several additional tests, “to better understand [the vaccine’s] general safety and long-term effectiveness.”²⁶ Later, in June 2006, the CDC Advisory Committee on Immunization Practices unanimously recommended that girls aged eleven and twelve should receive the vaccine.²⁷

In the wake of these events, at least thirty-nine states and the District of Columbia moved to introduce legislation mandating,

20. See *id.*; see also *FDA Update: FDA Approves HPV Vaccine*, NCI CANCER BULL. (Nat. Cancer Inst., Rockville, Md.), June 13, 2006, at 5, http://www.cancer.gov/NCICancerBulletin/NCI_Cancer_Bulletin_061306.pdf [hereinafter NCI CANCER BULLETIN].

21. FDA Press Release, *supra* note 11; see also NCI CANCER BULLETIN, *supra* note 20.

22. FDA Press Release, *supra* note 11; see also NCI CANCER BULLETIN, *supra* note 20.

23. NCI CANCER BULLETIN, *supra* note 20.

24. FDA Press Release, *supra* note 11.

25. *Id.*

26. *Id.*

27. See *HPV Vaccine Legislation Introduced in Colorado, Connecticut, Kansas, Michigan, Wisconsin; Maryland Bill to be Withdrawn*, MED. NEWS TODAY, Feb. 5, 2007, <http://www.medicalnewstoday.com/medicalnews.php?newsid=62117>; State Legislatures, *supra* note 13; see also CTRS. FOR DISEASE CONTROL & PREVENTION, HPV VACCINE QUESTIONS AND ANSWERS (2006), <http://www.cdc.gov/std/HPV/STDFact-HPV-vaccine.htm> [hereinafter HPV QUESTIONS AND ANSWERS].

funding, or educating the public about the HPV vaccine.²⁸ In New Hampshire, the State Health Department announced that it would make the vaccine available free of cost to girls eighteen years or younger.²⁹ In January 2007, South Dakota's Governor proposed a like plan which would have been funded by \$7.5 million from federal vaccine funds and \$1.7 million from general state funds.³⁰ By mid-2007, at least twenty-one states had considered introducing legislation specifically mandating the HPV vaccination of middle school age girls.³¹ In March of 2007, the Virginia Legislature passed such a bill, later incorporating additional parental exemption rights.³² In Texas, a similar bill met with opposition from parental rights advocates and those who felt that the requirement was "simply a money-making venture for Merck," who presently manufactures the only FDA-approved vaccine against HPV.³³ To overcome this opposition, on February 2, 2007, Texas Governor Rick Perry signed an executive order mandating the HPV vaccination of girls eighteen years-old or younger, while at the same time permitting parents to opt out of the program and to benefit from privacy safeguards.³⁴ The Texas Legislature responded by rejecting the Governor's executive order and instead sent him a bill that would prevent mandatory HPV vaccinations for at least four years.³⁵ The Governor then retreated from his mandatory vaccination plan and allowed the bill blocking officials from requiring the shots to become law in the absence of his signature.³⁶

Opposition to a mandatory HPV vaccination program has focused on concerns about the vaccine's cost, financing, safety, and parental

28. State Legislatures, *supra* note 13.

29. *Id.*

30. *Id.*

31. See ELENA CONIS & CAROL MEDLIN, HEALTH POLICY MONITOR, HPV VACCINATIONS IN CALIFORNIA (2007), available at <http://www.hpm.org/survey/us/c9/1>.

32. State Legislatures, *supra* note 13.

33. Women's Health News, <http://womenshealthnews.blogspot.com> (Feb. 4, 2007, *On the Texas HPV Vaccine Law*).

34. Exec. Order No. RP65 (Feb. 2, 2007), available at <http://www.governor.state.tx.us/divisions/press/exorders/rp65/view>.

35. Liz Austin Peterson, *Texas Showdown on HPV Vaccine Order*, ASSOCIATED PRESS, Apr. 25, 2007.

36. *Texas Governor Backs Down on HPV Vaccine Bill*, ASSOCIATED PRESS, May 9, 2007, available at <http://www.msnbc.msn.com/id/18575675>.

right to refuse.³⁷ Some have also expressed “moral objections” related to mandating a vaccine for a disease that is sexually transmitted.³⁸ This has created a heated debate on the advantages and disadvantages of requiring middle school girls to receive vaccination against HPV.³⁹

Bill Tracking

Consideration by the Senate

On February 14, 2007, SB 155, sponsored by Senator Don Balfour (R-9th), was read for the first time in the Senate and was referred to the Health and Human Services Committee.⁴⁰

SB 155 was heavily debated in committee.⁴¹ Supporters of the bill, including the bill’s sponsor, Senator Balfour, emphasized the fact that the bill can save lives.⁴² In addition, supporters pointed out that the bill can also save money: Senator Balfour explained later that he believes it makes sense to push SB 155 because “the cost of giving the shot is substantially less than the cost of paying for cervical cancer down the road.”⁴³

Senator Balfour moved to amend his bill in three ways: to make it effective beginning with the 2008 school year; to include a sunset clause that would rescind the legislation in 2011; and to rescind the mandatory vaccination provision in case of a federal recall by the FDA.⁴⁴ These changes were made to address the concerns of those who had earlier expressed opposition to the bill.⁴⁵ Regarding what prompted the changes to his earlier bill, Senator Balfour stated, “I was trying to do some kind of compromising in the bill to get a bill

37. State Legislatures, *supra* note 13.

38. *Id.*

39. *Id.*

40. State of Georgia Final Composite Status Sheet, SB 155, June 5, 2007.

41. See Interview with Sen. Don Balfour (R-9th) (Apr. 17, 2007) [hereinafter Balfour Interview].

42. *Id.*

43. *Id.*

44. See Email from Laurie Sparks, Legislative Assistant to Senators Don Thomas (R-54th) and William Hamrick (R-30th), to author (May 7, 2007, 11:59 EST) (on file with the Georgia State University Law Review) [hereinafter Sparks Email] (containing minutes from Senate Committee meeting on SB 155); see also SB 155 (SCA), 2007 Ga. Gen. Assem.

45. See Balfour Interview, *supra* note 41.

that we could pass. At the end I was willing to say that ‘any parent who wanted to opt out, could.’ Still mandated, but any parent that wants to opt out could.”⁴⁶

Testimony from those opposed to the bill was then heard.⁴⁷ Tanya Ditty, representing Concerned Women for America, voiced her organization’s concerns at the committee meeting.⁴⁸ In a separate interview, while first establishing that her organization was “not opposed to the HPV vaccine, or to a cure against cervical cancer” and that her organization “fully [supports] advances in science,” she stated that her organization was opposed to a mandatory vaccination program and enumerated several reasons underlying her organization’s opposition to the bill.⁴⁹ First, she stated that because HPV is a sexually transmitted disease, requiring vaccination of girls eleven- to twelve-years-old “would send a message” that girls at those ages are expected to be sexually active.⁵⁰ Moreover, she stated that “because there are other sexually transmitted diseases out there,” vaccinating only against HPV could lead to “a false sense of security.”⁵¹ Another reason for the opposition to the bill was based on parental rights concerns.⁵² She stated that her organization thought that a bill such as this was the “long arm of the government reaching into the homes of America,” interfering with the rights of parents to decide what is best for their children.⁵³ Her organization thought that “doctors and parents, who know [a young girl’s] body best, should be the ones to make the choice” whether to give that young girl the HPV vaccine.⁵⁴ In addition, she noted that Merck, the vaccine’s manufacturer, usually takes the initiative to educate the public and to promote its own products, but that in this case, Merck has “taken a back seat,” expecting the state taxpayers to fund the campaign to promote Gardasil and educate the public about HPV.⁵⁵ She also

46. *Id.*

47. *Id.*

48. See Balfour Interview, *supra* note 41; see also Telephone Interview with Tanya Ditty, State Director, Concerned Women of America (May 9, 2007) [hereinafter Ditty Interview].

49. See Ditty Interview, *supra* note 48.

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. Ditty Interview, *supra* note 48.

stated that because Peach Care, the state's health insurance plan for children of lower-income families, already has funding problems, a program such as this one could not be easily supported with public funds.⁵⁶

Others, including Dr. Carolyn Garcia, representing United for Life, Sadie Fields, representing the Georgia Christian Alliance, and Pat Chivers, from the Archdiocese of Atlanta also spoke in opposition to the bill.⁵⁷ Diane Hutchins, representing the Peach State Health Plan, and Helen Sloat, from the law firm of Nelson Mullins Riley & Scarborough, LLP, voiced their support for the bill.⁵⁸

Senator Johnny Grant (R-25th) then made a motion to table the bill to allow the committee to change the language of the bill to satisfy the concerns of those present.⁵⁹ The motion failed.⁶⁰ Senator Steve Henson (D-41st) then moved to pass Senator Balfour's bill by substitute, which Senator Nan Orrock (D-36th) seconded.⁶¹ The committee voted 8 to 3 to approve the bill and on February 28, 2007, the Senate Committee favorably reported the bill.⁶²

On March 1, 2007, the bill was read a second time.⁶³ However, on March 15, 2007, because of earlier opposition to the bill, Senator Balfour decided that the bill should not be placed on the legislative calendar for a full Senate debate during the 2007 session.⁶⁴ Senator Balfour indicated that there was "just too much sentiment against the bill."⁶⁵ However, Senator Balfour noted that the bill might be considered again in 2008.⁶⁶

56. *Id.*

57. See Sparks Email, *supra* note 44.

58. *Id.*

59. See *id.*

60. *Id.*

61. *Id.*

62. See *id.*; State of Georgia Final Composite Status Sheet, SB 155, June 5, 2007.

63. State of Georgia Final Composite Status Sheet, SB 155, June 5, 2007.

64. *Daily Women's Health Policy Report: Actions Taken on HPV Vaccine Proposals in Florida, Georgia, North Carolina, South Dakota*, KAISERNETWORK.ORG, Mar. 22, 2007, http://www.kaisernet.org/Daily_reports/rep_repro_recent_reports.cfm?dr_cat=2&show=yes&dr_DateTime=03-22-07#43759.

65. See Travis Fain, *HPV Bill Dead for This Session, Sponsor Says*, MACON TELEGRAPH, Mar. 15, 2007.

66. *Id.*; see also Balfour Interview, *supra* note 41.

The Bill

SB 155 would have amended section (c) of Code section 20-2-771, relating to immunization of students, to require that, “prior to admission into the sixth grade at any school in the State of Georgia, all female students must be vaccinated against human papillomavirus, unless the parent or guardian of a student certifies in writing that he or she cannot afford, with or without health care coverage, the costs associated with the vaccination.”⁶⁷ The bill allowed an exemption as provided in O.C.G.A. § 20-2-771(e), which allows exemptions from vaccination requirements for children whose parents object on the basis of religious beliefs.⁶⁸ The bill would have left unchanged the portions of Code section 20-2-771, which require schools and facilities to “maintain on file certificates of immunization for all children attending the school or facility” and “to report annually to the Department of Human Resources.”⁶⁹

Analysis

The bill would have mandated vaccination against HPV for all girls entering the sixth grade in the State of Georgia. This would have been the second government-mandated vaccination against a sexually transmitted disease, the first one being vaccination against Hepatitis B.⁷⁰ Critics of mandatory vaccination argue that mandatory vaccinations are most justified in cases of highly contagious airborne diseases, such as measles or pertussis.⁷¹ Because HPV is not a highly infectious disease and does not present a risk of rapid transmission to third parties, they argue that the primary motivation for the vaccination against HPV should be to shield girls from the long-term risks associated with HPV infection.⁷² Other critics of the mandatory

67. SB 155, as introduced, 2007 Ga. Gen. Assem.

68. *See id.*

69. Compare SB 155, as introduced, 2007 Ga. Gen. Assem., with O.C.G.A. § 20-2-771(c) (2000).

70. See Lawrence O. Gostin & Catherine D. DeAngelis, Editorial, *Mandatory HPV Vaccination: Public Health vs. Private Wealth*, 297 JAMA 1921 (2007), available at <http://jama.ama-assn.org/cgi/content/full/297/17/1921>. The majority of the arguments in this section are based on Dr. Gostin and Dr. DeAngelis’s JAMA editorial.

71. *Id.*; see also James Colgrove, *The Ethics and Politics of Compulsory Vaccination*, 355 NEW ENG. J. MED. 23, 2389 (2006), available at <http://content.nejm.org/cgi/content/full/355/23/2389>.

72. Gostin & DeAngelis, *supra* note 70; see also Colgrove, *supra* note 71.

vaccination have observed that while the vaccine may have potential benefits for girls and women who are at high risk of getting cervical cancer, this fact alone does not justify “subjecting millions to yet another vaccine.”⁷³ Therefore, they suggest that mandatory vaccination programs can and should be more carefully developed.⁷⁴

Lack of Efficacy Data for Middle School-Aged Girls

Preventing HPV infection and related diseases such as cervical cancer is undoubtedly a laudable public health goal.⁷⁵ But some critics doubt the true effectiveness of a mandatory HPV vaccine.⁷⁶ They point out that although statistics indicate an increasing prevalence of infection each year for ages fourteen to twenty-four (44.8% for ages twenty to twenty-four years) and then a gradual decline in infection rates through age fifty-nine (19.6% for ages fifty to fifty-nine years), infections with high risk types of HPV are relatively rare and not all of those infected with high-risk HPV strains will actually develop cervical cancer.⁷⁷ Furthermore, they note that although studies indicate that the vaccine is almost completely effective in stopping infection with HPV types 6, 11, 16, and 18 and related diseases and that the vaccine is safe for use in girls age nine to fifteen years,⁷⁸ how effective the vaccine is among girls of this age group has not yet been determined.⁷⁹ It is true that inferences from limited FDA studies suggest that the vaccine should be effective in this age group; however, the lack of adequate effectiveness data in the age group in which the vaccine would be mandated has been cited as one of many concerns by those who oppose the mandatory

73. Posting of Christiane Northrup, M.D., to <http://www.ghchealth.com/forum/vaccine-information-forum-13.php> (Aug. 24, 2006, *Does Your Daughter Need the HPV Vaccine?*) [hereinafter Northrup].

74. Gostin & DeAngelis, *supra* note 70.

75. See Northrup, *supra* note 73.

76. Gostin & DeAngelis, *supra* note 70.

77. *Id.*

78. *Id.*; see also *supra* text accompanying notes 19-20.

79. See Gostin & DeAngelis, *supra* note 70; see also Merck's Gardasil Not Proven Safe for Little Girls, PR NEWSWIRE, June 27, 2006, http://www.redorbit.com/news/health/552025/mercks_gardasil_vaccine_not_proven_safe_for_little_girls/index.html?source=r_health [hereinafter *Gardasil Not Proven Safe*].

vaccination program.⁸⁰ Moreover, critics point out that no long-term safety studies exist, in part because the vaccine was “fast-tracked” by the FDA and in part because there have been no opportunities for long-term patient follow-ups.⁸¹ Other critics go further to suggest that the vaccine is in fact dangerous, noting that when given in combination with the meningitis vaccine, it has led to joint pain, seizures, loss of consciousness, and more than forty cases of Guillain-Barre syndrome.⁸²

Parental Rights Concerns & Informed Consent Issues

Parental autonomy issues have been at the forefront of the debate over compulsory HPV vaccination.⁸³ Medical and legal commentators have expressed the view that, given the low overall rates of infection of HPV types associated with cervical cancer (3.4%) and that the long-term consequences of the vaccine are not yet known, it may be “unwise” to require a young girl with a very low lifetime risk of cervical cancer to be vaccinated perhaps against both her and her parents’ wishes.⁸⁴ Others have noted that making the vaccine mandatory raises “unique ethical and policy issues,” potentially protecting all members of the community, but also infringing upon patient autonomy and violating informed consent requirements.⁸⁵ Critics point out that mandating the HPV vaccine may also increase parental anxiety about the safety of school-mandated vaccinations.⁸⁶ Thus, critics note that an undesirable side-effect of a compulsory vaccination program may be an increase in the growing pattern of parental refusal of vaccinations and the

80. See *supra* text accompanying notes 20-22; Ditty Interview, *supra* note 48; see also *Gardasil Not Proven Safe*, *supra* note 79.

81. Bernadine Healy, *Don't Rush to Judgment*, U.S. NEWS & WORLD REP., Feb. 18, 2007, available at <http://health.usnews.com/usnews/health/articles/070218/26healy.htm>; see also Gostin & DeAngelis, *supra* note 70.

82. See Wendy Wright & Nancy Staible, *HPV Mandates: Parents Trump Politics*, 32 ETHICS & MEDICS 1 (2007), available at <http://www.ncbcenter.org/em/0707-1.aspx>.

83. See *id.*; see also *HPV Vaccination: Should States Make it Compulsory?*, HEALTH & HEALTH CARE IN SCH. (Ctr. for Health & Health Care in Sch., Washington, D.C.), Jan. 2007, at 2, http://www.healthinschools.org/News-Room/EJournals/Volume-7/Number-10/HPV-Vaccination_Should-States-Make-It-Compulsory.aspx [hereinafter *Compulsory Vaccination*].

84. See Gostin & DeAngelis, *supra* note 70.

85. *Compulsory Vaccination*, *supra* note 83.

86. Gostin & DeAngelis, *supra* note 70.

heightening of parental and public fears regarding childhood vaccinations.⁸⁷ Senator Don Balfour (R-9th), the sponsor of the bill, stated that he spoke with representatives of the U.S. Department of Health and Human Services about the concern that there could be too many “opt outs,” which might affect parents’ willingness to let their children take other vaccines as well.⁸⁸ Senator Balfour felt that “this [was] a valid concern, a very valid concern.”⁸⁹

Economic & Financing Concerns

A mandatory vaccination program also raises economic and financing concerns.⁹⁰ States which make the vaccine mandatory must address funding issues, such as Medicaid and State Children’s Health Insurance Program (SCHIP)⁹¹ coverage for children who are uninsured, and also whether to mandate coverage by private insurance plans.⁹² Critics note that the predicted cost of the HPV vaccine is \$360 for a series of three vaccines, which places it among the most costly immunizations.⁹³ States which have introduced HPV legislation have provided different funding mechanisms for the proposed vaccination programs.⁹⁴ Potential sources of funding are private insurance companies, state or federally funded health programs, or consumers themselves.⁹⁵ A bill introduced by the Georgia House of Representatives in 2006 would have mandated

87. See R. Alta Charo, *Politics, Parents, and Prophylaxis—Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 19, 1905–1908 (2007); Gostin & DeAngelis, *supra* note 70.

88. Balfour Interview, *supra* note 41.

89. *Id.*

90. See State Legislatures, *supra* note 13; see also Gostin & DeAngelis, *supra* note 70.

91. The State Children’s Insurance Program (SCHIP) provides low-cost healthcare to needy families and children. U.S. Dep’t of Health & Human Servs., Low Cost Health Insurance for Families & Children: Overview, <http://www.cms.hhs.gov/LowCostHealthInsFamChild> (last visited Nov. 15, 2007). It is a program jointly financed by the federal and state governments and administered by the states. *Id.*

92. See State Legislatures, *supra* note 13.

93. See Gostin & DeAngelis, *supra* note 70; see also RAPID PUB. HEALTH POLICY RESPONSE PROJECT, GEORGE WASHINGTON UNIV. SCH. OF PUB. HEALTH & HEALTH SERVS., HPV VACCINATION: SHOULD IT BE RECOMMENDED OR REQUIRED? (2007), available at http://www.gwumc.edu/sphhs/about/rapidresponse/download/HPV_Vaccine_Paper (January 2007).pdf [hereinafter GW PAPER].

94. See generally State Legislatures, *supra* note 13.

95. See generally *id.*; see also GW PAPER, *supra* note 93; Gostin & DeAngelis, *supra* note 70.

private insurance coverage for the Georgia vaccination program.⁹⁶ Critics have pointed out that neither of these funding options is problem-free.⁹⁷ In particular, they note that health inequalities would likely be amplified if consumers or insurers were required to pay, because those in the lower economic brackets (who are most often uninsured or underinsured) would likely find that they cannot meet the expense of the vaccine.⁹⁸ Further, those who are insured would likely find that the costs are passed to them through their insurance premiums.⁹⁹ Although the current proposal in Georgia would not have provided for state or federal funding of the vaccination program, if the legislature were to provide for government funding, it would most likely have to cut other public health programs to cover the cost of this program.¹⁰⁰ The fact that Peach Care, part of Georgia's SCHIP program, temporarily ran out of money in March 2007 indicates that the state would currently find it difficult to fund an additional mandatory vaccination program.¹⁰¹

The "Government Contractor" Defense & Sovereign Immunity

Yet another issue raised by critics is the issue of compensation of individuals who may be injured as a result of taking the vaccine.¹⁰² They note that those suffering from potential side effects of the vaccine may find it difficult to recover for their injuries if courts were to find that the manufacturer of the vaccine had decreased or perhaps no civil tort liability because the program was government-mandated.¹⁰³ Merck has raised this "government contractor defense" in a Nevada case in a similar context, namely injuries caused to an infant by the government-mandated measles, mumps and rubella (MMR) vaccine.¹⁰⁴ Although the court in that case rejected this

96. HB 11, 2006 Ga. Gen. Assem., http://www.legis.state.ga.us/legis/2007_08/fulltext/hb11.htm; see also State Legislatures, *supra* note 13.

97. See Gostin & DeAngelis, *supra* note 70.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Georgia's PeachCare Program Running Out of Funds, To Freeze Enrollment*, AP/AUGUSTA CHRON., Feb. 9, 2007, available at <http://www.medicalnewstoday.com/articles/62884.php>.

102. See Gostin & DeAngelis, *supra* note 70.

103. *Id.*

104. See *Allison v. Merck & Co.*, 878 P.2d 948 (Nev. 1994).

defense as “ill-defined,” especially because the vaccine was not manufactured to government specifications, the dissenting opinion of Justice Young thought the extension of “sovereign immunity” to contractors who act “in the sovereign’s stead” would have been appropriate.¹⁰⁵ An additional issue and related question is whether the government itself could face civil liability for injuries caused by the vaccine. This is unlikely because the state’s decision to mandate a vaccination program is most likely to be deemed an exercise of a political, discretionary governmental function and thus not subject to civil liability.¹⁰⁶ As a solution, critics of mandatory HPV vaccination programs have suggested that the state must also offer a state-funded “compensation-system” such as the National Vaccine Injury Compensation Program, for individuals injured by a government-mandated vaccine.¹⁰⁷

Constitutional Issues

A mandatory vaccination program that is only applicable to girls only may also raise equal protection issues.¹⁰⁸ By requiring only girls to be vaccinated against HPV, the bill creates a facial, express classification on the basis of gender. As a result the bill, if challenged, would be subjected to intermediate scrutiny.¹⁰⁹ To withstand scrutiny, the state would have to provide an “exceedingly persuasive justification” by showing that the classification is “substantially related” to an “important government interest.”¹¹⁰ The state may point to the fact that only girls can get cervical cancer as an “inherent difference” between the sexes that would justify the classification.¹¹¹ This may be a sufficient justification, given that a

105. See *id.* at 959; see also *id.* at 970 (Young, J., dissenting) (citing *Boruski v. United States*, 803 F.2d 1421, 1430 (7th Cir. 1986)).

106. See O.C.G.A. § 50-21-24(2) (2006) (“The state shall have no liability for losses resulting from . . . [t]he exercise or performance of or the failure to exercise or perform a discretionary function or duty on the part of a state officer or employee, whether or not the discretion involved is abused.”).

107. Gostin & DeAngelis, *supra* note 70.

108. See *id.*; Women’s Health News, <http://womenshealthnews.blogspot.com> (Feb. 6, 2007, *Backlash Against Texas HPV Vaccine Law Continues*).

109. See *United States v. Virginia*, 518 U.S. 515, 533 (1996) (applying intermediate scrutiny to facial, express gender-based classification).

110. *Id.*

111. See Balfour Interview, *supra* note 41.

gender classification which benefits rather than disadvantages women because of biological differences between men and women may satisfy equal protection requirements.¹¹² In addition, the state may point to the fact that vaccinating only girls would reduce the cost of administering the vaccine and thus alleviate some of the funding concerns, in order to bolster its argument that it has an “important” government goal.¹¹³ However, this argument is unlikely to go very far, because in *Reed v. Reed*¹¹⁴ and *Frontiero v. Richardson*,¹¹⁵ the Supreme Court has rejected administrative ease and convenience as sufficiently important objectives to justify gender-based discrimination.

Moreover, if boys also stand to benefit from the vaccine, the law arguably is not justified by gender-based, “inherent” differences. Arguably, in such a case, boys would be disadvantaged by this bill because they could not benefit from the potential health benefits of the state-funded vaccine, such as prevention of genital warts and rare forms of cancers, like penile and anal cancer.¹¹⁶ If studies that are currently being done to determine the efficacy of the vaccine in preventing HPV infection and disease demonstrate such an effect in males, the vaccine is likely to be licensed and approved for use by males as well.¹¹⁷ At such a time, it will be difficult to sustain a classification on the basis of gender for receiving the vaccine.

Another argument against the bill would be that it cannot be justified as a “benign,” compensatory measure, because it burdens rather than benefits women on account of a sex-based characteristic. Requiring young girls and not boys to be subjected to a series of three vaccinations and the additional health risks associated with the vaccine is seen by some as a burden, not a benefit.¹¹⁸ As a result, critics point out that questions of fairness and equality of treatment may emerge, because young girls’ publicly funded education would

112. See *Virginia*, 518 U.S. at 533-36 (1996) (noting that while “inherent” differences are no longer accepted as a ground for race or national origin classifications, “physical differences” between men and women are enduring and that classifications which are “benign” (benefiting women) may be constitutional so long as they are not “mere rationalizations for actions in fact differently grounded.”).

113. See Balfour Interview, *supra* note 41.

114. *Reed v. Reed*, 404 U.S. 71, 76 (1971).

115. *Frontiero v. Richardson*, 411 U.S. 677, 690-91 (1973).

116. See HPV QUESTIONS AND ANSWERS, *supra* note 27.

117. *Id.*

118. See, e.g., Ditty Interview, *supra* note 48

be conditioned on submitting to a new vaccine, while boys would be free to attend school without such compulsion.¹¹⁹ Again, the state would have to offer an “exceedingly persuasive justification” for its decision to vaccinate girls and not boys.¹²⁰ The government’s interest in preventing disease and promoting public health may be such an important goal, sufficient to justify a mandatory vaccination program, although the fact that the vaccine is not necessary to prevent immediate harm to others will weigh against the government interest.¹²¹

However, even if the government’s interest in promoting public health would be a sufficiently important government interest to justify the mandatory vaccination program, the program may still fail the second step of equal protection analysis. The “means” test of intermediate scrutiny equal protection analysis requires that the government achieve its important goal through means that are “substantially related” to the advancement of that goal.¹²² To establish this requirement, the state may be asked to show that it could not accomplish its important goal by “gender neutral” alternatives.¹²³ If HPV vaccination proves beneficial for both boys and girls, the state could not justify its girls-only mandate on traditional public health rationales—i.e. that it would promote the public health and prevent disease—because requiring all children (regardless of gender) to be vaccinated would be equally as effective, if not more so, in achieving its intended goal.¹²⁴

Prognosis

Although bills mandating the HPV vaccine have been introduced in at least thirty-seven states as of mid-2007, only the Virginia Legislature passed a mandatory vaccination bill for girls entering

119. See Gostin & DeAngelis, *supra* note 70.

120. See *United States v. Virginia*, 518 U.S. 515, 533 (1996).

121. See Gostin & DeAngelis, *supra* note 70.

122. *Id.*

123. See *Orr v. Orr*, 440 U.S. 278, 282 (1979) (striking down a gender classification and noting that it would “cost the State nothing more, if it were to treat men and women equally by making alimony decisions independent of sex.”).

124. See Gostin & DeAngelis, *supra* note 70.

sixth grade.¹²⁵ In New Mexico, a similar bill was introduced and passed out of both the House and the Senate, but Governor Bill Richardson vetoed the legislation.¹²⁶ In Texas, after a “show-down” between state lawmakers and the Governor, the legislature finally defeated the Governor’s efforts to mandate the vaccination program.¹²⁷ Similar bills were introduced but later withdrawn in California and Maryland.¹²⁸ However, programs to provide the vaccine free of cost to girls eighteen years-old or younger have met with success in New Hampshire and South Dakota.¹²⁹ Georgia’s experience could prove educational for the many other states that have introduced similar legislation.¹³⁰ Although enthusiasm about the development of a vaccine that could protect against cervical cancer prompted legislation to be introduced in the vast majority of states, it appears that there is currently not sufficient support for a mandatory vaccination program,¹³¹ especially for one that would be funded by private insurance.¹³² However, if children’s health-care funding concerns ease, perhaps a government-funded program, provided free of cost to young girls, would meet with more success. In addition, better addressing potential equal protection as well as remaining scientific and medical questions may also increase support for a vaccination program in Georgia as well as other states.

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125. See State Legislatures, *supra* note 13; Gostin & DeAngelis, *supra* note 70.

126. See Balfour Interview, *supra* note 41.

127. See discussion *supra* History.

128. State Legislatures, *supra* note 13.

129. *Id.*

130. *Id.*

131. *Id.*

132. See *id.*