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NOTES

WHY MANDATORY VACCINATION OF MALES AGAINST HPV IS UNCONSTITUTIONAL: OFFERING A NEW APPROACH TO AN OLD PROBLEM

BENJAMIN LEMKE

I. INTRODUCTION

The test of whether a proposed mandatory vaccination program is constitutional needs updating. *Jacobson v. Massachusetts*, decided by the U.S. Supreme Court over a century ago, laid out the proper reasoning and concerns to be addressed when determining the legality of mandatory vaccinations, but its analysis is tailored to the extreme case of the smallpox epidemic.¹ As more vaccinations are created to address decreasingly pressing needs, it becomes clear that because of the liberty interests involved when requiring their use, vaccinations should not be made mandatory simply because they can be created. Scientific possibility does not create individual necessity. A new test must seek to address the evolving subtleties related to the use of vaccinations while still maintaining the fundamental reasoning of *Jacobson*. This Note introduces the Modified Hand Formula, a new test that balances the key competing concerns inherent in any discussion of the constitutionality of mandatory vaccinations. The Modified Hand Formula asks whether the “Burdens” associated with implementing mandatory vaccination—both social economic burdens and the personal burden of sacrificing constitutionally protected liberty interests—exceed the reduction in “Probable Loss,” the lessening of human costs, achieved by such a program.²

The importance of developing a new test is underscored by a recent rise in discussion regarding mandatory vaccination for human papillomavirus (“HPV”).³ In June 2006, the Food and Drug Administration (“FDA”) approved and licensed Gardasil, manufactured by Merck, the first vaccine developed to prevent the transmission of HPV.⁴ With FDA approval for women finalized in

¹ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

² See *infra* Part IV.A.

³ See, e.g., Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731, 1755–64 (2008) (devoting ten pages to responding to objections to mandatory HPV vaccination).

⁴ 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; Rapid

2006 and probable FDA approval for men not far behind, states are gearing up to introduce mandatory vaccination programs that would condition school registration on vaccination for incoming female students.⁵ Because HPV is a sexually transmitted disease, mandatory vaccination programs focus on vaccinating younger girls, generally in the late pre-teen years.⁶ Gardasil is effective against HPV only prior to infection; thus, vaccinating girls when they are already older and already sexually active risks imposing a high price for little effect.⁷ Although the public discussion has been dominated by whether states *should* implement mandatory vaccination for pre-teen girls, the threshold question really should be whether states *can* do so.⁸ Since the seminal case of *Jacobson v. Massachusetts* legitimized the mandatory vaccination of smallpox, courts have essentially rubber stamped mandatory vaccination plans.⁹ As medical technology advances, the question arises, when is the line of authority to act in this manner crossed?¹⁰ To address this question, it is necessary to sharpen the blunt instrument that is *Jacobson*, put away the rubber stamp, and make

Approval Marks Major Advancement in Public Health (June 8, 2006), available at http://www.fda.gov/bbs/topics/news/2006/new_01385.html [hereinafter FDA Licenses New Vaccine].

⁵ National Conference of State Legislatures, *HPV Vaccine* (Feb. 2010), <http://www.ncsl.org/programs/health/HPVvaccine.htm> (“In 2007, at least 24 states and D.C. introduced legislation to specifically mandate the HPV vaccine for school (California and Maryland withdrew their bills).”); *Merck Seeks FDA Approval For HPV Vaccine Use In Boys, Young Men*, MEDICAL NEWS TODAY, Jan. 7, 2009, <http://www.medicalnewstoday.com/articles/134590.php> (reporting that Merck is seeking FDA approval for use of Gardasil to prevent transmission of HPV in males, ages nine to twenty-six).

⁶ FDA Licenses New Vaccine, *supra* note 4 (noting “HPV is the most common sexually-transmitted infection in the United States”); National Conference of State Legislatures, *supra* note 5 (mentioning that the national Advisory Committee on Immunization Practices (ACIP) recommends HPV vaccination for girls between ages eleven and twelve).

⁷ Law, *supra* note 3 (arguing that vaccinating older, already sexually active females “makes no sense”); FDA Licenses New Vaccine, *supra* note 4 (“The results show that the vaccine is only effective when given prior to infection.”).

⁸ Not surprisingly, there are no official studies investigating and discussing the prevalence of constitutional discussions of mandatory HPV vaccination programs as they relate to the overall frequency of discussions of mandatory HPV vaccination.

⁹ Only two federal cases have found provisions of mandatory immunization statutes unconstitutional: *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002), and *Sherr v. Northport-East Northport Union Free Sch. Dist.*, 672 F. Supp. 81 (E.D.N.Y. 1987). Note that in both cases the provisions were struck down on grounds related to religious exemptions, rather than anything related to the vaccines themselves.

¹⁰ See Note, *Toward a Twenty-First-Century Jacobson v. Massachusetts*, 121 HARV. L. REV. 1820, 1820 (2008) [hereinafter *Toward a Twenty-First-Century*] (“Biomedical advances are pushing the foundational public health law case *Jacobson v. Massachusetts* towards obsolescence.”).

a cogent, reasoned decision as to whether mandatory vaccination of HPV is constitutional.

Part II of the Note gives a brief examination of the history of vaccination and the development of the outdated *Jacobson* test. Part II also lays out the current regimes for mandatory and widely recommended vaccinations and gives a brief overview of the diseases that the vaccinations aim to prevent. Part III of this Note introduces Gardasil, examines its effectiveness at reducing the occurrence of HPV, and describes three different responses by legal scholars to the question of how state governments should implement HPV vaccination. Part IV lays out the Modified Hand Formula, describes how it addresses the inadequacies of the *Jacobson* test, and applies it to mandatory vaccination of females and males. Application of the Modified Hand Formula demonstrates that the cost of vaccination and health effects of HPV in females parallels the costs and benefits of other currently mandated vaccinations, while the same costs and health effects of HPV in males have no such parallel. This Note also examines whether it is reasonable to have two different standards for evaluating the constitutionality of mandatory vaccinations for males and females. Part V illustrates how it may be constitutional to adopt different regimes for vaccination of females and males and, finally, concludes that mandatory vaccination for either may be inadvisable, even though constitutional.

II. A BRIEF HISTORY OF VACCINATION AND ITS JURISPRUDENCE

A. *The Discovery of Vaccination and the Advent of Mandatory Vaccination Laws*

The foundational Supreme Court case addressing mandatory immunization in the United States was handed down a little more than a century ago, as widespread smallpox outbreaks ravaged the nation.¹¹ The idea that individuals could be vaccinated against smallpox arose when survivors of the disease realized that the ordeal had left them immune to it for the rest of their lives.¹² Looking to take advantage of this observation, the practice of variolation was conceived, whereby healthy persons would expose themselves to small doses of the disease in the hopes that they would contract a less virulent version but still gain the beneficial effect of immunization.¹³ The first written account of this practice is from an eleventh-century Buddhist nun who reportedly ground up scabs of infected persons into a powder to be inhaled by healthy persons.¹⁴ Two to three percent of those who engaged in variolation died as a result, but this represented an overwhelming success because non-variolated individuals

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

¹² Heather Brannon, *The History of Smallpox: The Rise and Fall of a Disease*, ABOUT.COM, Sept. 25, 2004, <http://dermatology.about.com/cs/smallpox/a/smallpoxhx.htm>.

¹³ *Id.*

¹⁴ *Id.*

died at much higher rates.¹⁵

In 1796, English physician Edward Jenner made a breakthrough in smallpox immunization when he noticed that milkmaids who developed cowpox, a less serious disease, proved to be immune from smallpox.¹⁶ Jenner tested this discovery by exposing an eight-year-old boy to a small amount of cowpox.¹⁷ Jenner declared success in creating the first modern vaccine when the boy did not develop smallpox, despite being exposed to the virus six weeks later.¹⁸ In tribute to the cowpox inoculation, Jenner coined the term “vaccine,” from the Latin for “cow”: *vaca*.¹⁹

Following Jenner’s advent of a safer smallpox vaccine, compulsory vaccination laws began to proliferate. In 1827, Boston became the first city to condition school attendance on vaccination, followed by several state laws in the second half of the nineteenth century.²⁰ By the early 1900s, “the vast majority of states had enacted compulsory smallpox vaccination laws.”²¹ It was theorized that if a large enough proportion of the population became immunized, the small remainder of persons who, for whatever reason, could not be vaccinated would be protected because the majority of the population could not contract the virus and pass it on to them.²² This concept is known as “herd immunity.”²³ While many flocked to get vaccinations, a certain segment of the population (“free riders”) sought to gain the benefits of “herd immunity” without exposing themselves to the risks of vaccination.²⁴

In response to this phenomenon, states and municipalities, including Massachusetts, passed mandatory vaccination laws.²⁵ Those seeking to avoid vacci-

¹⁵ *Id.* (noting variolation reported to have “decreased the total number of smallpox fatalities by 10-fold”).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Gail Javitt, Deena Berkowitz & Lawrence O. Gostin, *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 388 (2008).

²¹ *Id.*

²² CTRS. FOR DISEASE CONTROL & WORLD HEALTH ORG., HISTORY AND EPIDEMIOLOGY OF GLOBAL SMALLPOX ERADICATION 16–17 (2003), available at <http://www.bt.cdc.gov/agent/smallpox/training/overview/pdf/eradicationhistory.pdf> (from the joint Ctrs. for Disease Control and World Health Org. training course *Smallpox: Disease, Prevention, and Intervention*).

²³ Answers.com, Herd Immunity: Definition, <http://www.answers.com/topic/herd-immunity> (last visited Mar. 21, 2010).

²⁴ See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). Henning Jacobson was just such a “free rider.” See Law, *supra* note 3, at 1752 (“It is broadly understood to be unfair to allow exceptions for ‘free riders’ absent special and compelling circumstances.”).

²⁵ *Jacobson*, 197 U.S. at 12. Pursuant to a Massachusetts statute, the City of Cambridge passed a regulation requiring vaccination on February 27, 1902.

nation would generally be subject to fines.²⁶ In 1902, pursuant to a Massachusetts state statute, the city of Cambridge adopted a regulation requiring that all inhabitants who had not been vaccinated for smallpox in the previous five years be vaccinated or pay a five dollar fine.²⁷ Henning Jacobson, an inhabitant of Cambridge, refused to submit to the mandatory smallpox vaccination or pay the fine.²⁸ At trial, Jacobson argued that he feared the vaccination would injure his health, as he knew of people over the years who had suffered negative side effects.²⁹ Jacobson asserted that the Cambridge regulation and the underlying Massachusetts statute violated his Fourteenth Amendment Due Process rights.³⁰

The United States Supreme Court granted certiorari in *Jacobson v. Massachusetts* in 1904 and the following year issued a 7-2 opinion in which Justice Harlan affirmed the rights of the states to pass such mandatory vaccination laws so long as they were “necessary” and “reasonable.”³¹ The Court reasoned that even under the Constitution, the rights of the individual are not absolute, because pursuant to a state’s broad police powers, “persons and property are subject to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state.”³² Given these broad, flexible powers, the Court did not hesitate to affirm state action taken in the face of “paramount necessity” when the action taken was neither “arbitrary” nor “unreasonable.”³³ The Court emphasized that Cambridge employed “reasonable regulations, as the safety of the general public may demand.”³⁴ The Court also noted that smallpox presented an “imminent danger” that “imperiled an entire population.”³⁵

Less than two decades later, the Supreme Court re-affirmed *Jacobson* in *Zucht v. King* and extended the holding to allow the conditioning of school attendance on vaccination compliance.³⁶ The Court decided *Jacobson* and *Zucht* in an age when the only restraint on mandatory vaccination in schools was the science required to create such a vaccination: “Presently, new vaccine mandates are presumed constitutionally valid under *Jacobson*, even when the vaccines combat diseases that are not airborne and from which individuals have some other recourse to protect themselves.”³⁷ In the decades since these deci-

²⁶ *Id.* Massachusetts initially instituted a \$5 fine. *Id.*

²⁷ *Id.*

²⁸ *Id.* at 13.

²⁹ *Id.* at 23.

³⁰ *Id.* at 13.

³¹ *Id.* at 28.

³² *Id.* at 26 (quoting *Thorpe v. Rutland & Burlington R.R. Co.*, 27 Vt. 140, 1854 WL 370, at *7 (1855)).

³³ *Id.* at 27, 28.

³⁴ *Id.* at 29.

³⁵ *Id.* at 29, 31.

³⁶ *Zucht v. King*, 260 U.S. 174, 177 (1922).

³⁷ *Toward A Twenty-First-Century*, *supra* note 10, at 1821.

sions, *Jacobson* and *Zucht* have been used as rubber stamps for mandatory vaccination programs.³⁸ The approval and recommendation of immunizations by the Centers for Disease Control (“CDC”) and the Advisory Committee on Immunization Practices (“ACIP”) are inevitably followed soon after by state statutes and municipal regulations mandating vaccines of the latest diseases with an available preventive immunization.³⁹

B. *The Current State of Mandatory Vaccinations*

As time passes, the diseases being vaccinated against look less and less like smallpox. Current widely-recommended or required vaccinations include those to prevent diphtheria, tetanus, and acellular pertussis (“DTaP”);⁴⁰ Hepatitis B,⁴¹ Hepatitis A,⁴² polio,⁴³ measles,⁴⁴ mumps, and rubella (“MMR”);⁴⁵ varicella (“chicken pox”),⁴⁶ and influenza, rotavirus, haemophilus Influenza B (“HiB”),⁴⁷ and pneumococcus.⁴⁸ Smallpox constituted a national menace and no group of persons was out of its reach.⁴⁹ One reason that smallpox warranted mandatory vaccination is that it is readily contagious.⁵⁰ Vaccination is the only reasonable means to prevent smallpox transition, short of complete isolation from the

³⁸ Law, *supra* note 3, at 1754 (reflecting a widely held view that “our state and federal constitutions give state authorities broad discretion to determine whether vaccines are required”).

³⁹ CTRS. FOR DISEASE CONTROL AND PREVENTION, CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS 2005–2006 (Aug. 2006), available at http://www.immunize.org/laws/2005-06_izrequirements.pdf [hereinafter CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS]. All states condition school attendance on some form of immunization and each of the vaccinations listed below are required by at least seven states.

⁴⁰ *Id.* (immunization required in all fifty states).

⁴¹ *Id.* (immunization required at some age (for child care, kindergarten, or middle school) in forty-seven states).

⁴² *Id.* (immunization required in seven states and recommended in two others).

⁴³ *Id.* (immunization required in all fifty states).

⁴⁴ *Id.* (second dose of measles vaccination is required in all fifty states).

⁴⁵ *Id.* (immunization required in all fifty states).

⁴⁶ *Id.* (immunization required in forty-four states).

⁴⁷ *Id.* (immunization required in forty-eight states).

⁴⁸ *Id.* (immunization required in thirteen states).

⁴⁹ Ctrs. for Disease Control and Prevention, Smallpox Disease Overview, <http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp> (last visited Mar. 21, 2010). Smallpox can be contagious in carrier even without the presence of external symptoms, is fatal in nearly a third of all cases, and there is no known cure. Within the last century, smallpox has had outbreaks in a wide variety of countries, including the United States, Somalia, and West Germany. *Id.*

⁵⁰ Ctrs. for Disease Control and Prevention, Questions and Answers About Smallpox Disease, <http://www.bt.cdc.gov/agent/smallpox/disease/faq.asp> (last visited Mar. 21, 2010).

outside world.⁵¹ The more recent additions to the ubiquitous mandatory vaccine regimens, like tetanus⁵² and Hepatitis B⁵³, look nothing like smallpox.

Tetanus, though affecting large numbers of people, is not a contagious disease that would benefit from “herd immunity.”⁵⁴ Proponents defend the mandatory tetanus vaccination by pointing out that “children are at risk of tetanus exposure while in the school environment” and, therefore, it makes sense to condition school attendance on tetanus vaccination.⁵⁵ The Hepatitis B vaccination is also widely required prior to school registration.⁵⁶ Though Hepatitis B is contagious, in the vast majority of cases the virus is transmitted by sexual intercourse or other high risk behavior, such as sharing of needles for intravenous drug use, blood transfusions, and kidney dialysis.⁵⁷ This is hardly the airborne menace that smallpox posed, yet proponents of the mandatory Hepatitis B vaccination argue that the virus is often contracted from an indeterminate source and that high-risk activities are not the only way the virus can be contracted.⁵⁸

C. *Costs of Reducing Fatalities and Casualties for Other Diseases*

This section considers the cost of mandatory vaccinations that have been implemented on a widespread basis in the United States. The purpose is to lay out a basis for comparison with HPV, focusing on the factors most relevant to the Modified Hand Formula,⁵⁹ namely the economic costs of vaccinating a nation of school children and the human costs associated with those diseases.

DTaP (Diphtheria, Tetanus, and Pertussis): Vaccination is required in all fifty

⁵¹ *Id.* While there is a smallpox vaccine, as yet there is no known treatment for the virus. *Id.*

⁵² Immunization Action Coal., Tetanus Vaccine Questions and Answers (Feb. 2009), <http://www.vaccineinformation.org/tetanus/qandavax.asp>.

⁵³ World Health Org., Hepatitis B Factsheet (Aug. 2008), <http://www.who.int/mediacentre/factsheets/fs204/en/index.html>.

⁵⁴ Javitt, Berkowitz & Gostin, *supra* note 20, at 389 (noting no “herd immunity” benefit for tetanus); Charles Davis, Tetanus Causes, Symptoms, Treatment, Vaccine and Prevention, at 1 (2008), http://www.emedicinehealth.com/tetanus/article_em.htm (stating worldwide incidence of tetanus is 500,000 to 1,000,000 cases per year).

⁵⁵ Douglas J. Opel, Douglas S. Diekema & Edgar K. Marcuse, *A Critique of Criteria for Evaluating Vaccines for Inclusion in Mandatory School Immunization Programs*, 122 PEDIATRICS 504, 509 (2008).

⁵⁶ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3. Vaccination is required in forty-seven states.

⁵⁷ eMedicineHealth.com, Hepatitis B Causes, Symptoms, Diagnosis, Treatment, and Prevention Information, http://www.emedicinehealth.com/hepatitis_b/page2_em.htm (last visited Mar. 21, 2010).

⁵⁸ Opel, Diekema & Marcuse, *supra* note 55, at 509. The authors note that “there are no risk factors identified in 40% of cases of Hepatitis B infection in children and adolescents” and that “the routes for transmitting Hepatitis B from person to person that are known are not confined to high-risk activities.” *Id.*

⁵⁹ See *supra* Part IV.A.

states.⁶⁰ Diphtheria is relatively rare in developed countries where immunization is a decades-long tradition.⁶¹ Diphtheria is highly contagious and involves lengthy treatment periods.⁶² There was a recent outbreak of diphtheria in the former Soviet Union, where 50,000 cases were reported.⁶³ If untreated, the mortality rate of diphtheria is forty to fifty percent.⁶⁴ Tetanus is caused by infection of open wounds but is not contagious.⁶⁵ However, tetanus is deadly, causing death in more than ten percent of cases.⁶⁶ Pertussis, also known as Whooping Cough, is a highly contagious respiratory infection.⁶⁷ Vaccination programs in the United States have reduced annual death rates from 5000–10,000 to less than thirty.⁶⁸ The DTaP vaccination program consists of five doses,⁶⁹ with each dose costing upwards of twenty dollars each.⁷⁰

Hepatitis B: Vaccination is required in forty-seven states.⁷¹ The CDC reports that six to ten percent of persons over the age of five develop chronic Hepatitis B.⁷² Approximately fifteen to twenty-five percent of individuals with chronic Hepatitis B develop serious liver conditions, and 2000–4000 people per year die of Hepatitis B-related liver diseases.⁷³ Hepatitis B rates of infection have decreased by approximately eighty percent since the vaccination was introduced in 1991.⁷⁴ Hepatitis B vaccination consists of three or four doses⁷⁵ cost-

⁶⁰ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁶¹ Nemours Found., KidsHealth: Diphtheria, http://kidshealth.org/parent/infections/bacterial_viral/diphtheria.html (last visited May 4, 2010).

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Nemours Found., TeensHealth: Tetanus, http://kidshealth.org/teen/infections/bacterial_viral/tetanus.html (last visited May 4, 2010).

⁶⁶ Ctrs. for Disease Control and Prevention, Vaccines and Preventable Diseases: Tetanus (Lockjaw) Vaccination (May 18, 2009), <http://www.cdc.gov/vaccines/vpd-vac/tetanus/default.htm#disease>.

⁶⁷ Ctrs. for Disease Control and Prevention, Vaccines and Preventable Diseases: Pertussis (Whooping Cough) Vaccination (June 1, 2007), <http://www.cdc.gov/vaccines/vpd-vac/pertussis/default.htm>.

⁶⁸ Nemours Found., KidsHealth: Whooping Cough (Pertussis), http://kidshealth.org/parent/infections/bacterial_viral/whooping_cough.html (last visited May 4, 2010).

⁶⁹ CTRS. FOR DISEASE CONTROL AND PREVENTION, DIPHTHERIA TETANUS & PERTUSSIS VACCINES: WHAT YOU NEED TO KNOW (2007), available at <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-dtap.pdf>.

⁷⁰ Ctrs. for Disease Control and Prevention, CDC Vaccine Price List, <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm> (last visited Mar. 21, 2010) [hereinafter CDC Vaccine Price List].

⁷¹ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁷² Ctrs. for Disease Control and Prevention, Viral Hepatitis: FAQs For The Public (JUNE 9, 2009), <http://www.cdc.gov/hepatitis/B/bFAQ.htm#statistics>.

⁷³ *Id.*

⁷⁴ *Id.*

ing upwards of twenty dollars per dose.⁷⁶

Hepatitis A: Vaccination is required in only seven states.⁷⁷ There are an estimated 32,000 new infections of Hepatitis A per year in the United States, down significantly from when the vaccine was introduced in 1995.⁷⁸ Hepatitis A rarely causes liver failure and death, and the vast majority of cases end in complete recovery without any lasting effects.⁷⁹ The Hepatitis A vaccination consists of two doses⁸⁰ costing about thirty dollars per dose.⁸¹

Polio: Vaccination is required in all fifty states.⁸² Prior to advent of the polio vaccine, there were up to 60,000 new cases and 3000 deaths per year in the United States.⁸³ Polio is believed to have been eliminated in the United States in 1979.⁸⁴ The Polio vaccination consists of four doses,⁸⁵ costing about twenty-four dollars per dose.⁸⁶

MMR: Vaccination is required in all fifty states.⁸⁷ The MMR vaccination consists of two doses⁸⁸ costing upwards of forty-five dollars per dose.⁸⁹

Varicella (chicken pox): Vaccination is required in forty-four states.⁹⁰ Vari- cella is a highly infectious disease, commonly causing fever and itchy rashes, with possible complications including skin infection, swelling of the brain, and pneumonia.⁹¹ Vaccination reduces the risk of infection by up to ninety percent

⁷⁵ *Id.*

⁷⁶ CDC Vaccine Price List, *supra* note 70.

⁷⁷ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁷⁸ Centers for Disease Control and Prevention, Hepatitis A FAQs for the Public, <http://www.cdc.gov/hepatitis/A/aFAQ.htm#statistics> (last visited Mar. 21, 2010).

⁷⁹ *Id.*

⁸⁰ CTRS. FOR DISEASE CONTROL AND PREVENTION, HEPATITIS A VACCINE: WHAT YOU NEED TO KNOW (2006), available at <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-a.pdf>.

⁸¹ CDC Vaccine Price List, *supra* note 70.

⁸² CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁸³ Nemours Found., KidsHealth, Polio, http://kidshealth.org/parent/infections/bacterial_viral/polio.html (last visited Mar. 21, 2010).

⁸⁴ *Id.*

⁸⁵ CTRS. FOR DISEASE CONTROL AND PREVENTION, POLIO VACCINE: WHAT YOU NEED TO KNOW (2000), available at <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-IPV.pdf>.

⁸⁶ CDC Vaccine Price List, *supra* note 70. Note that the polio vaccine is listed as e-IPV.

⁸⁷ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁸⁸ CTRS. FOR DISEASE CONTROL AND PREVENTION, MEASLES, MUMPS & RUBELLA (MMR) VACCINES: WHAT YOU NEED TO KNOW (2008), available at <http://www.cdc.gov/vaccines/Pubs/vis/downloads/vis-mmr.pdf>.

⁸⁹ CDC Vaccine Price List, *supra* note 70.

⁹⁰ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁹¹ Ctrs. for Disease Control and Prevention, Vaccines and Preventable Diseases: Varicella (Chickenpox) In-Short (2008), <http://www.cdc.gov/vaccines/vpd-vac/varicella/in-short-adult.htm> (last visited Mar. 21, 2010) [hereinafter Varicella In-Short].

and results in more mild forms of the infection for over ninety-five percent.⁹² The varicella vaccination consists of two doses⁹³ costing upwards of eighty dollars per dose.⁹⁴

HiB: Vaccination is required in forty-eight states.⁹⁵ Prior to advent of the vaccine, HiB infected 20,000 children annually, resulting in nearly 1000 deaths.⁹⁶ The HiB vaccination consists of four doses⁹⁷ costing upwards of twenty dollars per dose.⁹⁸

Pneumococcus: Vaccination is required in only thirteen states.⁹⁹ Before availability of the vaccine, pneumococcus caused more than 700 cases of meningitis, 13,000 blood infections, and five million ear infections annually.¹⁰⁰ The pneumococcal vaccination consists of four doses¹⁰¹ and costs over eighty dollars per dose.¹⁰²

Meningococcus: Vaccination is not required by any state and recommended in only two states.¹⁰³ Between 1000 and 2600 people contract meningococcus each year. Ten to fifteen percent of cases are fatal and eleven to nineteen percent of survivors lose limbs or suffer serious neurological dysfunction, regardless of whether they receive antibiotic treatments.¹⁰⁴ The meningococcal vaccination is ninety percent effective and consists of one dose¹⁰⁵ costing over ninety dollars.¹⁰⁶

⁹² Ctrs. for Disease Control and Prevention, Vaccines and Preventable Diseases: Varicella (Chickenpox) Vaccination, <http://www.cdc.gov/vaccines/vpd-vac/varicella/#disease> (last visited Mar. 21, 2010).

⁹³ Varicella In-Short, *supra* note 91.

⁹⁴ CDC Vaccine Price List, *supra* note 70.

⁹⁵ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

⁹⁶ CTRS. FOR DISEASE CONTROL AND PREVENTION, HAEMOPHILUS INFLUENZAE TYPE B (HIB) VACCINE: WHAT YOU NEED TO KNOW (1998), available at <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hib.pdf>.

⁹⁷ *Id.*

⁹⁸ CDC Vaccine Price List, *supra* note 70.

⁹⁹ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

¹⁰⁰ CTRS. FOR DISEASE CONTROL AND PREVENTION, PNEUMOCOCCAL CONJUGATE VACCINE: WHAT YOU NEED TO KNOW (2002), available at <http://www.cdc.gov/vaccines/Pubs/vis/downloads/vis-pcv.pdf>.

¹⁰¹ *Id.*

¹⁰² CDC Vaccine Price List, *supra* note 70.

¹⁰³ CHILDCARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3.

¹⁰⁴ CTRS. FOR DISEASE CONTROL AND PREVENTION, MENINGOCOCCAL VACCINES: WHAT YOU NEED TO KNOW (2008), available at <http://www.immunize.org/vis/menin06.pdf>.

¹⁰⁵ *Id.*

¹⁰⁶ CDC Vaccine Price List, *supra* note 70.

III. HPV AND GARDASIL

A. *Gardasil Is Discovered as a Means to Prevent HPV Transmission*

While debate over the wisdom of mandating Hepatitis B vaccination for school age children has faded, the 2006 FDA approval of Gardasil for purposes of immunizing young women against HPV has once again stirred up the discussion of the propriety of mandating vaccinations.¹⁰⁷ HPV is an extremely common disease, affecting about 6.2 million Americans annually: “[O]ver half of all sexually active men and women become infected at some time in their lives.”¹⁰⁸ HPV is oftentimes relatively benign, and treatment is unnecessary more often than not; “the body’s own defense system will clear the virus” and no health problems will result.¹⁰⁹ While not harmful itself, HPV may cause a variety of related conditions, including genital warts, cervical cancer,¹¹⁰ penile cancer,¹¹¹ and anal cancer.¹¹² Despite the prevalence of HPV, it is preventable, even absent vaccination.¹¹³ HPV transmission can be effectively prevented through practicing abstinence¹¹⁴ or through the regular use of condoms.¹¹⁵

However, studies have shown that the surest method of preventing transmission of HPV among women, barring abstinence, is Merck’s Gardasil, the first

¹⁰⁷ FDA Licenses New Vaccine, *supra* note 4.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ Nat’l Cancer Inst., Penile Cancer Home Page, <http://www.cancer.gov/cancertopics/types/penile/> (last visited May 4, 2010) [hereinafter Penile Cancer Home Page].

¹¹² Am. Cancer Soc’y, Do We Know What Causes Anal Cancer? (Apr. 25, 2007), http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_Do_we_know_what_causes_Anal_Cancer_47.asp (noting that while no exact cause of anal cancer is known, there is a strong link between anal cancer and HPV).

¹¹³ Lisa Fayed, *How to Prevent and Reduce Your Risk of HPV*, ABOUT.COM, July 30, 2008, http://cervicalcancer.about.com/od/riskfactorsandprevention/a/hpv_prevention.htm (“Currently, there are only two HPV prevention methods: abstinence and the HPV vaccine.”). The website goes on to note that complete abstinence is an unrealistic form of prevention for most adults, but there are other ways to reduce the risk of transmission. The two risk reduction methods listed are using condoms, which reduces the transmission rate by seventy percent, and limiting your number of sexual partners. *Id.*

¹¹⁴ *Id.* I am in no way suggesting that abstinence or abstinence education should be the sole means of protection. Abstinence is 100% effective at preventing transmission of HPV, although it is acknowledged that given the known universe of far more lethal sexually transmitted diseases, abstinence is not likely to put much of a dent in the problem. However, education is a relatively inexpensive alternative to mandatory vaccination and may make some marginal impact.

¹¹⁵ Rachel L. Winer et al., *Condom Use and the Risk of Genital Humanpapillomavirus Infection in Young Women*, 354 NEW ENG. J. MED. 2645, 2651 (2006) (demonstrating a 70% decrease in occurrence of HPV in women who always used condoms and about a 50% decrease among those who used condoms more often than not).

HPV vaccine.¹¹⁶ Gardasil is nearly 100% effective in preventing transmission for HPV types 6, 11, 16, and 18.¹¹⁷ A five-year study showed only minimal adverse effects among 11,000 women injected with the vaccine.¹¹⁸ Most side effects involved irritation around the injection site.¹¹⁹ Long-term effects are as yet unknown, causing some commentators to question the FDA certification of Gardasil as a safe drug.¹²⁰ A recently-released study reported that Gardasil was ninety percent effective at preventing genital warts in males.¹²¹ No major studies have been released regarding the effects of Gardasil on penile or anal cancer in males. If approved, vaccination with Gardasil would require a three dose series over a period of six months costing upwards of \$375.¹²²

B. *The Policy Debate Over the Wisdom of Mandatory HPV Vaccination*

The prospect of adding a new mandatory vaccination program has prompted response by a number of legal scholars.¹²³ In investigating the social policy, public health, and legal implications that surround mandated vaccination of school-aged girls against a sexually transmitted disease, the following legal commentators have taken positions on whether such programs should or could be done.

1. Javitt, Berkowitz, and Gostin: Questioning the Wisdom and Legal Viability of the Mandatory Vaccine

A trio of commentators argues that social and fiscal policies militate against mandatory vaccination of HPV for girls, despite Gardasil's efficacy in preventing cervical cancer.¹²⁴ Gail Javitt, Deena Berkowitz, and Lawrence O. Gostin contend that the scientific evidence collected is not yet sufficient to ensure the long-term safety of such a vaccination regime.¹²⁵ In addition, they assert that mandating HPV vaccination may result in overall negative social effects.¹²⁶ The social backlash from concerned parents over the imposition of the HPV

¹¹⁶ FDA Licenses New Vaccine, *supra* note 4.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Javitt, Berkowitz & Gostin, *supra* note 20, at 393 (“[M]andating HPV vaccination at the present time would be premature and ill-advised. The vaccine is relatively new, and long-term safety and effectiveness in the general population is unknown.”).

¹²¹ Mike Stobbe, *HPV Vaccine Prevents Genital Warts in Men*, SFGATE.COM, Nov. 14, 2008, http://articles.sfgate.com/2008-11-14/news/17127836_1_vaccine-targets-expensive-vaccine-vaccine-s-maker.

¹²² *Id.*

¹²³ A search of Westlaw's database of journals and law reviews on April 10, 2010 resulted in seventy-three hits for the subject of HPV since 2009.

¹²⁴ Javitt, Berkowitz & Gostin, *supra* note 20.

¹²⁵ *Id.* at 388.

¹²⁶ *Id.* at 390.

vaccination before a full and fair debate has been completed may undermine the entire system of mandatory school vaccinations and national public health.¹²⁷ Moreover, the fiscal cost of funding HPV vaccination for millions of children on an annual basis could negatively impact existing health and vaccination programs by siphoning off what little funds are currently provided, stretching the system too thin.¹²⁸

Almost as an aside, Javitt, Berkowitz, and Gostin acknowledge that there may be constitutional issues with mandating vaccination for females only.¹²⁹ They point to the standard *Jacobson* argument that mandatory vaccination may violate the Due Process Clause because “it violates a protected interest in refusing medical treatment.”¹³⁰ They further suggest that it could be an Equal Protection violation to mandate HPV vaccination only for females, as states may be impermissibly distinguishing based on gender, especially in light of the fact that males would also benefit from vaccination.¹³¹

2. Sylvia Law: Defending the Public Health Necessity of Mandatory HPV Vaccination

New York University School of Law Professor Sylvia Law acknowledges some of the risks and possible negative effects of mandating HPV vaccination but contends that the negative effects of not mandating the vaccination would be much greater.¹³² Professor Law asserts that the public health consequences of cervical cancer, combined with the scientifically-demonstrated effectiveness of Gardasil of preventing HPV transmission, are too compelling to ignore.¹³³ Professor Law argues that mandatory HPV vaccination fits comfortably within the rubric set out by Justice John Marshall Harlan in *Jacobson v. Massachusetts*.¹³⁴ Professor Law recognizes the potential for an Equal Protection Clause violation in mandating HPV vaccination only for girls, but believes the risk is outweighed by the health necessity and benefits.¹³⁵

¹²⁷ *Id.* at 390.

¹²⁸ *Id.* at 392.

¹²⁹ *Id.* at 392.

¹³⁰ *Id.* at 392.

¹³¹ *Id.* at 392 (“The government must show that the challenged classification serves an important state interest and that the classification is at least substantially related to serving that interest.”).

¹³² Law, *supra* note 3, at 1772 (pointing out that the possible negative effects of mandating HPV vaccination are “uncertain and speculative” while the health related effects of not acting are “certain and preventable”).

¹³³ *Id.* at 1771.

¹³⁴ *Id.* at 1753 (“[I]n 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.”).

¹³⁵ *Id.* at 1763–64 (suggesting the testing discrepancy between females and males may

To overcome potential societal backlash and parental objections, Professor Law suggests pairing mandatory vaccination with a broad opt-out provision.¹³⁶ While this would lower immunization levels relative to a narrow exemption alternative, such a program would still have the advantage of extending the benefits “to racial minorities, the uninsured, and low-income children,” while also respecting the interest of parents in “preserving individual decision making.”¹³⁷

3. *Harvard Law Review* Note: “Practical Necessity” or “Medical Necessity”: Arguments to Update the *Jacobson* Test

An interesting approach is taken in an unsigned Note in the *Harvard Law Review* published in May 2008.¹³⁸ The author presents a two-tiered approach to evaluating the “necessity” of vaccination as a way to create more flexibility in balancing civil liberties and public health needs.¹³⁹ By offering broad exemption clauses in some circumstances while providing only narrow or restrictive opt-out provisions in others, the author suggests that the desired balance can be achieved.¹⁴⁰ The applicable exemption program would be determined by dividing the idea of “necessity” introduced in *Jacobson* into two separate categorizations: “medical necessity” and “practical necessity.”¹⁴¹

“Medical necessity” is present when vaccination is the only reasonable means of preventing transmission and spread of a disease, such as in *Jacobson*, where individuals could protect themselves from smallpox only by near complete isolation from society.¹⁴² In cases of “medical necessity,” vaccination will be mandatory, and although exemptions will be allowed, it will only be for very narrow categories so as to maximize the effect of “herd immunity.”¹⁴³ In cases of “practical necessity,” vaccination will still be labeled mandatory, in that vaccination is the default option, but broad, “no-questions-asked opt-outs”

have less than innocent origins: “it is 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”).

¹³⁶ *Id.* at 1772 (“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.”).

¹³⁷ *Id.* at 1769–70.

¹³⁸ *Toward a Twenty-First-Century*, *supra* note 10.

¹³⁹ *Id.* at 1821.

¹⁴⁰ *Id.* at 1826 (The author notes that broad exemption clauses allow parents to opt-out of vaccinating their children without providing any reason or rationale for doing so. The narrower, restrictive exemption clauses allowed opt-out only when parents could provide evidence of negative health effects of vaccination or certain religious or philosophical objections.).

¹⁴¹ *Id.* at 1838.

¹⁴² *Id.* at 1838.

¹⁴³ *Id.* at 1838.

will be allowed.¹⁴⁴

The reasons behind treating the two conceptions of “necessity” differently are based on deference for the rights of parents and the possibility of popular backlash.¹⁴⁵ The author also contends that the two-tiered system would allow concerned parents to exercise their parental prerogatives in cases where mandatory vaccination was only practically necessary while protecting mandatory vaccination of more insidious diseases that are medically necessary, like smallpox, from indiscriminate popular backlash.¹⁴⁶

IV. ANALYSIS: LAYING OUT A NEW TEST FOR MANDATORY VACCINATION

Jacobson is not archaic in its arguments or considerations; it simply describes the balancing of factors for what may be the most obvious case in support of the constitutionality of mandating vaccination.¹⁴⁷ Smallpox brought devastating effects to the communities it touched and vaccination was the only readily available and feasible method of preventing its spread.¹⁴⁸ The risks to society of not immunizing every available individual were simply too great to allow people to opt out of vaccination at will.¹⁴⁹ Due to these unique circumstances, the arguments of *Jacobson* addressed a situation where public safety issues dwarfed the individual liberty interest in controlling personal medical decisions.¹⁵⁰ The failure of *Jacobson* in today’s world is not that the reasoning is no longer valid, but that it fails to contemplate, and therefore address, the marginal cases that have arisen now, a century later.

The flaw of *Jacobson* that has been repeatedly noted and must now be remedied is that the case fails to provide sufficient guidance to courts on what constitutes “necessity.”¹⁵¹ In short, when is it necessary to inoculate a population such that mandating vaccinations is constitutional? In theory, if the dangers

¹⁴⁴ *Id.* at 1840.

¹⁴⁵ *Id.* at 1839 (“Such a distinction would give policymakers and perhaps courts a more precise way to balance civil liberties and public health. If a vaccine is a practical necessity but not a medical necessity, then the public may not accept a full mandate for that vaccine.”).

¹⁴⁶ *Id.* at 1841.

¹⁴⁷ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

¹⁴⁸ Ctrs. for Disease Control and Prevention, Questions and Answers About Smallpox (Mar. 13, 2009), <http://www.bt.cdc.gov/agent/smallpox/disease/faq.asp>. Variola major, the most common form of smallpox, accounting for 90% of all occurrences, is fatal in 30% of cases. *Id.* There is no proven treatment for smallpox, and, currently, the only form of prevention is immunization. *Id.*

¹⁴⁹ Law, *supra* note 3, at 1752 (“[I]t is broadly understood to be unfair to allow exceptions for ‘free riders’ absent special and compelling circumstances.”).

¹⁵⁰ *Jacobson v. Massachusetts*, 197 U.S. 11, 29, 31 (1905) (referring to smallpox as an “imminent danger” that “imperiled an entire population”).

¹⁵¹ *Id.* at 27–28 (validating mandatory vaccination in the face of the “paramount necessity” of preventing epidemics when it is “necessary in order to protect the public health and secure the public safety”). For complaints about *Jacobson*’s increasingly obsolete analytic

and potential consequences of an otherwise unchecked disease present a “necessity” to vaccinate against that disease, it must be constitutional for states to mandate such a vaccination regime.

There are scholars who would argue that determinations of necessity are inherently political and, thus, these issues are best handled by legislatures and not by the courts.¹⁵² Yet, the job of courts in this field is not to judge whether or not a particular program is advisable, cost-effective, or politically feasible. Rather, the courts’ job is to assess the importance and weight of the individual interests being sacrificed and then determine the bare minimum of “necessity” a disease must present to make mandating vaccination constitutional. Courts should then determine whether or not the particular disease being considered for a mandatory vaccination scheme surpasses that bare minimum level of “necessity.” This is not so nuanced or complex as to make it a completely unjusticiable issue, as courts are used to balancing a variety of interests in making determinations.¹⁵³

Not only is it possible for courts to make such decisions, but it is also their duty to do so.¹⁵⁴ The goal then is to provide the courts with sufficient guidance to make such a determination and to provide a paradigm for courts to use in measuring the relative importance of the interests involved. Judges need a way to think about all the relevant factors, but the lack of room for subtlety and variation inherent in a single factor distinction is inadequate for analyzing a complex issue.¹⁵⁵ Thus, it is appropriate to develop a multi-factor balancing test.

The framework of such a test may be judicially adopted, given that in the century since *Jacobson*, Congress has neither legislatively overturned nor

framework, see, for example, *Toward a Twenty-First-Century*, *supra* note 10, at 1820 (arguing that “necessity” should be separated into “medical necessity” and “practical necessity”).

¹⁵² See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984) (“The responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones: ‘Our Constitution vests such responsibilities in the political branches.’”) (quoting *TVA v. Hill*, 437 U.S. 153, 195 (1978)).

¹⁵³ See, e.g., *Goldberg v. Kelly*, 397 U.S. 254 (1970) (determining what procedures are required before termination of welfare benefits by balancing a variety of personal, public, and economic interests).

¹⁵⁴ *DeRolph v. Ohio*, 677 N.E.2d 733, 737 (Ohio 1997). Inspired by Chief Justice John Marshall’s opinion in *Marbury v. Madison*, Justice Sweeney commented on the duties of courts under the long-standing doctrine of judicial review: “The judiciary was created as a part of a system of checks and balances. We will not dodge our responsibility by asserting that this case involves a nonjusticiable political question.” *Id.* The *DeRolph* court was asserting its authority and duty to adjudicate in the field of education, which, like health care, is a field traditionally within the purview of the political branches.

¹⁵⁵ See *supra* Part III.B (discussing the flaws of categorizing diseases as presenting either “medical necessity” or “practical necessity”).

amended the Supreme Court's decision and authority. Because the morality, rights, and human costs at stake are important and variable, the test need not be conclusive. The test may act as a way of quantifying the financial and individual liberty costs and also the benefits to national security and the public health. For example, if 4000 lives could be saved annually by spending one million dollars on a painless vaccination program with no negative side effects, it would be difficult to find such a regime unconstitutional. On the other hand, if only ten lives could be saved annually by spending ten billion dollars on a painful and risky vaccination program, it would be difficult to find such a regime constitutional.

A. *The Modified Hand Formula as a Lens to View the Issue*

The Modified Hand Formula should be applied by courts to determine the constitutional validity of proposed mandatory vaccination schemes. The Modified Hand Formula's factors for determining the necessity of mandatory vaccination can be clearly laid out, allowing courts to easily compare those factors with one another and then conduct a balancing test. As in the original conception of the Hand Formula, a court compares the Burdens (B) of a program with the Probable Loss ($P \times L$) of not implementing the program.¹⁵⁶ Rather than using the formula to determine liability, as the original Hand Formula does,¹⁵⁷ courts could use the equation's result to determine the constitutionality of a given mandatory vaccination program. If the Burdens outweigh the Probable Loss ($B > P \times L$), then such a program should be deemed unconstitutional, and if the Probable Loss outweighs the Burdens ($B < P \times L$), then such a program should be found constitutional. Simply put:

If $B > P \times L$, then unconstitutional.

If $B < P \times L$, then constitutional.

The Burdens of a mandatory vaccination program break down into several factors. The most obvious and easiest to calculate is the economic burden. Courts can calculate this burden by taking the cost of a vaccination and multiplying it by the number of people to be vaccinated. A second burden is the potential for adverse effects; the good to be gained from vaccination must be balanced by the harm, or risk of harm, that those same vaccinations cause. The third and perhaps heaviest burden is that imposed by stripping an individual of the right to make choices regarding that individual's health. Also implicated in most of these cases is the right of parents to make healthcare decisions for their children.¹⁵⁸

The Probable Loss also involves sifting through and synthesizing a variety of

¹⁵⁶ *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947).

¹⁵⁷ *Id.*

¹⁵⁸ *See, e.g., Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534–35 (1925) (emphasizing “the liberty of parents and guardians to direct the upbringing . . . of children under their control”).

factors. Often the most compelling factor is the number of lives to be saved by the mandatory vaccination regime.¹⁵⁹ Another consideration is the prevention of non-lethal health issues. However, from this aggregate probable loss must be subtracted some number to account for the actual effectiveness of the vaccine. For example, if a vaccine were only seventy-five percent effective, the total number of possible fatalities and casualties to be prevented would have to be reduced by twenty-five percent. A final consideration is the availability of less restrictive methods of preventing transmission of the disease. The number of fatalities and casualties should also be reduced by the number that could be prevented by other methods that are voluntary and without question constitutional. This is because the number of lives to be saved under the mandatory vaccine program is only the number of lives over and above those that would be saved by other methods. Mandatory vaccination should be the last resort and employed only when all other methods have proven themselves inadequate.

B. *A Basis for Comparison*

Now that the mechanism for evaluating constitutionality has been laid out, it can be applied to the case of mandatory HPV vaccination for school-aged females. To be clear, this evaluation is not based on a subjective valuation of the factors involved, such as the value of a life, the importance of the liberty to make one's own health care choices, and the amount of financial resources necessary to implement such a program. Instead, other diseases are examined as a point of comparison. Comparisons are also limited to those diseases for which vaccination has already been widely mandated as a prerequisite for school enrollment.¹⁶⁰

These comparisons are made under the presumption that vaccinations that are widely mandated are constitutional. This presumption is followed even for vaccination regimes that have not been explicitly approved of by a federal court. Of course, this makes the comparisons less than perfect, as the mandatory vaccination regimes that have not been explicitly held constitutional may yet be successfully challenged. However, to limit comparison to only explicitly-approved mandatory vaccination programs would present only a skewed picture of what is and is not constitutional in this field. For example, comparing any mandatory vaccination program only to smallpox, thus defining the rampant epidemic of smallpox as the minimum level of destruction recognized as necessitating mandatory vaccination, would effectively make every other

¹⁵⁹ See *Jacobson v. Massachusetts*, 197 U.S. 11, 25, 27–28, 31 (1905) (repeatedly emphasizing that the State's police power to regulate public health stems from the need "to protect itself against an epidemic threatening the safety of all").

¹⁶⁰ As a matter of policy, it might also serve to compare the impact of HPV on people to diseases for which vaccinations have not been mandated, but only recommended. However, this truly is only a matter of policy and would not further the argument on whether or not it would be constitutional for such a vaccination to be mandated.

mandatory vaccination program unconstitutional. For the purposes of comparison, it is also presumed that vaccination programs that are only recommended would not be constitutional if mandatory.¹⁶¹

C. *Applying the Modified Hand Formula to Female Vaccination of HPV*

In evaluating the possible constitutionality of mandatory female vaccination of HPV, consideration should begin with the burdens. As of 2006, there were approximately 8.5 million females of the ages nine to fourteen in the United States.¹⁶² As of 2008, the cost of a Gardasil vaccination was approximately \$375.¹⁶³ Multiplying \$375 by 8.5 million females in the relevant range gives an estimated bill for nationwide mandatory adoption of vaccination of approximately \$3.2 billion. Clearly this is a considerable amount of money, but perhaps worthwhile given the vaccination's potential benefits. The health care burden due to potential negative side effects appears to be quite low,¹⁶⁴ with most complaints dealing with irritation around the injection site.¹⁶⁵ Perhaps the most onerous burden is that assumed by individuals who are forced to be vaccinated against their will. This is impossible to quantify in any meaningful way and probably varies from individual to individual. Therefore, the burdens include \$3.2 billion in vaccination costs, the risk of minor side effects, and the deprivation of a fundamental, but not a guaranteed right.

The next step of the Modified Hand Formula is to evaluate the Probable Loss of not implementing mandatory vaccination of HPV in females. The latest statistics show that HPV is present in seventy percent of women with cervical cancer.¹⁶⁶ Approximately 11,000 women per year are diagnosed with cervical cancer and another 4000 women die every year from the disease.¹⁶⁷ Presuming a causal connection between HPV and cervical cancer, eliminating HPV would prevent approximately 7700 cases of cervical cancer and save approximately 2800 lives. Subtracted from these totals should be an indeterminate number of diagnoses of cervical cancer and deaths that could be prevented by implementing less restrictive, alternative methods of prevention. HPV education is probably the least restrictive method. For example, young females could be informed that HPV cannot be transferred in the absence of skin to skin contact

¹⁶¹ Again, there are obvious flaws and limitations to this comparison, but if nothing else, these comparisons should aid in furthering the discussion about the constitutionality of mandatory vaccination for the type of diseases that were not explicitly considered by the Court in *Jacobson*.

¹⁶² U.S. CENSUS BUREAU, STATE FACTS FOR STUDENTS: UNITED STATES, http://www.census.gov/schools/facts/united_states.html (last visited May 4, 2010).

¹⁶³ Stobbe, *supra* note 121.

¹⁶⁴ See FDA Licenses New Vaccine, *supra* note 4.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ Nat'l Cancer Inst., Human Papillomaviruses and Cancer: Questions and Answers, <http://www.cancer.gov/cancertopics/factsheet/risk/HPV> (last visited Mar. 21, 2010).

and that use of condoms reduces transmission by seventy percent.¹⁶⁸ Another less restrictive method is that offered for many other diseases: voluntary vaccination. Voluntary vaccination has almost all the benefits of mandatory vaccination, without incurring the burden of impinging on individual liberty interests.

Assuming none of the alternative methods saved a single life, saving 2800 lives per year by way of mandatory vaccination would come at the cost of \$1.1 million per life. For every life that an alternative method would have saved, that cost increases. In comparison, haemophilus Influenza B (“HiB”) vaccination is mandatory for school attendance in forty-eight states.¹⁶⁹ A course of HiB vaccination costs about \$100 and prevents about 1000 deaths annually.¹⁷⁰ However, HiB vaccination is administered to both females and males. Vaccinating approximately seventeen million students at \$100 each would cost about \$1.7 billion. Saving the 1000 lives annually would come at the cost of \$1.7 million per life. Operating on the presumption that mandatory HiB vaccination is constitutional,¹⁷¹ it is not implausible to conclude that mandatory vaccination of females for HPV would also be constitutional.

D. *Applying the Modified Hand Formula to Male Vaccination of HPV*

Having concluded that mandatory vaccination of females for HPV would be constitutional, I will engage in a similar analysis of mandatory vaccination of males for HPV. The values for males are the same as those for females except that the number of lives affected by HPV-caused anal and penile cancer is at least four times less than the number lives affected by HPV-caused cervical cancer.¹⁷² Thus, the cost of saving approximately 1000 lives per year would be at least \$4.5 million per life plus the intangible cost of being denied the right to make one’s own health care choices. The case for mandating vaccination of HPV in men becomes even weaker if it can be shown that the alternative, less restrictive methods would be even somewhat successful at preventing cancer and death in men.

Application of the Modified Hand Formula demonstrates that mandatory

¹⁶⁸ Fayed, *supra* note 113.

¹⁶⁹ CHILD CARE AND SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 39, at 3. Immunization is required in forty-eight states and recommended in Kansas. *Id.* It is neither required nor recommended in Delaware. *Id.*

¹⁷⁰ See *supra* Part II.C. Pre-vaccination HiB death rates were approximately 1000 per year and a four dose vaccination regime at upwards of \$20 per dose would cost in the neighborhood of \$100. *Supra* Part II.C.

¹⁷¹ See Immunization Action Coal., HiB Vaccine Questions and Answers, <http://www.vaccineinformation.org/hib/qandavax.asp> (last visited Mar. 21, 2010). This presumption is based on the fact that the vaccine is nearly twenty-five years old, having first been licensed in the United States in 1985, and no mandatory HiB vaccination statute has ever been challenged in federal court on constitutional grounds. *Id.*

¹⁷² See *supra* Part IV.C and *infra* note 183.

vaccination of HPV in men is unconstitutional. It is illustrative to compare male vaccination against HPV to vaccination for meningococcus. Vaccination for meningococcus has not yet been mandated and it is only recommended in two states, despite relatively high rates of death and permanent damage.¹⁷³ Meningococcus causes up to 400 deaths and another 500 permanent physical and neurological injuries every year and would cost only \$90 to immunize against.¹⁷⁴ On the other hand, vaccinating HPV in men would prevent at most 560 deaths¹⁷⁵ at a cost of \$375 per person. Operating on the presumption that mandatory vaccination of meningococcus is unconstitutional, mandatory vaccination of HPV in males is also unconstitutional.

E. *Is It Reasonable to Have Two Different Standards for Mandatory Vaccination of Males and Females?*

Applying the Modified Hand Formula to mandatory vaccination of HPV creates an odd result. Specifically, application of the Modified Hand Formula suggests that the possibility of finding mandatory vaccination of women constitutional yet finding mandatory vaccination of men unconstitutional. This is because HPV negatively affects women at a significantly higher rate than men.¹⁷⁶ Taking men as an isolated group, mandatory vaccination would impose onerous economic and constitutional costs.¹⁷⁷ The potential loss of individual liberties is particularly significant given the availability of reasonable alternatives to preventing the spread of HPV through promotion of safe sex or

¹⁷³ See *supra* Part II.C.

¹⁷⁴ See *supra* Part II.C.

¹⁷⁵ Approximately 560 men die every year from penile and anal cancers. Nat'l Cancer Inst., Surveillance Epidemiology and End Results Stat Fact Sheets, http://seer.cancer.gov/csr/1975_2006/results_single/sect_01_table.01.pdf (last visited Mar. 21, 2010). The exact causes of both anal and penile cancers are not yet known. American Cancer Society, Can Anal Cancer Be Prevented?, http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_Can_Anal_Cancer_be_prevented_47.asp?sitearea (last visited Apr. 12, 2010); American Cancer Society, Do We Know What Causes Penile Cancer?, http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_Do_we_know_what_causes_penile_cancer_35.asp (last visited Apr. 12, 2010). Therefore, Gardasil would prevent at most 560 deaths, but more likely a smaller number.

¹⁷⁶ See Ctrs. for Disease Control and Prevention, STD Facts—Human Papillomavirus (HPV), <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm> (last visited Mar. 21, 2010) (noting over 20,000 women are diagnosed with cervical and other HPV-related genital cancers every year); Centers for Disease Control and Prevention, STD Facts, HPV and Men, <http://www.cdc.gov/std/hpv/stdfact-hpv-and-men.htm> (last visited Jan. 30, 2009) (reporting that approximately 3400 men are diagnosed each year with either penile or anal cancer). Under these figures women are more than six times more likely to be diagnosed with HPV.

¹⁷⁷ See Stobbe, *supra* note 121 (reporting that HPV vaccinations currently cost approximately \$375).

abstinence.¹⁷⁸ Moreover, the harm that would be avoided in implementing mandatory vaccinations for men is currently estimated at about than 560 lives per year.¹⁷⁹ This is not insignificant, but it is the *maximum* number of lives that could be saved by preventing HPV-related penile and anal cancers and not the actual number given that penile and anal cancers are not caused exclusively by HPV.¹⁸⁰ Comparing that number to the 3700 women lost every year due to cervical cancer,¹⁸¹ it is reasonable to institute different immunization regimes, whether mandatory or simply recommended, for women and men.

V. CONCLUSION: MANDATORY VACCINATION AND EQUAL PROTECTION

After the Supreme Court decided *Craig v. Boren* in 1976, statutes that allow different treatment based solely on gender are subject to intermediate scrutiny by the courts.¹⁸² In order to survive such scrutiny, the proponent of a gender-based statute would need to show that the classification serves an important governmental objective and that the means must be substantially related to that objective.¹⁸³

The important governmental objective in treating females and males differently regarding mandatory vaccination of HPV is the efficient protection of the public health.¹⁸⁴ This can be broken down into two parts: protection of the public health and efficient expenditure of government resources. The government would naturally like to prevent as many unnecessary deaths as possible. The government is operating with limited resources, however, which means

¹⁷⁸ Lisa Fayed, *Condoms and HPV*, About.com, Sept. 20, 2007, http://cervical-cancer.about.com/od/riskfactorsandprevention/a/condoms_HPV.htm (noting that abstinence is 100% effective at preventing transmission as HPV can only be contracted through skin-to-skin contact, and condoms are 70% effective). To be clear, I am not suggesting that abstinence or safe-sex education alone would be sufficient to prevent HPV transmission. These alternatives are suggested merely as complementary pieces to the prevention puzzle.

¹⁷⁹ Nat'l Cancer Inst., Surveillance Epidemiology and End Results Stat Fact Sheets, http://seer.cancer.gov/csr/1975_2006/results_single/sect_01_table.01.pdf (last visited Mar. 21, 2010) (showing 260 deaths due to anal cancer and 300 deaths due to penile cancer).

¹⁸⁰ See MedicineNet.com, *Penis Cancer Causes, Symptoms, Signs, Diagnosis and Treatment*, http://www.medicinenet.com/penis_cancer/article.htm (last visited on Mar. 21, 2010); MedicineNet.com, *Anal Cancer (Cancer of the Anus) Causes, Diagnosis, Information, Symptoms, and Treatment*, http://www.medicinenet.com/anal_cancer/article.htm (last visited Mar. 21, 2010).

¹⁸¹ FDA Licenses New Vaccine, *supra* note 4 (reporting that the strains of HPV vaccinated by Gardasil account for only 70% of cases of cervical cancer).

¹⁸² *Craig v. Boren*, 429 U.S. 190 (1976).

¹⁸³ *Id.* at 197.

¹⁸⁴ See Law, *supra* note 3, at 1764 (“[S]tates should add HPV vaccination to the list of mandatory school vaccinations [because] . . . [i]f 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.”).

that not all potentially beneficial public programs can be fully or even partially funded.

The basis for different treatment of females and males is the wide disparity of injury sought to be prevented. Assuming a roughly equivalent population of school-age males and females, the cost of vaccinating either group would be approximately equal. Yet HPV-related cancers occur and result in death at a rate more than six times higher in females than in males.¹⁸⁵ Thus, it would be nonsensical to dedicate equal amounts of resources to problems of greatly different sizes. Treating males and females differently would be substantially related to efficient expenditure of public resources.

Offering patently unequal treatment clearly violates the Equal Protection Clause.¹⁸⁶ Because the Supreme Court has never declared a mandatory vaccination program unconstitutional, it is impossible to say with any degree of certainty that mandatory vaccination of HPV in males is unconstitutional. However, the statistical impact of HPV-related cancers and deaths shows such a great disparity between the genders that treating them differently could be substantially related to fulfilling the important state objective of efficient protection of the public health.¹⁸⁷

It is reasonable to conclude that mandatory vaccination of HPV in females would be constitutional given the similarity of HPV to other diseases for which mandatory vaccination is widely accepted and, thus, presumptively constitutional. Conversely, the effects of HPV in males closely resemble diseases that are not widely vaccinated against and, thus, mandatory vaccination would possibly be unconstitutional. Whether or not mandatory vaccination of HPV in males would be constitutional, a comparison of the effects of HPV in females to the effects of HPV in males makes it apparent that disparate treatment along gender lines would not necessarily violate the Equal Protection Clause.

HPV-related cancer is clearly an important public health issue and one that deserves immediate attention. Given the myriad fundamental, sometimes conflicting interests at stake, it is difficult to conclude that mandating vaccination of HPV for either gender would be advisable at the current time. However, the specter of lives at risk militates in favor of swift attempts to provide access to Gardasil to as many young people as possible. Because FDA approval has been granted only to females thus far, this aim might best be achieved by a public school opt-in vaccination program, but only one that is strongly recommended by state vaccination programs. Any objections on Equal Protection grounds to providing vaccination only to females would be answered by the wide disparity between effects on the genders. Some may object that such an

¹⁸⁵ See *id.*

¹⁸⁶ See *United States v. Virginia*, 518 U.S. 515, 557 (1996) (finding a violation of Equal Protection Clause when the State of Virginia excludes women from a school that “offers an educational opportunity no other Virginia institution provides”).

¹⁸⁷ See discussion *supra* Part IV.E.

approach fails to reach a broad enough section of the population. However, as Justice Harlan asserted in *Jacobson*, vaccination should not “go so far beyond what [is] reasonably required for the safety of the public.”¹⁸⁸ Mandating vaccination of HPV may not go beyond that line, but it approaches the line. When fundamental liberty interests hang in the balance and reasonable alternatives exist, it is best not to go so far as even approaching that line.

¹⁸⁸ *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905).