

**COMPULSORY VACCINATION LAWS:
SEARCHING FOR A POLICY-MAKING
PROCESS IMMUNE TO BIAS**

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ABSTRACT

When Justice Harlan penned his opinion in Jacobson v. Massachusetts, the landmark case setting the paradigm for when states can mandate vaccination, he never imagined the innovative and unique vaccines that technology would produce in subsequent decades. Now, as new vaccines (such as the human papillomavirus vaccine) emerge that fit outside the bounds of precedential case law, state legislatures and courts face new territory when determining in what situations the need to protect public health via vaccination outweighs an individual's constitutionally-guaranteed rights. This Article explores the current process used when assessing vaccines that lay outside the Jacobson paradigm. Further, this Article critiques that process and argues that, when no set precedent exists, policy should be driven by those who are not swayed by social, cultural, religious, political, or economic factors. Instead, policy-makers should be those who can craft their decisions with an unbiased and scientifically-driven aim, one that will objectively weigh the interests of public health and private rights.

INTRODUCTION

On July 17, 1902, Henning Jacobson, facing a small fine, adamantly refused to be vaccinated for smallpox pursuant to a mandate ordered by the Board of Health of Cambridge, Massachusetts. Trumpeting his rights to “life, liberty and property,” Jacobson battled his way to the United States Supreme Court and for two-and-a-half years, managed to avoid the vaccine. Then, in December of 1904, the Supreme Court found for the Board of Health, holding that the Board's need to protect the public health and safety vindicated the compulsory vaccination law.

With *Jacobson* began a long history of courts empowering states to impose compulsory vaccination laws. Through *Jacobson*, the Supreme Court set a precedent that has provided the framework by which states determine when compulsory vaccination is appropriate. Since *Jacobson*, courts have readily upheld state compulsory vaccination laws for measles, smallpox, poliomyelitis, rubella, varicella, and other highly contagious and deadly diseases.

However, states' authority to create these laws is not always so clear. The less danger and imminence a given disease poses to the public health, the less necessary a compulsory vaccine is. This correlation inspires the question: what types of characteristics must a disease have to justify the invasion of an individual's rights to "life, liberty, and property" by mandating a vaccine? With the emergence of vaccines made for non-contagious but nonetheless prevalent and dangerous diseases (for example, the human papillomavirus (HPV) vaccine), the issue of state compulsory vaccination laws has become riddled with controversy. Mandating the HPV vaccine has caused a particularly heated debate due to the disease's origins as a sexually transmitted infection (STI).

As vaccines stray further from the Jacobson paradigm, state legislatures (which create mandatory vaccination laws) are given broader discretion for determining which vaccines should be mandatory. This process becomes especially disconcerting when controversial vaccines, such as the HPV vaccine, are used as political tools for garnering constituent votes.

Through the lens of the HPV vaccine, this Article discusses the process of mandating vaccines and asks who should be making those policy decisions. This Article proceeds in seven parts. Parts I, II, and III are predominantly dedicated to background and historical information critical to evaluating the way compulsory vaccination laws are treated today. Part I provides a background of HPV and its vaccine. Part II lays out the history of compulsory vaccination laws and describes the current paradigm for when mandatory vaccination is justified by public health and safety needs. Part III illustrates how the HPV vaccine does not fit within the existing paradigm.

Parts IV through VII transition into discussing how changes to the current policy-making process would lead to objective policies not swayed by social or economic pressures. Part IV discusses the current process for mandating a vaccine. Part V lists the problems with the current process, beginning with a discussion of social, cultural, and religious pressures faced by state representatives, followed by an explanation of how economic pressures play a role in the decision-making process as well. Part VI advocates for empowering other entities with policy-making authority so that they might offer a less-biased position on health policy decisions. Lastly, Part VII gives a brief introduction to a final consideration – accountability – that should be taken into account when deciding who should make these types of health policy decisions.

This Article makes no conclusions as to who should be making the decisions behind compulsory vaccination laws. However, it opens the discussion for reworking the process and incorporating other decision-making entities into the process. As this Article illustrates, the current process is too susceptible to social and economic pressures, and health policy should be premised on an unbiased, unclouded perspective that discerns the true needs of the public regarding safety and health.

I. HPV AND ITS VACCINE

HPV infects 6.2 million new people each year just in the United States,¹ making HPV the most common STI in the United States.² Globally, 50 percent of people who have had sex in their lifetime will be infected with HPV.³ In one study conducted in the United Kingdom, researchers found that even of women with only one lifetime sexual partner, 46 percent will acquire HPV within three years of becoming sexually active.⁴ While for most, HPV is innocuous, for others, HPV can lead to cervical cancer or genital warts. Specifically, HPV strains 16 and 18 reportedly cause 70 percent of cervical cancer cases and have also been attributed to anal, vulvar, vaginal, penile, and urethral cancers.⁵ HPV strains 6 and 11 cause 90 percent of anogenital warts and have also been attributed to recurrent respiratory papillomatosis.⁶

In June 2006, the United States Food & Drug Administration (FDA) announced its approval of Merck's Gardasil[®], the first vaccine against HPV,⁷ and in October 2009, the FDA announced its approval of GlaxoSmithKline's Cervarix[®], another HPV vaccine.⁸ Gardasil[®]

¹ Lawrence O. Gostin & Catherine D. DeAngelis, *Mandatory HPV Vaccination: Public Health vs Private Wealth*, 297 J. AM. MED. ASS'N 1921, 1921 (2007).

² Eileen F. Dunne et al., *Prevalence of HPV Infection Among Females in the United States*, 297 J. AM. MED. ASS'N 813, 813 (2007).

³ *Genital HPV Infection – Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/hpv/stdfact-hpv.htm> (last modified Aug. 9, 2012).

⁴ Stuart Collins et al., *High Incidence of Cervical Human Papillomavirus Infection in Women During Their First Sexual Relationship*, 109 BJOG 96, 96 (2002).

⁵ Gail Javitt, Deena Berkowitz, & Lawrence O. Gostin, *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?* 36 J.L. MED. & ETHICS 384, 385 (Summer 2008).

⁶ *Id.*

⁷ Letter from Norman W. Baylor, Director of Office of Vaccines, U.S. Food & Drug Administration, to Patrick Brill-Edwards, Director of Worldwide Regulatory Affairs, Merck & Co., Inc. (June 8, 2006), available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm111283.htm> [hereinafter Approval Letter (Gardasil) (June 8, 2006)].

⁸ Letter from Norman W. Baylor, Director of Office of Vaccines, U.S. Food & Drug

protects against HPV strains 6, 11, 16, and 18,⁹ while Cervarix[®] protects only against strains 16 and 18.¹⁰ Although clinical data has not yet proven that the HPV vaccine prevents cervical cancer, the HPV vaccine is nearly 100 percent effective at guarding against infections associated with HPV.¹¹

Subsequent to these FDA approvals, the Centers for Disease Control and Prevention (CDC), through its Advisory Committee on Immunization Practices (ACIP), issued recommendations regarding these vaccines. On June 29, 2006, the ACIP recommended that the HPV vaccine be routinely given to girls aged eleven to twelve years old, but noted that the vaccine can be given to girls as early as nine years old and as late as twenty-six years old.¹² The CDC has made additional recommendations relating to the use of the vaccine by boys. Following the FDA's approval of the vaccine for use in boys ages nine to twenty-six years old,¹³ the CDC recommended that, similar to young girls, the vaccine should be routinely given to boys aged eleven to twelve years old, but could also be administered to boys as young as nine years and as old as twenty-six.¹⁴ Professional medical associations, including the American Academy of Pediatrics, have recommended use of the vaccine for adolescent girls when appropriate.¹⁵

Administration, to Matthew Whitman, GlaxoSmithKlein Biologicals (Oct. 16, 2009), *available at* <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186959.htm> [hereinafter Approval Letter (Cervarix) (Oct. 16, 2009)].

⁹ Approval Letter (Gardasil) (June 8, 2006), *supra* note 7.

¹⁰ Approval Letter (Cervarix) (Oct. 16, 2009), *supra* note 8.

¹¹ Lawrence O. Gostin, *Mandatory HPV Vaccination and Political Debate*, 306 J. AM. MED. ASS'N, 1699, 1700 (2011).

¹² Press Release, The Centers for Disease Control & Prevention, CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination (June 29, 2006), *available at* <http://www.cdc.gov/media/pressrel/r060629.htm>.

¹³ Letter from Wellington Sun, Director of Division of Vaccines, U.S. Food & Drug Administration, to Patrick Brill-Edwards, Merck & Co., Inc. (Oct. 16, 2009), *available at* <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm186991.htm> [hereinafter Approval Letter (Gardasil) (Oct. 16, 2009)].

¹⁴ Press Briefing Transcript, *ACIP Recommends All 11-12 Year-Old Males Get Vaccinated Against HPV*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 25, 2011), *available at* http://www.cdc.gov/media/releases/2011/t1025_hpv_12yroldivaccine.html.

¹⁵ Gostin, *supra* note 11, at 1700.

II. POLICE POWERS: THE ESTABLISHED PARADIGM

Since the FDA approved Gardasil[®], forty-one state legislatures have proposed HPV vaccine-related legislation.¹⁶ Only Texas, Virginia, and the District of Columbia have successfully imposed state mandates.¹⁷ Virginia, for example, requires all girls to have received at least the first dose of the HPV vaccine before they enter the sixth grade.¹⁸ Although other states do not have mandatory vaccination laws, they have implemented public education, free vaccination, and other programs to promote the HPV vaccine.¹⁹

States have the authority to implement compulsory vaccination legislation through constitutionally-provided police powers.²⁰ Through police powers, states can create “such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.”²¹ It was first established that state compulsory vaccination laws were protected by police powers in the landmark case *Jacobson v. Massachusetts*.²² In *Jacobson*, the Supreme Court upheld a Massachusetts law mandating smallpox vaccination where such vaccination was “necessary for the public health or the public safety.”²³ In *Zucht v. King*, the Supreme Court affirmed “that it is within the police power of a state to provide for compulsory vaccination” when required for public health.²⁴

Certainly, precedent has firmly established that where states have a legitimate public health goal, states can exercise police powers to create compulsory vaccination laws. But what constitutes a legitimate public health goal?

The decision in *Jacobson* highlighted that legitimate public health goals are those that protect the community as a whole. As the Court stated in *Jacobson*, “[t]here are manifold restraints to which every person is necessarily subject for the *common good*.”²⁵ For vaccines, underlying this need to serve the common good is a concept called

¹⁶ *Id.*

¹⁷ *Id.* The Texas law, however, was subsequently revoked.

¹⁸ VA. CODE ANN. § 32.1 (2007).

¹⁹ Gostin, *supra* note 11, at 1700.

²⁰ U.S. CONST. amend. X.

²¹ *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

²² *Id.*

²³ *Id.* at 27.

²⁴ *Zucht v. King*, 260 U.S. 174, 176 (1922).

²⁵ *Jacobson*, 197 U.S. at 26 (emphasis added).

“herd immunity,” which is defined as:

[w]hen a sufficiently large proportion of individuals in a community is immunized, those persons serve as a protective barrier against the likelihood of transmission of the disease in the community, thus indirectly protecting those who are not immunized and those who received the vaccine but are not protected (vaccine failures).²⁶

In other words, even when some individuals are not immunized, disease transmission is hampered when the overall community is immunized.²⁷

For a disease like smallpox (the subject of *Jacobson*), the benefits of compulsory vaccination are immediately apparent because community vaccination contributes to the establishment of herd immunity. Smallpox is highly contagious because it is readily transmitted through face-to-face contact and contact with bodily fluids.²⁸ Although rarely, smallpox can also be transmitted through air in enclosed settings, such as buildings, buses, and trains.²⁹ Once infected, the disease is largely untreatable as soon as symptoms emerge (one to four days after exposure), and the disease can be fatal.³⁰ Further, smallpox can only be transmitted between humans; there are no insect or animal hosts.³¹ Accordingly, without human hosts, the disease cannot be transmitted. Indeed, the efforts to eradicate smallpox through compulsory vaccination have been successful with one hundred percent eradication since 1977.³²

State eradication programs for diseases with features similar to those of smallpox have likewise been found to promote public health and safety because they contribute to herd immunity. Various courts have upheld state compulsory vaccination laws for measles, diphtheria toxoid, poliomyelitis, rubella, mumps, and other diseases.³³ Measles, for example, like smallpox, is highly contagious with the estimate that if

²⁶ Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in *LAW IN PUBLIC HEALTH PRACTICE* 262, 264 (Richard A. Goodman et al. eds., 2003).

²⁷ Margaret J. Kochuba, *Public Health vs. Patent Rights: Reconciling Informed Consent with HPV Vaccination*, 58 *EMORY L.J.* 761, 765 (2009).

²⁸ *Smallpox Disease Overview*, *CTRS. FOR DISEASE CONTROL & PREVENTION*, <http://emergency.cdc.gov/agent/smallpox/overview/disease-facts.asp> (last modified Dec. 30, 2004).

²⁹ *Id.*

³⁰ *Smallpox*, *A.D.A.M. MED. ENCYCLOPEDIA*, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002332/> (last visited Nov 30, 2012).

³¹ *Smallpox Disease Overview*, *supra* note 28.

³² Malone & Hinman, *supra* note 26, at 265.

³³ *Id.* at 270.

one person contracts measles, ninety percent of people close to that individual will also get infected.³⁴ Further, measles can be highly fatal; today, 164,000 people per year die of measles, despite immensely successful eradication programs.³⁵ The disease can only be transmitted by humans.³⁶ The measles vaccine was introduced in 1963, and by 1983, all states had mandatory measles vaccine laws.³⁷ One court found that, “given the characteristics of measles,” the Arizona State Health Department was authorized to adopt measures, including prohibiting unvaccinated children from attending school, to protect the public from a measles outbreak.³⁸

However, not all diseases fit so neatly into the category of diseases that warrant mandatory vaccination laws. Not all diseases are so highly contagious, highly fatal, or narrowly transmitted (e.g. transmitted only by humans) as smallpox or measles and therefore, cannot be justified by the concept of herd immunity. As courts are presented with such diseases, they must stray from the paradigm established by *Jacobson* to find justification for compulsory vaccination laws established to prevent these diseases.

In *Boone v. Boozman*, the court was presented with such a decision when a plaintiff brought suit alleging that mandatory hepatitis B vaccination was unconstitutional.³⁹ Although hepatitis B is fatal in about one percent of cases and highly contagious,⁴⁰ it is distinct from measles or smallpox in that it is most commonly transmitted by affirmative action on the part of the infected, e.g. unprotected sex or intravenous drug use.⁴¹ Nonetheless, the court found that,

[although] Hepatitis B may not be airborne like smallpox . . . this is not the only factor by which a disease could be judged dangerous. Hepatitis B is spread by bodily fluids; the virus is “fairly hearty and

³⁴ *Transmission of Measles*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/measles/about/transmission.html> (last modified Aug. 31, 2009).

³⁵ *Overview of Measles Disease*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/measles/about/overview.html> (last modified Apr. 13, 2012).

³⁶ *Transmission of Measles*, *supra* note 34.

³⁷ Malone & Hinman, *supra* note 26, at 271.

³⁸ Maricopa Cty. Health Dep’t v. Harmon, 156 Ariz. 161, 166 (Ariz. Ct. App. 1987).

³⁹ Boone v. Boozman, 217 F. Supp. 2d 938, 952-54 (E.D. Ark. 2002).

⁴⁰ *Hepatitis B*, A.D.A.M. MED. ENCYC., <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001324/> (last visited Nov. 30, 2012).

⁴¹ *Hepatitis B*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/chooseb.htm> (last modified Apr. 1, 2008).

can survive on surfaces, door knobs, et cetera, for up to a month.”⁴²

The court further held that “[i]mmunization of school children against hepatitis B has a real and substantial relation to the protection of the public health and the public safety.”⁴³

Similarly, tetanus is highly fatal (leading to death in one out of ten cases⁴⁴) but is not at all transmittable between people. Rather, tetanus is caused by the bacteria *C. Tetani* that enters the body through injuries or wounds, hence its association with rusty nails and other piercing metal objects.⁴⁵ Thus, herd immunity is a complete impossibility for tetanus, and yet, forty-nine states mandate tetanus vaccination,⁴⁶ the reason perhaps being the grisly consequences of contracting tetanus. Tetanus “do[es] not fit the ‘paradigm’ for compulsory vaccination . . . yet declaring the tetanus mandate laws unconstitutional under *Jacobson* could lead to needless cases of the gruesome lockjaw caused by the disease.”⁴⁷ Through hepatitis B and tetanus, courts have opened the door to state mandates for vaccines that fit outside of the *Jacobson* paradigm.

III. THE HPV VACCINE: STEPPING OUTSIDE THE PARADIGM

No court has yet had the opportunity to review mandatory HPV vaccine laws for their constitutionality. In March 2010, a pro se plaintiff brought suit against the United States Government, challenging the distribution of the HPV vaccine in public schools in the District of Columbia.⁴⁸ The case was successfully dismissed in favor of the Government for lack of standing.⁴⁹

Despite the dearth of common law, when assessing the characteristics of HPV, it is evident that HPV more closely aligns with hepatitis B and tetanus, rather than with smallpox or measles. Thus, HPV falls outside of the *Jacobson* paradigm that protects state compulsory vaccination laws justified by herd immunity.

⁴² *Boone*, 217 F. Supp. 2d at 954 (internal quotations omitted).

⁴³ *Id.*

⁴⁴ *Tetanus (Lockjaw) Vaccination*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/vpd-vac/tetanus/default.htm#disease> (last modified Jan. 19, 2012).

⁴⁵ *Tetanus*, A.D.A.M. MED. ENCYC., <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001640/> (last visited Nov. 30, 2012).

⁴⁶ Malone & Hinman, *supra* note 26, at 270.

⁴⁷ Case Note, *Toward a Twenty-First-Century: Jacobson v. Massachusetts*, 121 HARV. L. REV. 1820, 1838 (2008).

⁴⁸ *Ndaba v. Obama*, 697 F. Supp. 2d 75, 76 (D.C. 2010).

⁴⁹ *Id.* at 78.

A. Contagiousness

Unlike measles and smallpox, HPV is not easily communicable. The virus resides in an individual's epithelial (a.k.a. skin) cells, particularly in mucous membranes, such as the genital areas, and is transmitted by contact with the infected area.⁵⁰ This means that HPV is largely transmitted by affirmative actions, namely vaginal, oral, and anal sex.⁵¹ Contagion, in and of itself, does not prevent a disease from warranting compulsory vaccination laws, as could be seen with hepatitis B and tetanus. However, unlike hepatitis B and tetanus, HPV is not a robust virus that can reside on surfaces or doorknobs. HPV is relegated to skin cells and thus, is truly limited in its ability to transmit.

B. Fatality

Although HPV is quite prevalent, genital warts, cervical cancer, and other types of cancers only occur in ten percent of HPV cases.⁵² Of the diseases caused by HPV, cervical cancer is the most common with twelve thousand new cases of cervical cancer each year in the United States.⁵³ A study conducted in 2007 (the most recent data available) showed that four thousand women die each year from cervical cancer,⁵⁴ equating to a morbidity rate of 2.4 deaths per one hundred thousand women.⁵⁵ To put that in context, in the three years before the measles vaccine was licensed in 1963, the average annual morbidity for children afflicted with measles in the United States was over five hundred thousand.⁵⁶ Further, incidence rates of cervical cancer continue to fall due to the development and greater availability of screening and treatment services. Since the 1960s, cervical cancer incidence rates have

⁵⁰ Debbie Bridges, *Information About the Human Papillomavirus (HPV)*, WEBMD, <http://www.webmd.com/sexual-conditions/hpv-genital-warts/hpv-virus-information-about-human-papillomavirus> (last viewed Nov. 13, 2012).

⁵¹ *Id.*

⁵² *Genital HPV Infection – Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/hpv/stdfact-hpv.htm> (last modified Aug. 9, 2012).

⁵³ *Id.*

⁵⁴ *Cervical Cancer Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/cancer/cervical/statistics/index.htm> (last modified Apr. 30, 2012) (citing U.S. Cancer Statistics Working Group, *United States Cancer Statistics: 1999–2007 Incidence and Mortality Web-based Report*, CTRS. FOR DISEASE CONTROL & PREVENTION, available at <http://www.cdc.gov/uscs> (last viewed Nov. 13, 2012)). (full site)

⁵⁵ *SEER Stat Fact Sheets: Cervix Uteri*, NAT'L CANCER INST., <http://seer.cancer.gov/statfacts/html/cervix.html> (last viewed Nov. 13, 2012).

⁵⁶ Malone & Hinman, *supra* note 26, at 266.

fallen by seventy-five percent because cytology screening (the “Pap smear”) was introduced and has become standard in women’s health care.⁵⁷

C. Modes of Transmission

Like measles and smallpox, HPV is transmitted between humans. However, thus far, no state mandates the HPV vaccine for men, despite the FDA having approved the vaccine for men in December 2010.⁵⁸ For herd immunity to be successful, immunization levels must reach a specified threshold to protect the total number of susceptible individuals.⁵⁹ As an example, a study in Brazil showed that nearly 100 percent immunization of infants, coupled with subsequent yearly vaccination of these infants for eight to nine years, was necessary to interrupt the transmission of poliomyelitis there.⁶⁰ While there is no indication of what immunization level is required for eradication of HPV to be successful, the lack of any mandates for men would at the very least make the eradication process slower, if not make eradication entirely impossible.

D. Summary

On the other hand, HPV hosts other characteristics that suggest that a compulsory vaccination law might be necessary. First, HPV is highly prevalent with at least fifty percent of sexually active men and women contracting it in their lifetime.⁶¹ Second, the disease is asymptomatic for ninety percent of people,⁶² which means that people can transmit HPV during sexual intercourse without even knowing that they carry the virus. Lastly, because the virus resides in skin cells that may not be covered by a condom, individuals can contract HPV even when they think they are engaging in “safe sex.”⁶³

⁵⁷ Vivien Davis Tsu, *Overcoming Barriers and Ensuring Access to HPV Vaccines in Low-Income Countries*, 35 AM. J.L. & MED. 401, 402 (2009).

⁵⁸ Letter from Wellington Sun, Director of Division of Vaccines, U.S. Food & Drug Administration, to Patrick Brill-Edwards, Merck & Co., Inc. (Dec. 22, 2010), available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm238074.htm> [hereinafter Approval Letter (Gardasil) (Dec. 22, 2010)].

⁵⁹ T. Jacob John & Reuben Samuel, *Herd Immunity and Herd Effect: New Insights and Definitions*, 16 EUR. J. OF EPIDEMIOLOGY 601, 602 (2000).

⁶⁰ *Id.*

⁶¹ *Genital HPV Infection – Fact Sheet*, *supra* note 52.

⁶² *Id.*

⁶³ Bridges, *supra* note 50.

Despite these characteristics, HPV does not lend itself to a mandatory vaccination law to the same extent that measles or smallpox does. Moreover, the HPV vaccine does not lend itself to a mandatory vaccination law even to the same extent that hepatitis B or tetanus does. Thus, the question then becomes, when a disease falls outside of the *Jacobson* paradigm and is not protected by the exceptions provided in *Boone*, who decides whether the vaccine should be mandatory?

IV. VACCINES: FROM RECOMMENDING TO REQUIRING

Understanding the current process for making a vaccine mandatory is necessary for evaluating who should be driving the process. While mandating a vaccine may seem like a singular decision, the entire process involves a series of discretionary choices from a variety of government agencies and representatives, starting with the FDA and ending with state legislatures.

Vaccines, like any other medical product, must first go through regulatory approval by the FDA. The FDA is a government agency within the Department of Health and Human Services, and it is “responsible for protecting the public health by assuring the safety, efficacy and security of . . . drugs, biological products, [and] medical devices”⁶⁴ Under the Federal Food, Drug & Cosmetics Act, the FDA holds the authority to review vaccines for safety and efficacy before the maker of a vaccine is permitted to distribute the vaccine to the public.⁶⁵ Upon review, the FDA will either approve or deny a new vaccine.

Once a vaccine has been approved, the Centers for Disease Control and Prevention (the “CDC”) establishes written recommendations for the administration of vaccines to the general public. The CDC is a federal agency under the Department of Health and Human Services, and a large part of its mission is to prevent disease.⁶⁶ The CDC specifically addresses vaccines through its Advisory Committee on Immunization Practices (ACIP). The ACIP consists of fifteen immunology experts (and additional non-voting members and liaisons) who advise the Secretary of the U.S. Department of Health and Human

⁶⁴ *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/default.htm> (last modified June 19, 2012).

⁶⁵ 42 U.S.C. § 262 (2012).

⁶⁶ *Vision, Mission, Core Values, and Pledge*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://cdc.gov/about/organization/mission.htm> (last modified Jan. 11, 2010).

Services, the Assistant Secretary for Health, and the CDC.⁶⁷

While one aspect of the CDC's mission is to prevent disease, another aspect is to "develop and advocate sound public health policies."⁶⁸ As such, the CDC's recommendations are often used by states to develop legislation. In fact, while the CDC's recommendations are non-binding, the "power and prestige of the CDC and other administrative heavy artillery easily intimidates state legislators and even health care professionals who might otherwise deviate from the official path."⁶⁹

After the CDC issues a recommendation regarding a vaccine, state representatives may propose a bill to state legislatures that will make the vaccine mandatory. Alternatively, some state legislatures grant authority to regulatory bodies, such as a Board of Health.⁷⁰ In some cases, state governors issue executive orders, which subsequently must pass through the state legislature. In any case, the bill must ultimately pass through the state legislature, which holds the power to mandate a vaccine through its constitutionally-provided police powers.⁷¹ Police powers give states the authority to create "such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety."⁷²

V. SOCIAL, ECONOMIC, AND OTHER PRESSURES: PROBLEMS WITH THE CURRENT METHOD

Currently, state representatives (whether state legislators or governors) are driving the policies behind mandatory vaccination. Of course, the nature of state representatives is that they are elected by their state constituents, which draws concern when assessing how effective representatives are at determining the best interests of the general public in terms of health and safety. A decision incentivized by social or economic pressures may not accurately reflect the best interests of the public.

⁶⁷ *About ACIP*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/acip/about.html> (last modified Aug. 16, 2012).

⁶⁸ *Vision, Mission, Core Values, and Pledge*, *supra* note 66.

⁶⁹ KURT LINK, *THE VACCINE CONTROVERSY: THE HISTORY, USE, AND SAFETY OF VACCINATIONS* 171 (2005).

⁷⁰ Richard Hughes, IV, *Using Law, Policy, and Research to Improve the Public's Health*, 39 J.L. MED. & ETHICS 37, 37 (2011).

⁷¹ U.S. CONST. amend. X.

⁷² *Jacobson*, 197 U.S. at 25.

A. *Social, Cultural, and Religious Pressures*

State representatives may seek to represent the interests of their constituents; however, to begin with, the general public is largely uninformed when it comes to HPV. A national survey conducted in 2000 found that less than two percent of Americans know that HPV is an STI.⁷³ Although public knowledge about HPV has increased since the introduction of the vaccine, knowledge is nonetheless limited, and the majority of women are still unaware of the link between HPV and cervical cancer.⁷⁴ As a result, the public depends on sources like health agencies, pharmaceutical companies, special interest groups, the media, and the internet for information, and these sources are largely conflicting and furthermore, biased.⁷⁵ On that point, because non-profit organizations, the CDC, and public health organizations have limited budgets and resources, the vaccine manufacturers (those with the biggest budgets) are best able to reach audiences, leaving public education in the hands of Merck and GlaxoSmithKline, companies that have been accused of heavily skewing the data.⁷⁶

To add to the misperceptions surrounding HPV, HPV is a largely stigmatized disease, mostly because it elicits the taboo topic of sexual health.⁷⁷ In one study, participants were asked to list words they associated with sexually transmitted diseases, and the most common words named were promiscuity, infidelity, shame, embarrassment, guilt, and divorce.⁷⁸ In the United States, there is a strong belief that mandating an HPV vaccine will encourage young girls to become sexually active at an early age and will encourage sexual promiscuity.⁷⁹

⁷³ Allison L. Friedman & Hilda Sheppard, *Exploring the Knowledge, Attitudes, Beliefs, and Communication Preferences of the General Public Regarding HPV: Findings From CDC Focus Group Research and Implications for Practice*, 34 HEALTH EDUC. BEHAV. 471, 472 (2007).

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ Ilene Albala, *Mandatory HPV Vaccination: Is There a Happy Medium?* 12 U. PA. J.L. & SOC. CHANGE 221, 244 (2008-2009).

⁷⁷ Suellen Hopfer & Jessie R. Clippard, *College Women's HPV Vaccine Decision Narratives*, 21 QUALITATIVE HEALTH RES. 262, 262-63 (2011).

⁷⁸ Friedman & Sheppard, *supra* note 73, at 475.

⁷⁹ See e.g., J. Waller et al., *Mothers' Attitudes Towards Preventing Cervical Cancer Through Human Papillomavirus Vaccination: A Qualitative Study*, 15 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 1257, 1259 (2006); N. Liddon et al., *Parents'/Guardians' Willingness to Vaccinate Their Children against Genital Herpes*, 37 J. OF ADOLESCENT HEALTH 187 (2005).

In addition to stigmatizing the disease, the public has stigmatized the vaccine itself. There is a popular misperception that the vaccine is unsafe, was not satisfactorily tested before FDA approval, and leads to afflictions such as autism.⁸⁰ On the contrary, the safety profile for the HPV vaccine is quite robust. Clinical trials have been conducted with over 59,000 participants,⁸¹ and as of January 2010, an estimated 28 million doses of Gardasil[®] alone had been administered in the United States.⁸² As of June 2011, the only vaccine side effects reported to the FDA were minor (dizziness, fainting, headache, nausea, and injection-site reactions), and autism and other types of mental and development disorders have never been reported.⁸³

Representatives making decisions regarding the HPV vaccine face pressure due to these public perceptions. In February 2007, Governor Rick Perry issued an executive order and singlehandedly mandated the HPV vaccine in Texas for girls entering the sixth grade in 2007.⁸⁴ Even before Governor Perry introduced the action, the National Vaccine Information Center (NVIC), a non-profit organization that has been described as “the most powerful anti-vaccine organization in America,”⁸⁵ had begun its campaign to thwart implementation of a mandatory HPV vaccine.⁸⁶ The NVIC based its campaign on the premise that Merck had failed to prove the safety of Gardasil[®].⁸⁷ It was successful, and only a few months later, in May 2007, the Texas legislature voted to overturn Governor Perry’s executive order.⁸⁸

⁸⁰ See e.g., Press Release, National Vaccine Information Center, Merck’s Gardasil Vaccine Not Proven Safe for Little Girls (June 27, 2006), available at <http://www.nvic.org/nvic-archives/pressrelease/gardasilgirls.aspx>.

⁸¹ *Human Papillomavirus (HPV) Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html#data> (last modified Oct. 21, 2012).

⁸² Claudia Vellozzi, *CDC Commentary: New Safety Data on the HPV Vaccine – Reassuring Your Patients*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.medscape.com/viewarticle/722555> (last visited Nov. 26, 2012).

⁸³ *Information from FDA and CDC on Gardasil and its Safety*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccinesafety/vaccines/HPV/Index.html> (last visited Dec. 23, 2012).

⁸⁴ Tex. Exec. Order No. RP65 (Feb. 2, 2007), available at <http://governor.state.tx.us/news/executive-order/3455/>.

⁸⁵ MICHAEL SPECTER, DENIALISM: HOW IRRATIONAL THINKING HINDERS SCIENTIFIC PROGRESS, HARMS THE PLANET, AND THREATENS OUR LIVES 7 (2009).

⁸⁶ See e.g., Merck’s Gardasil Vaccine Not Proven Safe for Little Girls, *supra* note 80.

⁸⁷ *Id.*

⁸⁸ 2007 Tex. Gen. Laws 43 § 1 (amending TEX. EDUC. CODE ANN. § 38.001 (West 2007)) (girls entering sixth grade no longer required to receive HPV vaccination effective

Even recently, as Governor Perry ran for the Republican Presidential ticket, his campaign reopened old wounds. While Governor Perry defended his decision to mandate the vaccine in 2007, his opponents fueled common false beliefs and perpetuated the HPV vaccine stigma. For example, during the Republican Presidential debate held September 12, 2011, Republican Presidential candidate Michele Bachmann argued,

to have innocent little 12-year-old girls be forced to have a government injection through an executive order is just flat out wrong . . . little girls who have a negative reaction to this potentially dangerous drug don't get a mulligan. They don't get a do-over. The parents don't get a do-over.⁸⁹

One day later, in an interview on the *Today Show*, Ms. Bachmann stated,

Well, I will tell you that I had a mother last night come up to me here in Tampa, Florida after the debate and tell me that her little daughter took that vaccine, that injection, and she suffered from mental retardation thereafter. It can have very serious side effects.⁹⁰

Representatives seeking to please constituents may play into these social and cultural beliefs just to get a vote, and in fact, research shows that their strategy may not be entirely without merit. Voters are more likely to vote according to their moral beliefs because of the low cost of voting and the absence of any significant effect on the voter's interests.⁹¹ Furthermore, because HPV relates to sexual health, it may get lumped with other single-issue voting topics, such as abortion.

B. Economic and Political Pressures

When issuing his executive order, Governor Perry faced pressures just as pervasive as social, cultural, and religious pressures; he confronted economic pressures from the patent-holders, namely Merck. The pharmaceutical and biotechnology industries are notoriously strong

May 8, 2007); see also Dan Frosch, *Texas House Rejects Order by Governor on Vaccines*, N.Y. TIMES, Mar. 14, 2007, available at <http://www.nytimes.com/2007/03/14/us/14vaccine.html>.

⁸⁹ CNN Live Event/Special: *Tea Party Republican Debate* (CNN television broadcast Sept. 12, 2011), <http://archives.cnn.com/TRANSCRIPTS/1109/12/se.06.html>.

⁹⁰ *The Today Show* (MSNBC television broadcast Sept. 13, 2011), http://today.msnbc.msn.com/id/44489617/ns/today-today_news/t/perry-assailed-rivals-forced-defend-record/.

⁹¹ Jonathan Baron, *Preference and Rational Choice: New Perspectives and Legal Implications*, 151 U. PA. L. REV. 1135, 1142-43 (2003).

lobbyists, and so their influence on law-making cannot be understated.⁹² According to the Center for Responsive Politics, the drug lobby spent over \$2.5 billion in lobbying funds between 1998 and 2012.⁹³ This figure surpasses any other industry by more than 700 million dollars.⁹⁴

The HPV vaccine is unique because both vaccines available (Gardasil[®] and Cervarix[®]) are still under patent, which provides the manufacturers of these drugs a near monopoly on the market and permits the manufacturers to charge high prices. Both vaccines require three doses.⁹⁵ For children, the CDC can provide Gardasil[®] at a cost of \$98.60 per dose and Cervarix[®] at a cost of \$96.08 per dose, while the private sector cost is \$135.45 per dose for Gardasil[®] and \$128.75 per dose for Cervarix[®].⁹⁶

Notably, there are no generic versions of the HPV vaccine in development due to previously-existing rules that prohibited the creation of follow-on biologics (which includes vaccines). The Patient Protection and Affordable Care Act laid out instructions for the Secretary of the Department of Health and Human Services and the FDA to create a follow-on biologics regulatory pathway.⁹⁷ The creation of a generic HPV vaccine would ultimately reduce the cost of the vaccine, but until then, patients are subject to high prices.

Due to this near monopoly on the market, Merck and GlaxoSmithKline have great incentive to encourage states to pass compulsory vaccination laws, and in fact, Merck has been actively lobbying for state compulsory laws. According to records from New York's Temporary State Commission on Lobbying, Merck spent almost 400 thousand dollars between 2003 and 2006 on lobbying for Gardasil[®].⁹⁸ The CDC has also implied that vaccine manufacturers have

⁹² See Peter Overby, *Senators Against Drug Imports Got More Pharma Money*, SHOTS: NPR'S HEALTH BLOG (Dec. 17, 2009, 8:58 AM), http://www.npr.org/blogs/health/2009/12/pharma_friends_an_analysis.html.

⁹³ *Lobbying: Top Industries*, CTR FOR RESPONSIVE POLITICS, <http://www.opensecrets.org/lobby/top.php?showYear=a&indexType=i> (last viewed Nov. 13, 2012).

⁹⁴ *Id.*

⁹⁵ *HPV Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hpv/vaccine.html> (last modified Mar. 21, 2012).

⁹⁶ *CDC Vaccine Price List*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html> (last modified Nov. 1, 2012).

⁹⁷ H.R. 3590, 111th Cong. § 7002(f)(1)(A) (2009).

⁹⁸ Tracy Solomon Dowling, *Mandating a Human Papillomavirus Vaccine: An Investigation into Whether Such Legislation is Constitutional and Prudent*, 34 AM. J.L. &

heavily influenced the adoption of mandatory HPV laws.⁹⁹ According to Governor Perry, Merck only donated 5,000 dollars to his gubernatorial campaign at the time he issued the executive order mandating the HPV vaccine in Texas.¹⁰⁰ In reality, Merck donated \$28,500 to his gubernatorial campaign and \$377,500 to the Republican Governors Association,¹⁰¹ an organization for which Governor Perry served as Chairman and whose mission it is to help elect Republican candidates to governorships throughout the country.¹⁰²

Despite this apparent conflict of interest, Governor Perry had other, less controversial economic pressures that weighed towards the passage of a compulsory vaccination law. The costs of HPV-related diseases are staggering, with an estimated \$4 billion in annual direct medical costs for the prevention and treatment of genital warts and cervical cancer.¹⁰³ That \$4 billion is comprised of the following estimates of annual direct medical costs: cervical cancer (\$300-400 million), cervical intraepithelial neoplasia (\$700 million-\$2.3 billion), anogenital warts (\$200 million), and routine cervical cancer screening (\$2.3 billion).¹⁰⁴ The total excludes lost productivity costs and medical costs attributed to other HPV-related diseases, such as anal, penile, vaginal, and vulvar cancers.¹⁰⁵

Even with such high costs related to the treatment and prevention of cervical cancer and genital warts, drug industry lobbying reflects poorly on state representatives' ability to make unbiased decisions when it comes to public health.¹⁰⁶

MED. 65, 82 (2008).

⁹⁹ Kathryn M. Edwards, *State Mandates and Childhood Immunization*, 284 J. AM. MED. ASS'N 3171, 3171 (2000).

¹⁰⁰ Gostin, *supra* note 11, at 1700.

¹⁰¹ *Id.*

¹⁰² *Governor Rick Perry Elected Chairman of the Republican Governors Association*, REPUBLICAN GOVERNORS ASS'N, http://rga.org.myrga.org/index.php?option=com_content&view=article&id=18:governor-rick-perry-elected-chairman-of-the-republican-governors-association&catid=1:press-releases&Itemid=5 (last viewed Nov. 12, 2012); *About*, REPUBLICAN GOVERNORS ASS'N, <http://www.rga.org/homepage/about/>, (last viewed Nov. 12, 2012).

¹⁰³ Ralph P. Insinga, Erik J. Dasbach & Elamin H. Elbasha, *Assessing the Annual Economic Burden of Preventing and Treating Anogenital Human Papillomavirus-Related Disease in the US: Analytic Framework and Review of the Literature*, 23 PHARMACOECONOMICS 1107, 1108 (2005).

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ Gostin, *supra* note 11, at 1700.

VI. UNBIASED ENTITIES: MOVING TOWARDS AN OBJECTIVE DECISION-MAKING PROCESS

State representatives are subject to an immense amount of pressure that draws into question their ability to effectively make decisions regarding the public's health and safety. When presented with vaccines that fall outside of the *Jacobson* paradigm, is it best to defer policy-making decisions to other more objective entities? The FDA, the CDC, the ACIP, and professional medical associations could potentially fill that role; however, each entity faces its own set of political pressures and areas of vulnerability that make it arguably unsuitable for such policy-making.

A. The FDA

When considering other entities that could assume the responsibility of developing compulsory vaccination policies, the FDA is an immediately apparent choice. The FDA is historically a science-based agency¹⁰⁷ and was originally responsible for the HPV vaccine's approval. The FDA has followed Merck and GlaxoSmithKline through, collectively, the administration of over 59,000 doses of the HPV vaccine.¹⁰⁸ It has been intimately involved in the approval of package inserts and patient information pamphlets.¹⁰⁹ The FDA receives and reviews any and all adverse side effects reports.¹¹⁰ In summary, the FDA holds an immense amount of information about the HPV vaccine and at

¹⁰⁷ David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of a Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 982 (2008).

¹⁰⁸ *Human Papilloma Virus (HPV) Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html> (last modified Oct. 11, 2012); *What Is the Approval Process for a Biological Product?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194562.htm> (last modified Dec. 30, 2009).

¹⁰⁹ See, e.g., Letter from Wellington Sun, Director of Division of Vaccines and Related Products Applications, U.S. Food & Drug Administration, to Cynthia D'Ambrosio, Merck & Co., Inc. (July 16, 2012), available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm312766.htm>.

¹¹⁰ *FDA Adverse Event Reporting System (FAERS) (formerly AERS)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm> (last modified Sept. 10, 2012); *How Does FDA Assess the Safety of Vaccines?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194586.htm> (last modified Dec. 30, 2009).

least from a purely scientific point of view, could formulate a conclusion regarding whether it should be mandatory.

Yet despite the FDA's wealth of knowledge, the FDA is not without bias. FDA agents lack any sort of sustained relationship with consumers but regularly interact with pharmaceutical and biotechnology manufacturers.¹¹¹ This close relationship with the pharmaceutical and biotechnology industries is all the more true because of the "revolving door" which rotates FDA employees from the FDA to the pharmaceutical and biotechnology industries and back again.¹¹²

To make matters worse, senior appointees to FDA offices are typically appointed for political reasons, and as such, senior appointees marginalize the opinions of FDA scientists in exchange for the political opinions of their appointers.¹¹³ Most recently, FDA Commissioner Margaret Hamburg substituted the opinion of FDA scientists for the wishes of Kathleen Sebelius, the Secretary of the Department of Health and Human Services, regarding Plan B, an emergency contraceptive.¹¹⁴ The Center for Drug Evaluation and Research (CDER), a division within the FDA, reviewed Plan B to determine if it was safe as an over-the-counter product for girls under seventeen years of age.¹¹⁵ CDER determined that Plan B was in fact safe for those purposes.¹¹⁶

Dr. Hamburg agreed, stating,

I reviewed and thoughtfully considered the data, clinical information, and analysis provided by CDER, and I agree with the Center that there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential.¹¹⁷

However, after receiving a memorandum from Secretary Sebelius disapproving of CDER's findings, Dr. Hamburg ordered Plan B to remain prescription-only for girls under seventeen years old.¹¹⁸

¹¹¹ James T. O'Reilly, *Drug Review "Behind the Curtain": A Response to Professor Struve*, 93 CORNELL L. REV. 1075, 1079 (2008).

¹¹² Vladeck, *supra* note 107, at 982.

¹¹³ *Id.*

¹¹⁴ Margaret Hamburg, Comm'r, Dept. of Health & Human Servs., U.S. Food & Drug Admin., Statement on Plan B One-Step (Dec. 7, 2011) (transcript available at <http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm>).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

The Plan B decision serves as a pointed example of how the FDA is not immune to pressure from politicians and may not be the wholly scientific authority it espouses itself to be. In addition, even if the FDA had the authority to do so, determining whether a vaccine should be mandatory may be outside the bounds of what is feasible for it both in terms of its resources and its expertise.

B. The CDC and the ACIP

The CDC and ACIP stand in a similar position as the FDA when it comes to the broad scope of knowledge they hold regarding the HPV vaccine. If anything, the CDC's knowledge is even more comprehensive than the FDA's because the CDC has a thorough understanding of the epidemiological context in which the HPV vaccine lies.

First, the CDC aims to “monitor health, detect and investigate health problems, [and] conduct research to enhance prevention.”¹¹⁹ When it comes to vaccines, maintaining a regularly and constantly updated database that catalogues the distribution and coverage of vaccines is critical to this goal. The CDC collects vaccination information by two methods: the National Immunization Survey (NIS) and school and childcare vaccination surveys.¹²⁰

The NIS first began in 1994 to track the immunization rates of diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella, and *Haemophilus Influenza* type B (whooping cough).¹²¹ Starting in 2006, the NIS created an on-going survey of HPV immunization coverage among teens aged thirteen to seventeen years old.¹²² The survey provides annual data from 2006 to 2011.¹²³ The NIS has also put together an adult study, which analyzes why some adults have chosen to receive the HPV vaccine and why others have not.¹²⁴

¹¹⁹ *Vision, Mission, Core Values, and Pledge*, *supra* note 66.

¹²⁰ *Vaccination Coverage and Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/stats-surv/default.htm> (last modified Oct. 22, 2012).

¹²¹ Philip J. Smith et al., *Compensating for Provider Nonresponse Using Response Propensities to Form Adjustment Cells: The National Immunization Survey*, 133 *VITAL & HEALTH STATS.* 1, 1 (2001).

¹²² *U.S. Vaccination Coverage Reported via NIS*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/stats-surv/nis/default.htm> (last modified Sep. 6, 2012).

¹²³ *Id.*

¹²⁴ *Id.*

The school and childcare vaccination surveys are a second data-collection method employed by the CDC. For those states that have enacted compulsory vaccination laws, the CDC has asked those states to report on vaccination coverage.¹²⁵ As states review and assess vaccination coverage in their own mandatory vaccination programs, they report those findings to the CDC.¹²⁶ These reports are mandatory for any schools and childcare facilities that receive grants from the CDC.¹²⁷ Between the NIS and the school and childcare vaccination surveys, the CDC has gathered extensive information about the distribution and coverage of the HPV vaccine since its approval by the FDA.

Second, the CDC has developed the Vaccine Management Business Improvement Project (VMBIP). Through VMBIP, the CDC performs a “top-to-bottom” assessment of the entire national vaccination program, including everything from vaccine ordering to vaccine distribution.¹²⁸ The CDC has partnered with state and local governments to review and improve the current vaccination process.¹²⁹ Through this program, the CDC has become familiar with HPV vaccine supply, demand, and coverage and has aided states to develop streamlined HPV vaccine management programs.¹³⁰

Third, the CDC has the biggest representation from various medical, scientific, and industry organizations and associations. Although the ACIP only consists of fifteen voting members, the committee receives input from other non-voting members.¹³¹ The voting members consist almost entirely of doctors, lawyers, and nurses who specialize in immunology and currently serve as professors at various universities across the country.¹³² The *Ex Officio* members, on the other

¹²⁵ *School and Childcare Vaccination Surveys*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/stats-surv/schoolsurv/default.htm> (last modified June 20, 2011).

¹²⁶ *Id.*

¹²⁷ *School and Childcare Assessment Activities*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/stats-surv/schoolsurv/activities.htm#why> (last modified Jan. 25, 2012).

¹²⁸ *Vaccine Management Business Improvement Project (VMBIP)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/programs/vmbip/default.htm> (last modified Nov. 20, 2009).

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *About ACIP*, *supra* note 67.

¹³² *ACIP Members*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/recs/acip/members.htm> (last modified Jul. 18, 2012).

hand, are federal agency representatives.¹³³ Moreover, the ACIP has liaison representatives from numerous medical associations and organizations, as well as the biotechnology and pharmaceutical industries.¹³⁴ While not all of these members are voting members, at least the ACIP involves the opinions of experts from a broad spectrum of medical fields.

Lastly, the CDC already has as part of its mission to “develop and advocate sound public health policies.”¹³⁵ Specifically, the ACIP’s role is to

provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. The Committee develops written recommendations for the routine administration of vaccines to children and adults . . . The ACIP is the only entity in the federal government that makes such recommendations.¹³⁶

Thus, the CDC and ACIP are already equipped with the expertise and capabilities to make recommendations regarding vaccine mandates.

Despite the CDC and ACIP’s qualifications, they are subject to the same criticisms as the FDA. To begin with, the voting members of the ACIP are exposed to political pressure because they are all elected by

¹³³ *Id. Ex Officio* members come from Centers for Medicare and Medicaid Services, Department of Defense, Department of Veterans Affairs, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Vaccine Program Office, and National Institutes of Health.

¹³⁴ *Id.* Liaison members come from American Academy of Family Physicians, American Academy of Pediatrics, American Academy of Physician Assistants, American College Health Association, American College of Obstetricians and Gynecologists, American College of Physicians, American Geriatrics Society, America’s Health Insurance Plans, American Medical Association, American Nurses Association, American Osteopathic Association, American Pharmacists Association, Association of Immunization Managers, Association for Prevention Teaching and Research, Association of State and Territorial Health Officials, Biotechnology Industry Organization, Council of State and Territorial Epidemiologists, Canadian National Advisory Committee on Immunization, Department of Health (United Kingdom), Healthcare Infection Control Practices Advisory Committee, Infectious Diseases Society of America, National Association of County and City Health Officials, National Association of Pediatric Nurse Practitioners, National Foundation for Infectious Diseases, National Immunization Council and Child Health Program (Mexico), National Medical Association, National Vaccine Advisory Committee, Pharmaceutical Research and Manufacturers of America, Society for Adolescent Health and Medicine, and Society for Healthcare Epidemiology of America.

¹³⁵ *Vision, Mission, Core Values, and Pledge*, *supra* note 66.

¹³⁶ *CDC Recommendations*, CTRS. FOR DISEASE CONTROL & PREVENTION, available at <http://www.nfid.org/about-vaccines/cdc> (last viewed Nov. 13, 2012).

the Secretary of the Department of Health and Human Services.¹³⁷ In addition, the CDC holds tight relationships with pharmaceutical and biotechnology companies. To provide vaccines at discounted prices to state and city immunization programs, the CDC enters into contracts with vaccine manufacturers.¹³⁸ In fact, the CDC is the largest purchaser and distributor of vaccines.¹³⁹ Although the CDC provides dozens of different vaccines to immunization programs, these vaccines are manufactured by a relatively small number of companies: GlaxoSmithKline, MassBiologics, MedImmune, Merck, Novartis, Pfizer, and Sanofi Pasteur.¹⁴⁰ In effect, the CDC's dedication to the success of the immunization programs it assists may in some ways also serve as its Achilles' heel because it depends so heavily on these pharmaceutical and biotechnology companies to provide vaccines at a discounted rate.

The CDC and ACIP have been criticized in particular because of their relationship with Merck and the HPV vaccine. At the time the FDA approved the use of Gardasil[®], Merck had only carried the vaccine through three-and-a-half years of clinical trials with 12,000 patients, which is a relatively small number.¹⁴¹ Many assailed the vaccine for not being supported by sufficient safety and efficacy data, and yet, in the same month as the FDA gave its stamp of approval, so did the CDC and ACIP.¹⁴² Without addressing the low amount of clinical testing, the CDC recommended that the vaccine be "routinely given to girls when they are 11-12 years old."¹⁴³

To add fuel to the fire, on January 25, 2010, Dr. Julie Gerberding became President of Merck Vaccines after having served as the Director of the CDC from 2002 to 2009.¹⁴⁴ Dr. Gerberding's tenure as CDC Director included the time period that the CDC reviewed and

¹³⁷ *About ACIP*, *supra* note 67.

¹³⁸ *CDC Vaccine Price List*, *supra* note 96.

¹³⁹ Colin O'Regan & Edan Shertzer, *Bruesewitz v. Wyeth Inc. (09-152) Appealed from the U.S. Court of Appeals for the Third Circuit (Mar. 8, 2010) Oral Argument: Oct. 6, 2010*, 57 FED. LAW 58, 58 (Fed. Bar Ass'n 2010).

¹⁴⁰ *CDC Vaccine Price List*, *supra* note 96.

¹⁴¹ Lane Wood, *A Young Vaccine for Young Girls: Should the Human Papillomavirus Vaccination Be Mandatory for Public School Attendance?* 20 HEALTH LAW. 30, 31 (2008).

¹⁴² *Id.*

¹⁴³ *CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination*, *supra* note 12.

¹⁴⁴ John George, *Former CDC Director Gerberding to Lead Merck Vaccines*, PHILA. BUS. J., Dec. 21, 2009, available at <http://www.bizjournals.com/philadelphia/stories/2009/12/21/daily7.html>.

recommended the HPV vaccine. Her move to “big pharma” prompted a flurry of charged and aggressive articles and blogs accusing Dr. Gerberding of having been in the back pocket of Merck during her entire time as CDC Director.¹⁴⁵

Whether or not the accusations against Dr. Gerberding are true, certainly the CDC is not a stranger to the concept of the “revolving door,” just as is true for the FDA. Unlike the FDA, however, the CDC has this additional interdependent relationship with the pharmaceutical and biotechnology industries, which draws further skepticism to the CDC’s ability to remain an unbiased decision-making entity.

C. Professional Medical Associations

Until recently, professional medical associations did not make recommendations regarding the use of various drugs, biologics, and other medications.¹⁴⁶ However, it is not entirely out of the question that perhaps they should. After all, physicians ultimately should care about patient health and safety above all else. The mission statements of most professional medical associations echo this sentiment. The American Academy of Pediatrics “dedicate[s] their efforts and resources to the health, safety and well-being of infants, children, adolescents and young adults.”¹⁴⁷ Likewise, the American Medical Association “promote[s] the art and science of medicine and the betterment of public health.”¹⁴⁸ This commitment to the public health provides professional medical associations with a uniquely objective perspective.

Because professional medical associations have only recently started making vaccine recommendations, when state laws mandating the HPV vaccine first started being proposed, state legislatures were doing so without physician input.¹⁴⁹ Now, many prominent professional

¹⁴⁵ See, e.g., Joanne Silberner, *Merck Hires Ex-CDC Chief Gerberding to Run Vaccine Unit*, NPR HEALTH BLOG, Dec. 21, 2009, http://www.npr.org/blogs/health/2009/12/merck_hires_gerberding_to_run.html; Robert Scott Bell, *Julie Gerberding Primed BIG PHARMA’s Pump with Flu and HPV Vaccines*, ROBERT SCOTT BELL BLOG (Jan. 4, 2010, 2:20 PM), <http://robertscottbell.blogspot.com/2010/01/julie-gerberding-primed-big-pharmas.html>.

¹⁴⁶ Dowling, *supra* note 98, at 82.

¹⁴⁷ *About the American Academy of Pediatrics (AAP)*, AM. ACAD. OF PEDIATRICS, <http://www.healthychildren.org/English/Pages/About-AAP.aspx> (last viewed Nov. 13, 2012).

¹⁴⁸ *Our Mission*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/about-ama/our-mission.page?> (last viewed Nov. 13, 2012).

¹⁴⁹ Dowling, *supra* note 98, at 82.

medical associations, including the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians, have recommended the administration of the vaccine to females aged eleven to twelve years old.¹⁵⁰

However, these professional medical associations largely shy away from making recommendations regarding state mandates. The exception is the American Medical Association, which allows physician commentators to contribute to its *Journal of the American Medical Association (JAMA)*. It should be noted that the editorials published in *JAMA* do not represent the opinions of the American Medical Association; however, they do offer insight into the thoughts and perspectives of individual physicians. For example, one article lauded the potential of the HPV vaccine but strongly advised against compulsory vaccination laws, calling them a “last resort.”¹⁵¹

Physician perspectives given in *JAMA* vary greatly,¹⁵² and this accurately reflects the fragmented opinions of physicians in general regarding the HPV vaccine. In a study conducted by Medimix International, a healthcare marketing research company, 57 percent of physicians thought the HPV vaccine should not be mandated, even though 97 percent of physicians believed that the HPV vaccine should be administered.¹⁵³

In addition to the lack of unity among physicians regarding mandatory HPV vaccination, an even greater concern is that, while physicians may have their patients’ health in mind, they are nonetheless susceptible to aggressive marketing tactics by large pharmaceutical and biotechnology companies. Nowhere has this been truer than with Merck’s hard-lined and novel marketing campaign for Gardasil®.

¹⁵⁰ O. Marion Burton, President, Am. Acad. of Pediatrics, American Academy of Pediatrics Statement on HPV Vaccine (Sept. 14, 2011) (transcript available at <http://www.healthychildren.org/English/news/Pages/American-Academy-of-Pediatrics-Statement-on-HPV-Vaccine.aspx?nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token>); *Recommended Adult Immunization Schedule*, CTRS. FOR DISEASE CONTROL & PREVENTION (2009), available at http://www.acponline.org/about_acp/chapters/wi/09mtg/mejicano2.pdf.

¹⁵¹ Gostin & DeAngelis, *supra* note 1, at 1921-1923.

¹⁵² See generally Sheila M. Rothman & David J. Rothman, *Marketing HPV Vaccine: Implications for Adolescent Health and Medical Professionalism*, 302 J. AM. MED. ASS’N 781 (2009).

¹⁵³ *Mandate for Sex? Doctors in the US Speak Out About Mandating the HPV Vaccine*, MEDIMEX INT’L (March 20, 2007), <http://www.medimix.net/content/doctors-us-speak-out-about-mandating-new-hpv-vaccine>.

Merck started by cherry-picking its disease. Fearing parent opposition to a vaccine that immunized against sexually transmitted disease, Merck chose instead to focus on HPV's implications for cervical cancer,¹⁵⁴ and what parent would not want to protect his or her daughter against cancer? Merck next appealed to a broad audience. Rather than focus on highly susceptible populations, Merck indiscriminately targeted every adolescent girl in America, inspiring them to be "1 less" victim of cervical cancer.¹⁵⁵ Merck successfully made the HPV vaccine into a sensation, so much so that, in 2007, shortly after the FDA approved Gardasil[®], *Pharmaceutical Executive* rewarded Gardasil[®] the "Brand of the Year" for having created a "market out of thin air."¹⁵⁶

Merck understood that the best method for reaching individual consumers was through physicians, and it further realized that physicians follow recommendations from professional medical associations.¹⁵⁷ Thus began a directed campaign by Merck to heighten associations' involvement in vaccine promotion.¹⁵⁸ Merck provided professional medical associations with funding, which these associations then used for educational programs and Gardasil[®]-specific speakers' bureaus.¹⁵⁹ Unsurprisingly, these educational programs and speakers' bureaus were one-sided, often omitting critical information necessary for physicians to accurately determine if administering the vaccine is best for their patients.¹⁶⁰ Furthermore, Merck required these associations to report back to it with progress updates.¹⁶¹

Merck specifically targeted the following professional medical associations: the American College of Obstetricians and Gynecologists, the American Society for Colposcopy and Cervical Pathology (ASCCP), the Society of Gynecologic Oncologists (SGO), and the American College Health Association (ACHA).¹⁶² Each association in turn developed a unique program with Merck's donated funds. For example, ASCCP developed an "Educate the Educators" program that

¹⁵⁴ Rothman & Rothman, *supra* note 152, at 781.

¹⁵⁵ *Id.* at 782.

¹⁵⁶ Beth Herskovitz, *Brand of the Year*, 27 PHARM. EXEC. 58, 58 (2007).

¹⁵⁷ Rothman & Rothman, *supra* note 152, at 782.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 781.

¹⁶⁰ *Id.* at 781-85.

¹⁶¹ *Id.* at 785.

¹⁶² *Id.* at 783.

taught physicians how to educate the public about the vaccine.¹⁶³ Each physician who attended the program received a “Speaker Lecture Kit” that provided a set of educational tools, including a 173-slide PowerPoint presentation.¹⁶⁴ The slideshow urged physicians to contact local and state governments about funding the vaccine, encouraging insurance companies to cover the vaccine, and mandating the vaccine.¹⁶⁵ The slideshow further advocated that physicians avoid discussing the sexually transmitted aspect of HPV, if they feel that parents would be uncomfortable doing so.¹⁶⁶

The SGO similarly developed a program that provided incomprehensive, biased information to physicians. The SGO started an HPV vaccine speakers’ bureau, which was comprised of panelists who were financially connected to Merck and who drafted all of the lecture materials.¹⁶⁷ The speaker series puffed up the HPV vaccine’s notoriety as “the first vaccine directed against a cancer,” while completely ignoring the cautionary details.¹⁶⁸ For example, the teaching materials failed to provide comprehensive data on cervical cancer incidence rates and declined to discuss secondary prevention methods, safety and efficacy data, and potential risks.¹⁶⁹

Nowhere in any of the educational materials produced by these professional medical associations did these associations mention their connection to Merck or that Merck was funding their efforts.¹⁷⁰ This lack of transparency is disconcerting because it shows that these associations are either being blindly manipulated or willingly eating out of the hands of their donors, knowing that public health and safety may be at risk.

If professional medical associations are so willing to act as pawns for the pharmaceutical industry, then they are ill-suited to make recommendations to states regarding compulsory vaccination laws. Professional medical associations should not be engaging in product-specific speakers’ bureaus or reporting their educational activity to Merck (or any other industry donor).¹⁷¹ As their mission statements

¹⁶³ Rothman & Rothman, *supra* note 152, at 783.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 784.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ Rothman & Rothman, *supra* note 152, at 784.

¹⁷⁰ *See generally id.*

¹⁷¹ *Id.* at 785.

suggest, professional medical associations should be dedicated to disseminating unbiased, scientifically-backed information that benefits patients, not pharmaceutical companies.¹⁷² If associations can achieve those ends, then perhaps they will emerge as authorities on state compulsory vaccination laws.

VII. ACCOUNTABILITY: HOW DO WE HOLD FEDERAL AGENCIES RESPONSIBLE FOR MANDATORY VACCINATION LAWS?

This Article has proposed the idea of shifting decision-making behind compulsory vaccination laws from state legislatures to another entity, such as the FDA or the CDC. Both the CDC and FDA are armed with a greater level of vaccine knowledge and familiarity than a state legislature could ever hope to glean. Yet passing the buck from state legislatures to federal agencies elicits discomfort because inevitably, granting greater authority to a federal agency (like the FDA or CDC) means stripping state legislatures of power. Part of this discomfort stems from the federalist tradition that residual power in the United States is reserved for the states.¹⁷³

As a democratic republic, the power of the government rests in the hands of the United States citizens.¹⁷⁴ More specifically, through voting, the public is able to hold incumbents accountable for the policy decisions they make.¹⁷⁵ As a result, incumbents work to respond to the public's interests and demands, and thus, public interests shape public policy.¹⁷⁶ In the case of compulsory vaccination laws, incumbent accountability is a very attractive privilege because if a state legislature makes a decision regarding public health that is contrary to the public interest, the public is able to resolve the problem via the ballot box. In summary, the public has recourse through the electoral process.

¹⁷² *Id.*

¹⁷³ Timothy Meyer, *Federalism and Accountability: State Attorneys General, Regulatory Litigation, and the New Federalism*, 95 CALIF. L. REV. 885, 885 (2007).

¹⁷⁴ John Ferejohn, *Accountability and Authority: Toward a Theory of Political Accountability*, in *DEMOCRACY, ACCOUNTABILITY, AND REPRESENTATION* 131, 131 (Adam Przeworski, Susan C. Stokes & Bernard Manin eds. 1999).

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

This type of accountability does not exist with federal agencies, at least not to the same extent that state legislatures can be held accountable.¹⁷⁷ Some argue that there is Presidential accountability.¹⁷⁸ In other words, if an individual citizen has an issue with an action taken by an administrative agency, he or she can raise that issue in the next Presidential election. However, the relationship between the President's accountability and for example, the Secretary of the Department of Health and Human Service's accountability seems attenuated at best and hardly satisfactory. This is particularly apparent to the mother whose daughter has just been ordered to receive the HPV vaccine before she is permitted to enter the sixth grade.

That said, perhaps compulsory vaccination laws fit well within the area of lawmaking for which federal agencies were designed. Courts and commentators have argued that "agencies are better situated to address technical and scientific issues on the 'frontiers of science,'" and in fact, agencies originated with one strength in mind: expertise in particular policy areas that are uniquely technical.¹⁸⁰ In effect, agencies exist for the very purpose of providing the expertise that legislatures lack.¹⁸¹ This specialization is reflected in agency structures, which have a small staff of appointed officials coupled with a large staff of technological and scientific experts.¹⁸²

Although agencies may have little direct accountability, that problem can be mitigated. Congress can exert additional authority over administrative agencies by shaping their authoritative boundaries through legislation.¹⁸³ Additionally, accountability can be assured through proper oversight.¹⁸⁴

Administrative law is a complex area, and this Article does not provide a solution to the question of whether a federal agency or a state legislature is better adapted to decide if a given compulsory vaccination law should be passed. However, addressing the issue of accountability highlights the need to take administrative law into consideration when

¹⁷⁷ Meyer, *supra* note 173, at 885.

¹⁷⁸ Emily Hammon Mezell, *Deference and Dialogue in Administrative Law*, 111 COLUM. L. REV. 1722, 1727 (2011).

¹⁷⁹ *Id.*

¹⁸⁰ Eric Berger, *Individual Rights, Judicial Deference, and Administrative Law Norms in Constitutional Decision Making*, 91 B.U. L. REV. 2029, 2067 (2011).

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.* at 2061.

¹⁸⁴ *Id.* at 2063.

determining who should be making compulsory vaccination laws.

CONCLUSION

The HPV vaccine stands front and center in a long line of vaccines for which compulsory vaccination will be proposed and subsequently debated. The HPV vaccine is not unique in its controversy; it is only the first of many vaccines that exist in a type of purgatory where compulsory vaccination is not obvious, but at the same time, is not completely implausible either.

With the rapid development of science and technology, drug and biologic manufacturers will continue to discover vaccines for a myriad of different diseases, ranging from the most contagious to the completely incommunicable, from the severely life-threatening to the borderline innocuous. As it stands, the current process inadequately deals with those vaccines that do not fit squarely into the protocol defined in *Jacobson*.

Currently, state legislatures have seemingly limitless power to mandate vaccines, even when they are neither contagious nor largely life-threatening. What is more concerning is that state legislatures' decisions seem largely driven by social and economic demands that they readily succumb to in an effort to earn constituent votes. Should compulsory HPV vaccine laws be upheld, there is the possibility that vaccination policy will cascade down a slippery slope, at the bottom of which state legislatures have the ability to strip individuals of their privacy rights for unwarranted public health policies.

Somehow, the current system must be cleansed of its biases, but at the same time, no suitable substitute appears readily available. It seems that government agencies and professional medical associations are haunted by similar industry pressures as state legislatures. To delegate authority to the CDC, for example, may only serve to perpetuate biased decision-making when it comes to compulsory vaccination laws. At the same time, the CDC and the FDA are bastions of expertise and knowledge that could prove instrumental in shifting the focus of vaccine law from socio-economic concerns to scientific-technical concerns.

Perhaps the solution is to foster more collaboration between federal agencies and state legislatures rather than to provide single-handed authority to either entity. Instead of the CDC and ACIP disseminating isolated recommendations upon which state legislatures must impetuously rely, the CDC and state legislatures could collaborate to

develop comprehensive legislation drafted with the perspectives of multiple disciplines in mind. After all, most states already adhere to CDC recommendations, so making the process more informed would only serve to bolster the quality of state legislation.

For clarification, this Article does not make any conclusions as to whether the HPV vaccine should be mandatory in international settings. Certainly, the need for the government to protect public health and safety may be greater in areas where access to medical attention (including secondary prevention methods, such as the Pap smear) is limited, where gender discrimination prohibits adequate reproductive health care, and where cost (especially with on-patent drugs) is a limiting factor for individuals in making health care decisions. The topic of international mandatory vaccination is reserved for future discussion.

Further, this Article does not condemn the HPV vaccine. On the contrary, this Article supports the determinations of the FDA, CDC, and ACIP, which recommend the HPV vaccine where appropriate. However, this Article does advocate for sound public health policies that are not motivated by politics or bureaucracy but instead find their basis in rigorous and legitimized scientific study and assessment. State representatives' inability to objectively assess the HPV vaccine has undermined the vaccine's immense potential health benefits and distracted law-makers from their true obligations: to make decisions that are in the best interest of the public health and safety.