HPV Vaccine School Entry Requirements: Confronting the Myths, Misperceptions and Misgivings

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Introduction

The introduction of a vaccine against human papillomavirus (HPV) infection, has been heralded as a long-awaited tool to combat cervical cancer.1 Similar to all vaccines licensed in the United States, HPV vaccine has traversed a highly regulated, tested and monitored path. The prospect of requiring its administration as a prerequisite for school entry, however, has engendered unprecedented controversy.

Proponents of mandatory vaccination cite national immunization policymakers who have universally attested to the efficacy, safety and appropriateness of the vaccine. Experts indicate that widespread administration of the vaccine will greatly reduce the incidence of the HPV infections that lead to most cervical cancer in the United States.2 They argue that the vaccine delivery system should employ the customary mechanism of school vaccination requirements to ensure that the target population has access to necessary doses.

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Opponents of school requirements for HPV vaccination present several arguments as proof that the vaccine is not a good candidate. They claim that a mandate represents inappropriate governmental infringement upon parental rights, HPV is not casually communicable, and that compulsory administration would be inconsistent with familial values and messages regarding abstinence.

This article will address the primary objections that opponents cite when discussing whether to include HPV vaccine as a school entry requirement. The Background will outline the importance of vaccination to personal and public health, the influence that the Advisory Committee on Immunization Practices has on national vaccine policy, the HPV infection, vaccine, and recommendations, and how state legislative bodies have responded to the vaccine. Each argument in opposition to requiring the vaccine for school entry will be addressed including: (1) government intrusion, (2) infection transmission, (3) sexual disinhibition, and (4) undermining abstinence only messages. The article concludes by asserting that HPV vaccine should be required for school entry.

Background

Vaccines: Personal and Public Health

Vaccines and recommended immunizations have saved more lives than any surgical technique or any medication, including antibiotics. Population wide vaccination has eradicated smallpox worldwide and the incidence of diphtheria, polio, congenital rubella S., and influenzae type b have decreased by almost 100% in the United States.³ Immunization programs have reduced U.S. infant mortality rates to less than 1% today, from 20% a century ago.⁴ It is not surprising then, that vaccines are widely recognized as one of the greatest achievements of public health.⁵ From Edward Jenner’s first smallpox vaccine until today, governments have supported comprehensive population-

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³ Centers for Disease Control and Prevention, What Would Happen if we Stopped Vaccinations? http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm (last visited Oct. 6, 2008) (discussing various eradicated diseases and describing potential threat if vaccinations were to cease).


wide immunization programs.\textsuperscript{6}

The primary public health objectives for vaccines are to achieve and maintain the highest possible vaccination coverage rates, and resist disease among individuals and throughout a community. When these conditions are met, herd immunity, the resistance to a disease that develops in an entire community when a sufficient number of individuals are vaccinated, is established.\textsuperscript{7} In order to ensure that appropriate populations are immunized, public and private stakeholders including government, academia, vaccine manufacturers, healthcare providers and consumers have long collaborated.\textsuperscript{8}

\textbf{ACIP Recommendations Influence Immunization Policy}

The Advisory Committee on Immunization Practices (ACIP) was created by the Omnibus Budget Reconciliation Act of 1993.\textsuperscript{9} The goals of ACIP are to reduce the incidence of vaccine preventable diseases and to increase the safe use of vaccines.\textsuperscript{10} In order to develop its recommendations, the Committee reviews population-based studies that examine a broad range of vaccine-related issues including: efficacy, cost, administration, adverse events, proper storage, and handling as they apply to pediatric and adult populations.\textsuperscript{11} The advice is submitted to the Secretary, Health and Human


\textsuperscript{7} Herd immunity protects those few individuals who are unable to receive vaccinations due to age, or health status. Each vaccine-preventable disease requires a different percentage of coverage before herd immunity is achieved and ranges from 75% for mumps to 94% for pertussis. JoNel Aleccia, \textit{Vaccine-wary parents spark public health worry}, MSNBC.COM, Aug. 22, 2008, http://today.msnbc.msn.com/id/26291109/.

\textsuperscript{8} Walter A. Orenstein, et al., \textit{Immunizations In The United States: Success, Structure, And Stress}, 24 \textit{HEALTH AFF.} 599, 603-605 (2005) (detailing collaborative effort of federal government, state and local governments, and private vaccine industry to eradicate disease through immunization).

\textsuperscript{9} Public Health Service Act, 42 U.S.C.A. § 217a. The committee is governed by the provisions of Public Law 92-463, as amended 5 U.S.C.A. app. § 2 (Westlaw 2008), which sets forth standards for the formation and use of advisory committees. The Advisory Committee on Immunization Practices has been given a statutory role under Section 13631 of the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66 (42 U.S.C.A. § 1396s(c)(2)(B)(i) and (e).

\textsuperscript{10} Centers for Disease Control and Prevention, \textit{Advisory Committee on Immunization Practices}, http://www.cdc.gov/vaccines/recs/acip/default.htm (last visited Oct. 6, 2008).

\textsuperscript{11} Id.
Services, the Assistant Secretary for Health, and the Director of the Centers for Disease Control and Prevention (CDC).\textsuperscript{12} Even after a vaccine is approved, the Committee may alter or withdraw their opinion as new information comes to light or the risk of disease changes.\textsuperscript{13}

ACIP recommendations become the national standard of care and are adopted by state immunization programs, medical professional societies, and consumers, both in the United States and abroad. ACIP directives trigger the inclusion of the vaccine into government and private programs that are designed to increase access to vaccines among certain populations. Additionally, states often implement ACIP recommendations by incorporating new vaccines into school entry laws. Meetings are conducted three times per year and are open to the public unless the Secretary, HHS determines otherwise.\textsuperscript{14} Minutes of the meetings are made available to the public as well.\textsuperscript{15}

The Committee is comprised of fifteen voting members who have expertise in immunization practices and public health, the use of vaccines in clinical practice or preventive medicine, vaccine research, or assessment of vaccine efficacy and safety.\textsuperscript{16} The Committee must include persons who have knowledge of consumer perspectives and social and community aspects of immunization programs.\textsuperscript{17} Non-voting liaison representatives from medical and healthcare associations, Canadian, Mexican, and British public health organizations and health insurance and pharmaceutical industry associations also sit on the Committee.\textsuperscript{18}

\begin{thebibliography}{9}
\item 12 Id.
\item 13 Id.
\item 14 5 U.S.C.A. § 552b(c) (West 2008) (describing situations where public attendance is prohibited).
\item 15 Centers for Disease Control and Prevention, \textit{ACIP Meetings, Agendas, and Registration}, http://www.cdc.gov/vaccines/recs/ACIP/meetings.htm (last visited Oct. 6, 2008).
\item 17 Id.
\item 18 Id. The non-voting liaison representatives are: American Academy of Family Physicians; the American Academy of Pediatrics; the American College Health Association; the American College of Obstetricians and Gynecologists; the American College of Physicians; the American Geriatrics Society; the America's Health Insurance Plans; the American Medical Association; the American Osteopathic Association; the American Pharmacists Association; the Association for Prevention Teaching and Research; the Biotechnology Industry Organization; the Canadian National Advisory Committee on Immunization; the Department of Health of the United Kingdom; the Healthcare Infection Control Practices Advisory Committee, CDC; the Infectious Diseases Society of America; the National Association of County and City Health Officials; the National Association for Pediatric Nurse Practitioners; the National Foundation for Infectious
\end{thebibliography}
HPV Infection and Vaccine

HPV infection is the most common sexually transmitted infection (STI) in the United States. Over 20 million individuals, half of whom are ages fifteen through twenty-four, are currently infected, and 6.2 million additional persons become newly infected each year. Of these 6.2 million newly infected individuals, 4.2 million are ages fifteen through twenty-four. The infection usually develops shortly after the onset of sexual activity. Two years after sexual debut, cumulative incidence of any HPV infection is 40%, and four years later, the incidence is over 50%. More than 80% of all sexually active women will have acquired genital HPV infection by age fifty.

Of the over 100 strains of HPV, it is persistent and invasive infection with strains sixteen and eighteen that are associated with high grade cervical intraepithelial neoplasias (CIN) which are responsible for 70% of cervical cancer in the United States.

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Diseases; the National Immunization Council and Child Health Program, Mexico; the National Medical Association; the National Vaccine Advisory Committee, HHS; the Pharmaceutical Research Manufacturers of America; the Society for Adolescent Medicine; the Society for Healthcare Epidemiology of America; and such other non-voting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the committee. See id.

Centers for Disease Control (CDC), Quadrivalent Human Papillomavirus Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 56(No RR-2) MORBIDITY MORTALITY WkLY. REP. (Mar. 12, 2007), at 2 available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm (last visited Oct. 6, 2008) [hereinafter Recommendations of the Advisory Committee] (detailing prevalence of HPV infection in the United States where it tops list of sexually transmitted diseases).

Id. at 2.

Id.

Id. at 4.

Centers for Disease Control and Prevention, National Immunization Program, RECORD OF THE MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES 10 (Feb. 21-22, 2006), http://www.cdc.gov/vaccines/recs/acip/downloads/min-f eb06.pdf [hereinafter ACIP Meeting 02/06].

Recommendations of the Advisory Committee at 4.

Id. at 4. Persistent HPV is defined as infection detected at more than one visit, usually at four to six months apart.

Strains sixteen and eighteen also cause cervical abnormalities, anal and anogenital cancers, and is present in approximately one-fourth of head and neck cancers. Frequently Asked Questions About Human Papilloma Virus (HPV) Vaccines, AMERICAN CANCER SOCIETY, http://www.cancer.org/docroot/CRI/content/CRI_2_6x_FAQ_HPV_Vaccines.asp (last visited Oct. 9, 2008); HPV Linked to Some Head and Neck Cancers, AMERICAN CANCER SOCIETY, http://www.cancer.org/docroot/NWS/content/NWS_1_1x_HPV_Linked_to_Some_Head_and_Neck_Cancers.asp (last visited Oct. 9, 2008). The annual incidence of head and neck cancers in the United States is about 39,000, which accounts for 3% to 5% of all cancer in the United States, and is more
An estimated 11,150 women will be diagnosed with cervical cancer in 2008 and 3,870 will die. Strains six and eleven cause 90% of genital warts, recurrent respiratory papillomatosis (RRP), and low-grade cervical cell abnormalities. Gardasil, produced by Merck and Co., Inc., is the first vaccine to protect against HPV strains six, eleven, sixteen and eighteen. The vaccine is a prophylactic, conferring almost 100% protection for a minimum of five years.

**ACIP Recommends Gardasil**

On June 29, 2006, ACIP voted to recommend Gardasil to girls and women ages nine through twenty-six, as follows: (1) girls ages nine and ten may be vaccinated at the discretion of their parents or guardians and physician; (2) girls ages eleven or twelve are to be routinely vaccinated; and (3) girls and women ages thirteen through twenty-six should be vaccinated as a “catch-up” if they have not already received the vaccine.

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28 Approximately 20,000 cases of RRP develop per year in the United States. See Recommendations of the Advisory Committee at 7. RRP affects males and females. Id. It is a rare, debilitating and recurrent disease that causes obstructive papillomas (non-cancerous tumors or warts) to grow in the respiratory tract. Id. It is most common in juveniles and is believed to be maternally transmitted during birth. Id. The median number of surgeries to remove the growths and maintain an open airway is 13, with a range of 2 to 179. Id.

29 Id. at 2.

30 See id. at 8; Press Release, Centers for Disease Control and Prevention, CDC’s Advisory Committee Recommends Human Papillomavirus Virus Vaccination (June 29, 2006), available at http://www.cdc.gov/od/oc/media/pressrel/r060629.htm.


32 See Recommendations of the Advisory Committee at 1; Press Release, Centers for Disease Control and Prevention, supra note 30.
Legislative Response to HPV Vaccine

During the 2006 - 2007 legislative sessions, twenty-five states and the District of Columbia considered whether to require vaccination with the HPV vaccine, usually before entering grade six.33 Vaccine advocates, cervical cancer survivors, public health policymakers, parents, healthcare providers, and other interested stakeholders have testified before various committees to express widely divergent views. Social conservatives, anti-vaccine groups, and even many vaccine policy experts have united to challenge the adoption of HPV vaccine mandates. Their arguments against a mandate include: unnecessary governmental infringement upon parental rights, mode of infection transmission, preservation of family values, vaccine cost, safety and efficacy.

Despite community protests,34 the District of Columbia and Virginia are the first jurisdictions to enact legislation requiring all girls entering the 6th grade to be vaccinated against HPV.35 Virginia's law is effective as of October 1, 2008,36 and the District's mandate will be effective in the fall, 2009.

Opposition To Requiring HPV Vaccine For School Entry

Government Intrusion

Opponents of mandatory immunization often argue that the government has no right to interfere with parents' decision-making ability regarding medical care for

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their children. They insist that:

The decision . . . whether to vaccinate a minor against this or other sexually transmitted infections should remain with the child's parent or guardian. As in all areas of sexual health and education, [we] uphold parents' right to be the primary decision maker and educator for their children.\(^3\)

The judicial system has addressed this question repeatedly. Beginning with the landmark 1905 decision, *Jacobson v. Massachusetts*, the Supreme Court recognized that the legal authority to require immunization rests on states' 10th Amendment "police powers." Police powers are the inherent authority of a government to impose restrictions on private rights for the sake of public welfare, order, and security. States can exercise this power directly or delegate their powers to local governments.\(^3\)

In 1902, Cambridge, Massachusetts, was faced with an outbreak of smallpox.\(^3\) In response, the Board of Health required the vaccination of all residents who had not previously been successfully vaccinated against smallpox since March 1, 1897.\(^4\) Reverend Henning Jacobson refused to comply, citing his concerns regarding the safety of the vaccine and claiming that the requirement was an infringement on his personal liberty and his constitutional right to due process.\(^4\) He was convicted of violating the ordinance and fined five dollars.\(^4\) After his appeal to the Massachusetts Supreme Judicial Court was denied,\(^4\) he appealed to the Supreme Court. The Court held that states' 10th Amendment "police powers" allowed the adoption of measures intended to "protect the health and safety" of its citizens:

[T]he liberty secured by the Constitution . . . to every person . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold


\(^4\) Id. (outlining requirements of Cambridge Board of Health).

\(^4\) Id. (explaining Jacobson's objection to mandatory vaccination as violations of due process and equal protection).

\(^4\) Id. (mentioning Jacobson's fine for refusal).

restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes that the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.

Thus, states, through their health administrators, may develop measures that compel individuals to accept vaccinations in order to protect the public’s health. Any violation of such measures may be prosecuted. However, Jacobson was an adult. Would the Court’s reasoning extend to children?

How School Entry Requirements for Immunizations Affect Public Health

State laws that require vaccination as a condition for school attendance are critical elements of an effective vaccine delivery system. School mandates have worked in tandem with national vaccine policy decisions by converting recommendations for new vaccines into legally enforceable obligations. Over time, school mandates have created the impetus for increased coverage rates among all children, have decreased the incidence of infectious disease, and have reduced racial and ethnic disparities among school-age children. Children who live in low-income families or in families that have been unable to establish a medical home have benefitted from school mandates by receiving recommended immunizations. For example, in 2006, an estimated 23% of children aged nineteen to thirty-five months had not received all the recommended immunizations. By age five, however, 95% of children were up-to-date. The increase in coverage rates is directly attributable to vaccine mandates.

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44 Jacobson, 197 U.S. at 26, 25 S. Ct. at 361.
The Growth of School Entry Requirements for Immunizations

In 1827, Boston enacted the first school entry requirement in response to newly ratified mandatory school attendance laws, continuing disease outbreaks, and the availability of effective vaccines. The statute required all students to receive inoculations against smallpox. By the early 1900s, nearly half of all states had developed mandates of their own. These initiatives presented the Supreme Court with its second opportunity to consider compulsory immunization. In 1922 the Court decided Zucht v. King.

A San Antonio, Texas ordinance prohibited any child from attending "a public school or other place of education without having first presented a certificate of vaccination." Rosalyn Zucht refused, asserting that the requirement constituted a deprivation of her liberty without due process of law and was a violation of her equal protection rights under the 14th amendment. She sought an injunction against enforcement of the ordinance, a writ of mandamus to compel her admission to the public school and damages in the sum of $10,000. The trial court dismissed the complaint, the Court of Civil Appeals for the Fourth Supreme Judicial District affirmed the judgment, a motion for rehearing was overruled, and the Supreme Court of Texas denied an application for a writ of error. The Supreme Court granted the second petition for a writ of certiorari. The Court quickly dispatched of her complaints and relied on the precedent set in Jacobson:

Long before this suit was instituted, Jacobson v. Massachusetts . . . had settled that it is within the police power of a state to provide for

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49 Id.
50 Id.
51 260 U.S. 174 (1922).
52 Id. at 175.
53 Id. at 176.
54 Zucht, 260 U.S. at 175.
55 Zucht v. King, 225 S.W. 267, 270 (1920).
56 Zucht, 260 U.S. at 175.
57 Id. at 175-76.
58 Id. at 176.
compulsory vaccination. That case... had also settled that a state may, consistently with the federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative. . . . the municipality may vest in its officials broad discretion in matters affecting the application and enforcement of a health law. . . . [T]hese ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health. 59

Therefore, the Court confirmed that states may require parents to have their children vaccinated in order to promote the best interests of the broader community. In the aftermath of Zucht, additional states instituted mandates and by 1963, 20 states and the District of Columbia required various inoculations for school entry. Not all states enforced the mandates with equal vigor, however. Outbreaks of measles in the late 1960s and early 1970s highlighted the effectiveness of school entry requirements and the need for strong enforcement. 60 Districts that had robust enforcement policies experienced lower rates of disease than districts that had failed to employ stringent measures to facilitate compliance with the laws. 61 By the early 1980s, every state required students to demonstrate that they had received certain immunizations as a prerequisite for school attendance. 62

Opting-out of School Entry Requirements for Immunizations

All jurisdictions include “opt-out” provisions in their statutes. Opt-outs, or exemptions, permit parents to refuse immunizations for their children for one of three reasons depending on the state. All states and the District of Columbia grant exemptions for medical contraindication when it can be reasonably predicted that a child would experience adverse effects from a vaccination. All states except Arizona, Mississippi, Missouri and West Virginia, grant exemptions based on a claim that a religious belief opposes vaccination. 63 Finally, eighteen states allow exemptions based on a parent’s personal, moral, or philosophical beliefs. 64

59 Id. at 176-77.
61 Id. at 177.
62 Id.
64 See id. The states that permit philosophical or moral belief exemptions are Arizona, Arkansas,
Some states offer exemptions without requiring rigorous review or extensive documentation, making exemptions easy for parents to obtain. In these states, decreased coverage rates are present, and disease incidence is higher than in states that have developed more difficult opt-out procedures.\(^5\) Despite the availability of opt outs, more than 95% of all school-age children receive mandated immunizations with only approximately 2-3% of parents nationwide choosing to reject immunizations.\(^6\)

Opponents of school entry requirements have repeatedly challenged the laws, with arguments that have been grounded in a variety of legal theories.\(^67\) Claims against compulsory immunization laws have included the charge that the laws: (1) constitute an illegal search and seizure under the 4th Amendment;\(^68\) (2) violate the 14th Amendment Equal Protection Clause;\(^69\) or (3) violate the Establishment Clause of the First Amendment.\(^70\) In case after case, the judiciary has held fast to the principles outlined in \textit{Jacobson} and \textit{Zucht} and have affirmed that when properly weighed, community-wide protection against vaccine-preventable disease trumps an individual's right to refuse immunization.

\section*{Expanding Opt-out Possibilities}

As indicated above, the District of Columbia and Virginia require HPV vaccination for school entry. Before HPV vaccine was required, both jurisdictions permitted only two exemption possibilities for required vaccines: for medical or for religious reasons.\(^71\) When HPV vaccine became mandatory, however, legislators expanded opportunities for parents or guardians to refuse vaccination of their daughters. Neither law requires parents or guardians to offer any reason for refusal; yet both laws

\footnotesize{California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Texas, Utah, Vermont, Washington and Wisconsin.}

\footnotesize{\(^5\) Saad B. Omer, et al., \textit{Nonmedical exemptions to school immunization requirements: secular trends and association of state policies with pertussis incidence}, 296 J. AM. MED. ASS'N 1757, 1761 (October 11, 2006).}


\footnotesize{\(^68\) McSween v. Board of School Trustees, 129 S.W. 206, 207-08 (Tex. Civ. App. 1910).}

\footnotesize{\(^69\) Adams v. Milwaukee, 228 U.S. 572, 579 (1913).}

\footnotesize{\(^70\) Mason v. General Brown Cent. School Dist., 851 F.2d 47, 49 (2d Cir. 1988).}

have provisions that necessitate parents or guardians to receive educational material about cervical cancer and the vaccine before exercising their right to refuse:

The parent or legal guardian, in his or her discretion, has elected to opt out of the HPV vaccination program, for any reason, by signing a form prepared by the Department of Health that states the parent or legal guardian has been informed of the HPV vaccination requirement and has elected not to participate.72

The Virginia law indicates that the broad opt-out was included because HPV is transmitted only through more intimate contact:

Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent or guardian’s sole discretion, may elect for their child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board. 73

The inclusion of educational requirements could ease parental concern regarding HPV, adolescent sexuality and immunization, as well as facilitate informed decision-making before parents can refuse the vaccine. The educational requirement could support optimal acceptance and utilization of the immunization platform.

**Infection Transmission**

Opponents of HPV mandates also claim that “[s]ince genital HPV is not spread by casual contact . . . there is not sufficient public health justification to require vaccination for school attendance.”74 The “Parental Right to Decide Protection Act,” introduced by Georgia Congressman Phil Gingrey (R), on February 16, 2007,75 seeks to

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codify this stance:

Federal funds should not be used to implement a mandatory vaccine program for a disease that does not threaten the public health of schoolchildren in the course of casual, daily interaction between classmates and inserts the government into the lives of children, parents, and physicians.\textsuperscript{76}

No Federal funds or other assistance may be made available to any State or political subdivision of a State to establish or implement any requirement that individuals receive vaccination for human papillomavirus (HPV).\textsuperscript{77}

As legislators determine whether to vote for an HPV mandate, they may find the case of hepatitis B vaccine relevant to their deliberations. There are many similarities between the two vaccines and the implementation of the vaccine school entry requirement should be illustrative.

\textbf{Implementation of Hepatitis B Vaccine School Entry Requirements}

Hepatitis B (HBV) virus infection is a bloodborne and sexually transmitted virus that is a leading cause of primary\textsuperscript{78} liver cancer.\textsuperscript{79} In 2008, an estimated 21,370 new cases of primary liver cancer will be diagnosed in the United States.\textsuperscript{80} The most

\begin{itemize}
\item Parental Right to Decide Protection Act, H.R. 1153, 110th Cong. at § 2(10).
\item \textit{Id.} at § 3.
\item Primary liver cancer is cancer that originates in the liver. Secondary cancer in the liver is cancer that originated in another part of the body and spread to the liver. The secondary cancer is named for the organ in which it began. \textit{See National Cancer Institute, What You Need to Know About Liver Cancer}, http://www.cancer.gov/cancertopics/wyntk/liver (last visited Sept. 29, 2008).
\item American Cancer Society, \textit{What Are the Key Statistics About Liver Cancer?}, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_liver_cancer_25.asp?sitearea= (last visited Sept. 29, 2008).
\item In 1991, an estimated 1 to 1.25 million individuals were infected with chronic HBV. During 1980 through 1991, an estimated 200,000 to 300,000 new infections occurred annually. The infection may be transmitted in four ways: (1) through injection-drug use, (2) through sexual contact with an infected person, (3) through the household contacts of a person with chronic HBV infection or (4) from an infected mother to her infant during delivery. Perinatal transmission of HBV ranges from 10% to 85%, depending on each mother's hepatitis B antigen status. Perinatal transmission is particularly problematic because infants who become infected
effective means to prevent HBV infection is to immunize with hepatitis B vaccine.\textsuperscript{82} The vaccine is delivered through a series of 3 doses over 6 months.\textsuperscript{83} Vaccine efficacy is 80-95\% against infection and 100\% against clinical illness.\textsuperscript{84} The vaccine will provide protection against infection for a minimum of nine years.\textsuperscript{85}

From 1991 to 2005, ACIP issued a series of recommendations regarding the best methods to implement immunization policy for hepatitis B vaccine.\textsuperscript{86} The final recommendations indicated routine immunization for all children and adolescents under age nineteen.\textsuperscript{87} In order to implement the policy, ACIP noted that "[s]tates are encouraged to adopt regulations or laws that require hepatitis B vaccination before entry into middle school or its equivalent . . . Vaccination requirements should be considered for older high school students and for students before college entry, when feasible."\textsuperscript{88}

The institution of Hep B vaccine mandates has had a dramatic effect on the overall incidence of acute hepatitis B.\textsuperscript{89} From 1990 to 2006, disease incidence declined
81% to the lowest rate ever recorded since surveillance began in 1966.\textsuperscript{90} In 2006, there were 4,713 cases, (1.6 cases per 100,000) and 46,000 new infections.\textsuperscript{91} Declines were greatest among those subject to the new immunization recommendations – children under age 15 (98%) and those ages 15 through 24 years (93%).\textsuperscript{92}

In 1993, based on the earliest recommendations, Massachusetts was the first state to enact a mandate for daycare entry and was followed by a steady stream of legislative activity in other states.\textsuperscript{93} By 2007, forty-seven states and the District of Columbia had legislated hepatitis B vaccine requirements for daycare, elementary and/or middle school entry.\textsuperscript{94} Alabama, Montana and South Dakota are the only states that do not require the vaccination, even though the South Dakota Department of Health recommends the vaccine.\textsuperscript{95}

**Judicial Response to Hepatitis B Immunization Requirements**

In 2000, the Arkansas legislature required all children entering daycare, elementary and middle schools to receive hepatitis B vaccine.\textsuperscript{96} Parents who opposed the new vaccination requirement turned to the courts, complaining that the new law violated the 1\textsuperscript{st} and 14\textsuperscript{th} amendments:\textsuperscript{97}

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\text{[s]cripture commands me to teach my children to live a lifestyle of sexual purity and not to be sexually promiscuous. I also believe that [I must] teach my children to take excellent care of their bodies and to remain free from sexual promiscuity and drug use as a way of showing respect for the Temple of God. I do not want in any way to teach my children that sexual promiscuity and drug use is an acceptable lifestyle. I believe that immunizing my children against Hepatitis B gives the appearance that my children will be sexually promiscuous or}
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\textsuperscript{90} Id. at 1-2.  
\textsuperscript{91} Id. at 7.  
\textsuperscript{92} Id.  
\textsuperscript{94} See id.  
\textsuperscript{96} ARK. CODE ANN. § 6-18-702 (2008).  
drug users.\textsuperscript{98}

The Court agreed that the religious exemption provision violated the Establishment and Free Exercise Clauses of the 1\textsuperscript{st} amendment, severed the terms, and found “the remaining portions of the statute remain in full force and effect.”\textsuperscript{99} This meant that the law would not allow parents to refuse vaccination based on their religious beliefs.

The parents argued further that both \textit{Jacobson} and \textit{Zucht} were decided in the midst of a declared health emergency involving smallpox, while Hepatitis B presents no “clear and present danger.”\textsuperscript{100} However, the Court rejected their position and bestowed a sweeping endorsement of \textit{Jacobson} and the notion that vaccination requirements are appropriate even when the targeted infection is not casually communicable:

The Supreme Court did not limit its holding in \textit{Jacobson} to diseases presenting a clear and present danger. Even if such a distinction could be made, the Court cannot say that hepatitis B presents no such clear and present danger. Hepatitis B may not be airborne like smallpox; however, 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 can survive on surfaces, door knobs, et cetera, for up to a month’... Immunization of schoolchildren against Hepatitis B has a real and substantial relation to the protection of the public health and the public safety. The Court therefore finds that requiring schoolchildren to be immunized against Hepatitis B is a reasonable exercise of the State’s police power and is constitutionally permissible.\textsuperscript{101}

As the \textit{Boone} and \textit{Brock} decisions show, courts are clearly willing to embrace new vaccine technology, and recognize that traditional precedents can adapt to incorporate innovations. The case of Hepatitis B vaccine mandates may set the standard regarding how to resolve future challenges that will arise as states contemplate how to incorporate HPV vaccine into effective mandates.

\textsuperscript{98} \textit{Brock}, 2002 U.S. Dist. LEXIS 15479, at *6-7.
\textsuperscript{99} \textit{Boone}, 217 F. Supp. 2d at 952.
\textsuperscript{100} See id. at 954.
\textsuperscript{101} Id.
Sexual Disinhibition

The third argument from those who oppose mandating HPV vaccine centers on the belief that the administration of the vaccine will persuade their children to become "sexually disinhibited." They contend that the vaccinated adolescent would be more likely than her peers to engage in risky sexual activity because she will perceive that the HPV vaccine will protect her. In turn, increased sexual activity would heighten the risk for cervical cancer and other sexually transmitted infections.102

Studies show that 6% to 12% of adults fear sexual disinhibition in their HPV-vaccinated children,103 social conservatives among them. They have claimed that their "primary concern is with the message that would be delivered to nine-to-twelve-year-olds with the administration of the vaccine. Care must be taken not to communicate that such an intervention makes all sex 'safe.'"104 They insist that "[g]iving the vaccine to young girls before they are sexually active provides them with a false sense of security, possibly leading to risky sexual behavior that would not have occurred had the threat of cervical cancer been present."105

However, there is no empirical evidence to support this claim. To date, no research has been conducted regarding whether HPV vaccination would result in an increase in risky sexual conduct.106 If results from behavioral disinhibition research can be applied to HPV vaccine, adolescents would not demonstrate an increase in sexual disinhibition. In fact, existing studies show that: 1) Injection drug users did not increase drug use when they were offered free needle exchanges to reduce HIV infection;107 2) Adolescents did not change reported rates of sexual activity or increase the frequency of unprotected intercourse when adolescents were made aware of the availability of emergency contraception;108 and 3) The percentage of adolescents who had ever had sex

103 See id.
106 Brewer, supra note 105, at 96.
108 Alastair J.J. Wood et al., A Sad Day for Science at the FDA, 353 NEW ENG. J. MED. 1197, 1198
did not change after having condoms available, or between schools that have instituted Condom Availability Programs (CAPs) and those without such programs.109

As Dr. Judy Monroe, the Indiana Health Commissioner has stated, "[t]here's no evidence that seat belts have increased reckless driving. There is no evidence that when we get tetanus shots, we seek rusty nails."110

Undermining Abstinence Only Messages

Social conservatives argue that their "concern is that this vaccine will be marketed to a segment of the population that should be getting a message about abstinence."111 They declare that "[i]t sends the wrong message."112 The U.S. Department of Health and Human Services (HHS), has developed programs that teach abstinence until marriage as the sole strategy for preventing early sexual activity and sexually transmitted infections among adolescents.113

Studies show that abstinence-only programs are not particularly effective. A Congressionally authorized evaluation of the State Abstinence Education Program found that there were no significant differences between adolescents receiving abstinence education and a control group that did not, either in their likelihood of delaying the initiation of sexual intercourse, or in the number of their sexual partners.114 Other studies show that students who have taken virginity pledges have only slightly

(2005).


112 Id.


lower rates of pre-marital sexual activity than those who do not. Further, students who have pledged abstinence have the same rates of STIs and unintended pregnancies as those who do not pledge, because they do not practice safe sex.

While the abstinence message may reflect the values and aspirations of many parents, clearly, it is not a reality for millions of adolescents. Reliable measurements of sexual activity among adolescents indicate that 25% have had sex by age fifteen and 48% by age seventeen. Once they initiate sexual activity, young people have more than one partner during their life. Of all 9th graders, 8.7% have had four or more partners, as have 22.4% of all 12th graders.

The use of condoms is low. Among currently sexually active high school students, 38.5% had not used a condom during their last sexual intercourse. Additionally, millions report having experienced nonconsensual sex. Nationwide, 11.3% of females were forced to have sex. Of all 9th grade females, 9.2% reported having nonconsensual sex.

An estimated 9.1 million new cases occur annually among youth ages fifteen to twenty-four. Among girls ages fourteen to nineteen, 26%, more than 3 million

\[\text{References:}\]


\[116\] See id.


\[118\] Id. at 21.

\[119\] Id. at 22, 101.

\[120\] Id. at 7-8, 47.

\[121\] Id.

\[122\] Id. at 8, 47.

\[123\] Hillard Weinstock et al., Sexually Transmitted Disease Among American Youths: Incidence and Prevalence Estimates 2000, 36 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 6, 8-9 (2004). These data include eight STDs – chlamydia; gonorrhea; syphilis; genital herpes simplex type 2; HPV; hepatitis B; trichomoniasis; and HIV. Id. at 6-10. This research is based on an analysis of published surveillance studies that drew primarily on health department-required reports filed by clinicians and on national surveys. Id. at 6. Such data are less reliable than testing individuals directly for the presence of an infection and the researchers who assessed the studies considered the quality of most evidence only “fair.” Id. at 6-10.
adolescents, have at least one of the four most common STIs.\textsuperscript{124} HPV is the most prevalent infection, present in 18% of all girls, and in almost 30% of those who are sexually experienced.\textsuperscript{125} Prevalence rates rise sharply with the number of partners. While at least one STI is evident among 20% of girls who have had only one partner, 55% of those who have had three or more partners have at least one STI.

Conclusion

Parents throughout the country are divided about whether to vaccinate their daughters against HPV and whether the vaccine should be subject to school entry requirements. Some studies show that the majority of parents in the United States are willing to vaccinate their children, even those who are under age thirteen.\textsuperscript{126} Vaccine acceptance is highest among parents who are Hispanic, those who have achieved high-school or less educational attainment, those who are Catholic, those who rarely attend religious services, and those who hold liberal political views.\textsuperscript{127}

On the other hand, the first national study to measure attitudes towards the HPV vaccine since it was approved showed that 51% of women would not vaccinate a daughter who was nine to twelve years of age, despite the existence of national public health recommendations.\textsuperscript{128} Social conservatives are united in their opposition to HPV mandates and have forcefully expressed their views.

As legislators consider and communicate the most effective and safe policy, they should carefully study the recent, successful implementation of policy recommendations


\textsuperscript{125} See id.


for hepatitis B vaccine and adopt the position outlined in Boone and Brock. The hepatitis B vaccination campaign shows that vaccines that protect against non-airborne infection can be successfully incorporated into school entry requirements. High immunization coverage rates can be maintained and improved. In the end, the individual and society will benefit.