Evaluation of Senate Bill 80 in the State of Colorado

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This policy analysis, based on a fictitious but plausible request from the Governor of Colorado, evaluates proposed legislation strongly to encourage high school girls to be vaccinated for Human Papillomavirus (HPV), the nation’s most common sexually transmitted disease (STD). After careful analysis of the proposal and alternatives to it, these authors come to the counter-intuitive conclusion that the governor should veto this legislation, if approved by the legislature. This paper is a model of solid policy analysis that arrives at a surprising but well-supported recommendation.
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Executive Summary

The Human Papillomavirus (HPV) is the nation’s most common sexually transmitted disease (STD).\(^1\) HPV can cause genital warts and cervical cancer in infected women.\(^2\) Recently, a vaccine Gardasil was introduced which protects women against contracting four types of HPV.\(^3\) The State of Colorado has introduced legislation to combat the HPV problem within its constituency. The legislation, Senate Bill 80 (S.B. 80), requires a female student and her parent or guardian to be presented with information regarding the link between HPV and cervical cancer and the availability of a vaccine to prevent certain types of HPV. It also requires female students to present evidence of the receipt of the vaccine prior to attending school or the election of the parent or guardian for the student not to receive the vaccine.\(^4\)

Before this legislation is signed into law, the Governor of Colorado, Bill Ritter (D), has requested an evaluation of all HPV vaccination legislation in the United States in order to measure whether or not the State of Colorado’s legislation is an appropriate response to the issue. In this evaluation an analysis of possible policy alternatives will be conducted. The analysis will include current public awareness campaigns, school mandates, insurance mandates and funding issues relating to the legislation and programs associated with it. Additionally, the criteria used to determine the overall recommendation to Governor Ritter will also be discussed. The recommendation is that Governor Ritter should veto S.B. 80 if passed by the State’s Legislative bodies and should continue to promote adherence to the state’s current HPV prevention and vaccination policies.
Background

HPV is the nation’s most common sexually transmitted disease (STD). There are more than 40 types of HPV, which causes genital warts and cervical cancer in infected women. The American Cancer Society estimates that 11,070 women will contract cervical cancer in 2008. It is estimated that 20 million Americans are currently infected with HPV and close to 6.2 million people become newly infected each year. Although traditional means of prevention of STDs such as the use of condoms during sexual intercourse reduce the risk of infection, they do not fully protect against contracting HPV.

To combat this growing concern, the United States Food and Drug Administration (FDA) has approved the use of the vaccine, Gardasil, which protects women against contracting four types of HPV. These types of HPV together account for some 70% of cervical cancer in women and 90% of genital warts. The Advisory Committee on Immunization Practices (ACIP), a national group of experts that advises the Centers for Disease Control and Prevention (CDC), has recommended that girls aged 11-12 years old, and possibly girls as young as 9 be given the vaccination. ACIP has also recommended that the vaccination be given to girls/women ages 13-26 year olds who have not yet received or completed the vaccination. Following the approval of the drug by the FDA and the recommendations of the ACIP, state legislatures across the country began introducing state-specific legislation to address the issue. The legislation is varied and creates a patchwork of policy approaches and alternatives to address the HPV issue at the state level.

- If you would like further information as to the history and role of state governments in mandatory vaccination programs, see Appendix B.
**Funding**

There are three options available for citizens to obtain vaccines and prevent the spread of disease. They are as follows: private health insurance companies cover the entire cost of the patient’s immunization, through federal or state programs, or the vaccination is paid for entirely out of the citizen’s pocket. Children and adults who do not have private insurance or the ability to pay the out-of-pocket expenses must seek federal or state aid for the vaccine. According to the National Council of State Legislatures, “Federal sources pay for almost 90 percent of total public vaccine expenditures providing funding for purchase and distribution, as well as for infrastructure such as statewide registries.” Two funds are available at the federal level for immunizations: the Vaccines for Children (VFC) Program and Section 317 of the Public Health Service Act.

The VFC program was created by Public Law 103-66, Omnibus Budget Reconciliation Act of 1993. Under this program, federal funding is dispersed to the states to provide immunizations to children who might not otherwise be able to afford to be vaccinated. In 1994, the Office of Management and Budget provided the allocation for the Centers for Medicare, Medicaid and the CDC to purchase necessary vaccines. According to the CDC:

> [The] CDC buys vaccines at a discount and distributes them to grantees—i.e., state health departments and certain local and territorial public health agencies—which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices.
Section 317 was created in 1962 to allow the federal government to allocate funds to all states to provide vaccines for children and adults served in public health clinics instead of offering cash. Vaccines purchased through the Section 317 program can be provided to anyone, including adults.

Approximately 25% of children in the United States receive some or all of their immunizations through public health departments, including:

- S-CHIP children seeking vaccines at public health clinics
- Children and teens without insurance coverage for vaccines ("underinsured")
- Fully insured children with high insurance deductible or co-pays
- Adults without adequate insurance coverage
- Children in need of vaccination who do not have a current healthcare provider

In addition to Section 317, several states made the commitment to "universal purchase." In this situation, states using a combination of federal and state funding sources, purchase and distribute vaccines recommended for children to all public and private immunization providers. In December 2000, there were 15 universal purchase states.

According to the CDC, in 2002 childhood vaccines in the US were purchased by:

- The private sector – 43 percent
- The VFC program – 41 percent
- Section 317 – 11 percent
- State/local governments – 5 percent

**Alternatives**
To most effectively evaluate the possible benefits of S.B. 80, it is important to first investigate and study the variety of options state governments have used to combat the spread of HPV.

**Health Insurance Mandates**

Insurance mandate legislation has taken a number of forms in different states, including:

- A mandate that insurers cover the cost of the vaccine
- A vaccine mandate plus mandate to cover cervical cancer screenings
- Requirement that if a health plan currently provides coverage for cervical cancer screenings and/or surgery then they must also provide coverage for the vaccine
- Require a referral for the vaccine
- Mandate coverage for the vaccine only for specific age ranges, such at ages 9-26, 9-14 or 11 and older

One approach that states have taken to reduce the spread of HPV is to mandate that insurance companies provide coverage for the FDA-approved HPV vaccine. Sixteen states have mandated insurance coverage for this vaccine and numerous other states have considered legislative mandates. Most insurance plans already provide coverage for the HPV vaccine. Coverage policies typically follow the ACIP immunization recommendations. In addition, a survey conducted by the pharmaceutical industry found that more than 120 health insurance plans representing at least 96% of the privately insured citizens in the U.S. now cover Gardasil. Further, Colorado passed legislation (H.B. 1301) that mandates certain health insurance cover the cost of the vaccine.

**Public Awareness Programs**

Public awareness programs are essential to preventing the spread of HPV as much of the public is significantly undereducated about HPV. Although the virus is relatively widespread, a majority of people in the United States are not familiar with HPV, its links
to cancer and genital warts or the methods of preventing infection. The public is equally unaware of the connection between HPV and cervical cancer, which may hinder public acceptance of the new vaccine for HPV.\textsuperscript{30}

Multiple states have either passed or are considering legislation to create awareness programs in regards to HPV and its links to cervical cancer. While State legislatures differ in their approach to disseminating information, the following methods are most commonly used:

- Integrating vaccine information into sexual education programs
- Sending information home to parents through schools
- Cervical cancer awareness campaigns through the health department\textsuperscript{31}

Various states mandate information to be included in the public awareness campaigns but leave the exact content and means of distribution to the local agencies, care providers and school districts. Colorado’s current policy requires adding HPV information and vaccine information to the sexual education curriculum in public schools and creating an awareness campaign within the Cervical Cancer Immunization Program.\textsuperscript{32} Effective awareness programs must cover prevention – including the vaccine, transmission, treatment and links to cancer. Programs must also stress the continued need for routine pap smears and screenings.\textsuperscript{33}

**School Mandates**

State mandated school immunizations are not a recent trend. By 1963, twenty different states mandated a number of immunizations for contagious diseases for school attendance.\textsuperscript{34} As evidence of their effectiveness grew, other states followed with their own mandates. By 1980 all fifty states had mandated school immunization programs in place.\textsuperscript{35}
With the introduction of the FDA approved HPV vaccine, many states are facing the issue of including the HPV vaccine on their list of mandated school immunizations. Twenty-four states and the District of Colombia have attempted to pass legislation aimed at requiring the vaccine for school attendance. There are two basic options for school mandates: mandate with no opportunity for an opt-out, and mandates with a variety of opt-out possibilities.

School Mandates have a variety of age or grade requirements:

- Before the age of 12
- Before the age of 13
- Between the ages of 9 and 14
- Before entering the sixth grade
- Before entering middle school

School mandates also vary in the kinds of opt-out opportunities they offer:

- Parent/Guardian objection for any reason
- Religious belief
- Medical reasons
- Moral beliefs
- Financial constraints
- Opportunity to opt-out after parents are given information regarding the link between HPV and cervical cancer

In regards to Colorado’s policy allowing for exemptions of the currently mandated vaccines such as chicken pox, tetanus, etc., the state allows exemptions for religious beliefs, medical reasons and personal beliefs. All exemptions require that an official form be completed.

Colorado does not currently mandate girls to have the HPV vaccine administered before they enter school. However, S.B. 80 would require girls to be given the vaccine before the age of 12 in order to attend school.
Criteria

Given the above alternatives, further considerations herein will focus on the possibility of a school mandated HPV vaccine, as suggested by S.B. 80. The following criteria will ultimately be used to determine whether or not a school mandate is appropriate for the State of Colorado.

Political Feasibility

Political Makeup

Colorado is a politically diverse state. It has typically been considered Republican, but has trended towards Democratic in recent years. In the 2006 election, Democrats won the Governorship and took control of the state legislature. On the other hand, Colorado also passed the socially conservative Marriage Protection Amendment in that same election. 40

Because of this political diversity, the HPV school mandate bill had strong bipartisan support with both House Republican Minority Leader Mike May and State Democratic State Senator Suzanne Williams sponsoring the legislation. 42

Public Opinion

There is not widespread public support for mandating that girls receive the HPV vaccine in order to attend school. A University of Michigan poll found that less than half
of parents in the U.S. support a school mandate for the HPV vaccine.\textsuperscript{43} In addition to opposition from religious organizations, some medical groups, such as the American Academy of Pediatrics, also oppose a school-mandated vaccine.\textsuperscript{44} Further, coalitions have been developed to oppose school mandates, including “Hands Off Our Kids”, which brought together parents, medical groups and other activists to oppose similar legislation in other states.\textsuperscript{45}

While there are many groups who support a school mandate for the HPV vaccine, public outcry from opposition groups has managed to stop similar proposals in other states and eventually forced Merck to end its campaign at motivating states to require the HPV vaccine.\textsuperscript{46}

\textit{Cultural Reality}

Colorado currently has a population of approximately 4.6 million people. Anglo Americans make up the largest portion of the population with 82.8 percent, while Hispanics make up the next largest group, 19.7 percent of the population. African-Americans make up 3.7 percent of the population. Eighty-nine percent of Colorado citizens have completed their high school degree, while 34.3 percent have completed a bachelor’s degree. The average per capita income is estimated at $27,750, with 12 percent of the population living in poverty.\textsuperscript{47}

Because many parents and activists object to the HPV vaccine on religious grounds, it is important to evaluate the religious make-up of Colorado. Sixty-eight percent of Coloradoans identify themselves as Christian, with 23 percent of those identifying themselves as Roman Catholics, making up the largest sub group of the
Christian demographic. As a result, two politically powerful religious groups deserving consideration in the discussion of HPV vaccines are Roman Catholics and Evangelicals.

Colorado has a large population of Roman Catholics, as mentioned above. The Church’s strict adherence to the idea of abstinence until marriage makes it difficult for them to encourage mandating the HPV vaccine. The Catholic Medical Association does not support mandating the HPV vaccine because they believe that the ultimate choice for medical treatments should be left up to the parent.

Catholic leaders in other countries like Canada have also been vocal in their opposition to the HPV vaccine mandate. HPV and other sexually transmitted diseases “are preventable if abstinence is followed,” explains the executive director of Canadian Catholic Bioethics Institute.

While Evangelicals only made up 1 percent of Christians in 2001, Colorado Springs is the home of an influential evangelical group – Focus on the Family. According to its website, the non-profit organization is dedicated to promoting social conservative public policy and family values. Focus on the Family, a major group both inside and outside the evangelical movement, has declared that they support the widespread availability of the HPV vaccine, but do not support a mandate.

Safety Concerns

Before a vaccine is licensed, the FDA determines the safety and efficacy of the vaccine. At least 10,000 people must receive the vaccine in the testing phase to be licensed. Of the two HPV vaccines that have been under development only one, Gardasil, has been licensed, which was approved in June 2006. In recommending that a vaccine be mandated in schools, the public health community sets forth immunization
requirements to determine if a mandate is in the best interest of the public. These requirements include both sufficient testing of the vaccine and adequate supply of the vaccine. The HPV vaccine has been tested in 11,000 women (9-26 years of age) and was found to have no serious side affects. Although, the HPV vaccine has been sufficiently tested, the FDA considers 10,000 participants a relatively small number and public health officials recommend further testing on the HPV vaccine before mandating it in schools because the “possibility for serious side effects may not be detected until many more people have been vaccinated.”

Another requirement before approving a mandated vaccination program is the assurance of an adequate vaccine supply. Vaccine shortages have been a problem in recent years and are expected to be an issue in the future. For example, in 2000, the United States experienced a shortage of influenza, diphtheria-tetanus-acellular pertussis (DTaP), tetanus and diphtheria (Td), measles-mumps-rubella (MMR), varicella, and pneumococcal conjugate vaccines. In 2004, the U.S. suffered from a shortage of the influenza vaccine. These shortages are commonly due to manufacturing or production problems, companies leaving the vaccine marketplace and changes in manufacturing recommendations.

In order to curb vaccine shortages, the US General Accounting Office and Department of Health and Human Services’ National Vaccine Advisory Committee assessed possible avenues to ensure there is a consistent supply of vaccines. In ensuring this supply, vaccines for diseases that pose significant threats to public health are prioritized over those of a lesser threat level. Also, producing new vaccines can be problematic, thus inhibiting an adequate supply.
In order for the public health community to recommend a vaccine be mandated within schools, there must be a proven history that the vaccine is safe with minimal side affects and that there is a large enough supply to vaccinate everyone mandated. The HPV vaccine does not meet either requirement.

**Personal Freedom**

Mandating a vaccine for girls entering school raises ethical questions about if it is appropriate for a state to restrict the right of individuals to make their own health care decisions. Most would argue that states need to have very strong reasons, such as public safety, to justify restrictions on personal freedoms. When it comes to mandating specific vaccines for school age children, states typically limit these actions to immunizations for contagious diseases – such as measles, small pox, and tuberculosis – that can spread easily to other children at school.64

Because HPV is a sexually transmitted disease, and not a potential harm to a third party, opponents argue that there is not sufficient rationale for mandating that children receive the vaccine in order to enroll in school.65 They believe that health care decisions should be made by parents and patients, not the state. This opposition is of concern to the medical community, as they worry that in allowing for vaccine exemptions, even on religious or philosophical grounds, could set a dangerous precedent for other, more communicable diseases. Despite this opposition, the head of the CDC vaccine recommendation panel, Dr. Jon Abramson, argued against school mandates saying, “The vaccines out there now are for very communicable diseases. A child in school is not at an increased risk for HPV like he is for measles.”66
Efficacy of Vaccine Programs

Success of vaccines is contingent upon widespread vaccination. This has been accomplished in the U.S. through state mandated vaccination programs requiring vaccination prior to entering public schools.\textsuperscript{67}

These state mandates have reduced the cases of measles, mumps, rubella, diphtheria and other diseases to an all-time low. A study of the effectiveness of the current school mandated vaccines found that even those who are fully covered by health insurance had low coverage rates in the absence of a mandate.\textsuperscript{68} However, voluntary vaccination programs for hepatitis B (a sometimes sexually transmitted disease with a three-series vaccine recommended for middle school students) were successful in immunizing 61.8 percent at the start of the 1997 school year.\textsuperscript{69} This example shows that sometimes a voluntary program can be more efficient than a mandated one, avoiding the drawbacks while still achieving significant vaccination.

Colorado has had success with a combined public awareness and vaccination program. Viral hepatitis, Hepatitis A (HAV) and Hepatitis B (HBV) in particular, are STDs that have been widely reduced in Colorado through the Viral Hepatitis Program. Established in 2000, the program saw an 80 percent decline in HAV cases and a 48 percent decline of acute HBV cases in five years.\textsuperscript{70}

The Viral Hepatitis Program activities include surveillance for HBV and Hepatitis C cases, testing, professional and public education programs, and referral services for those infected and partnerships with outside organizations. A similar program targeting
HPV, inclusive of a voluntary vaccination program, could prevent the spread of HPV through the population. It would also have the additional benefit of addressing public health problems caused by HPV infection such as cervical cancer and genital warts.\textsuperscript{71}

**Cost-Effectiveness**

The CDC evaluated the cost-effectiveness of vaccinating girls for HPV in relation to current practices. They found that vaccination was a relatively cost-effective approach even in situations of low vaccine efficacy. Additionally, vaccination of 12 year old girls against high-risk strains of the virus is predicted to prevent more than 1,300 cervical cancer related deaths a year\textsuperscript{72}. Adjusting for quality of life, the incremental cost effectiveness ranges from $22,755 to $52,398 dependent on efficacy.\textsuperscript{73} According to this study, although a vaccination program will be more expensive than current alternatives, the increase in life expectancy and the quality of life outweighs the increased expense. From this study, the recommendation was to vaccinate 12-year olds (mostly to ensure vaccination prior to sexual activity) through the school system rather than clinical settings while continuing current screening and treatment programs.\textsuperscript{74}

**Fairness**

The development of vaccination programs has shown that the best method for inducing herd immunity is universal sex-neutral vaccination.\textsuperscript{75} Thus the ideal situation would be to vaccinate both sexes, however, the HPV vaccine is currently not approved for male use because it has not been tested.\textsuperscript{76}

Mandating the HPV vaccine for females raises a fairness issue. HPV not only effects males through warts and penile and anal cancers, but also is spread to women by men. Opponents of an HPV school mandate say that it places the burden of a community
disease on middle school girls. Furthermore, they argue that mandating this vaccination puts girls that may have a low risk for contracting HPV or cervical cancer open to the yet unstudied long-term effects of the vaccine. To alleviate these concerns, more gender informed and long-term testing needs to be done.

**Recommendation**

Governor Ritter should veto S.B. 80 if passed by the Colorado’s Legislative bodies, and should continue to promote adherence to the state’s current HPV prevention and vaccination policies. Upon careful evaluation of the policy alternatives and criteria (See Appendix B), the implementation of a mandated school vaccination program for girls in the State of Colorado is an inappropriate policy course to pursue. Although it is Constitutional for a vaccination program to be implemented by a state government (See Appendix A), the need for a vaccination program of a sexually transmitted disease is not warranted based on the given information relating to the contagiousness of this disease.

Additionally, the long-term effects of the vaccination itself are not yet known to either the scientific or general communities. The HPV vaccine is recommended for young girls, who are not commonly afflicted with cervical cancer, yet the vaccine has not been tested on 9 – 12 year olds. The aim is to prevent cancer 30 years in the future, but long-term efficacy of the vaccine has not yet been determined. There may be a need for booster shots every 10 years. The possibility for better, more effective and safer methods for preventing cervical cancer may be developed in the future, rendering the current vaccine null. Additionally, adult vaccinations are poorly used, under funded and immunization opportunities not utilized, meaning the immunity induced prior to high school may not extend into adulthood when cervical cancer risks are higher.
situation presents concern as mandating the administration of a vaccine to a large population, could potentially lead to the exposure of harmful side effects to the recipients.

The socio-political environment in the State of Colorado also does not present a supportive atmosphere for the adoption of the mandate. Large percentages of Republican and Democratic constituencies, religious congregations and communities, as well as school and parent organizations have issued statements declaring that they would like the drug to be widely available, but the decision to receive the vaccine should be made in the home.

Finally, the current state system for HPV prevention in Colorado has already taken adequate measures to ensure that vaccines are available to those who choose to receive them. Colorado has established the Cervical Cancer Immunization Program which will receive four percent of Tobacco settlement funding. Also, Colorado requires health insurance providers to cover the vaccine for those who choose to receive it, and has mandated that information concerning HPV and links to cancer be included in sexual education in schools.
Appendix A

Colorado Governor Bill Ritter is part of the Democratic Party and was elected as the 41st governor in 2006. As the Governor, Ritter is commissioned with the task of ensuring the general well being of the public’s health.

Over the last few years, high rates of infection of the human papillomavirus (HPV) in women have gained national attention. HPV is thought to be the most common sexually transmitted disease. Made up of many strains, four types of HPV are thought to cause 70 percent of all cervical cancers in women. Additionally, 50 percent of sexually active women are infected with HPV at some point in their lives. However, HPV infection rates are found to be the highest among young persons at the onset of sexual activity.

With the creation of the HPV vaccine, the most dangerous types of HPV are preventable. The CDC and Advisory Committee on Immunization Practices have recommended that all females from the ages of 11-12 receive the vaccine. With the possibility of preventing HPV from transmitting at such a high rate, many states are determining if the vaccine should be mandated up school entry.

Governor Ritter must determine if a school mandate of the HPV vaccine is in the best interest for Colorado or if the vaccine should simply be encouraged. Funding to provide for the vaccine comes from federal government grants and programs such as Vaccines for Children and the Section 317 program. This analysis will make a recommendation on whether or not mandating the HPV vaccine upon school entry is beneficial to the state of Colorado.
Appendix B

Mandatory vaccination laws were first enacted in the early nineteenth century. In 1809, the United States Supreme Court upheld a Massachusetts law that gave municipal boards of health the authority to require the vaccination of persons over the age of 21 against smallpox. In *Jacobson v. Massachusetts* the Court determined that the vaccination program originating in the city of Cambridge had “a real and substantial relation to the protection of the public health and safety.” In upholding the law, the Court noted that “the police power of a State must be held to embrace; at least, such reasonable regulations established directly by legislative enactment as will protect the public health and public safety.” Additionally, the Court added that such law as was within the full discretion of the State, and that Federal powers with respect to such laws extended only to ensure that the state laws did not “contravene the Constitution of the United States or infringe any right granted or secured by that instrument.”

Every state in the union has laws requiring children to vaccinate against certain communicable diseases before they enroll in public or private school. Following *Jacobson v. Massachusetts*, states adopted statutes requiring student vaccinations against smallpox, which were later amended as new vaccines were introduced to combat emerging public health emergencies like the measles outbreaks of the 1960’s and 1970’s. Generally, states use the Center for Disease Control and Prevention’s schedule of immunizations as a guide, and require children to be vaccinated against a number of diseases on the schedule, including diphtheria, measles, rubella, and polio. Despite the widespread imposition of school vaccination requirements, many states provide exemptions for medical, religious, and, to a lesser extent, philosophical reasons.
States may also implement laws providing for mandatory vaccinations during a public health emergency or outbreak of a communicable disease. The power to command this authority typically lies in the hands of state governors, boards of health, and the state health officer. A citizen may opt out of the mandatory vaccination, but may be subsequently quarantined throughout the duration of the emergency. Additionally, many states are interested in or pursuing provisions contained in the Model State Emergency Health Powers Act, which was drafted by The Center for Law and the Public’s Health at Georgetown and Johns Hopkins Universities. The Model State Emergency Health Powers Act addresses a number of issues likely to arise during a public health emergency and offer guidelines for states with respect to what powers may be necessary during such an emergency. Many states will take elements of the Model Act, but tailor their statutes and regulations to respond to unique of novel situations within their jurisdiction.

Appendix C
Table 1 – Justification of Recommendation

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1 – Does Not Fit Criteria

2

3 – No Effect

4

5 – Fits Criteria

According the above table, the best policy option for the state of Colorado, in regards to school mandates, is to not pass S.B. 80 into legislation.

Notes

2 Ibid.

3 Ibid.


5 Center for Disease Control, “Genital HPV Infection - CDC Fact Sheet.”

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7 Ibid.

8 Ibid.

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10 Ibid.

11 Ibid.

12 Ibid.


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State of New York, Bill A0 7403, April 13, 2007.
State of South Carolina, House Bill 3136, April 18, 2007.
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