SPECIAL REPORT

HPV Vaccination Mandates — Lawmaking amid Political and Scientific Controversy

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The June 2006 licensure of Merck's human papillomavirus (HPV) vaccine, Gardasil, and the recommendation of the Advisory Committee on Immunization Practices that it be routinely given to girls starting at 11 or 12 years of age set off a flurry of state-level policymaking. The vaccine protects against four strains of HPV, the most common sexually transmitted infection in the country and the major cause of cervical cancer. Within a year, legislators in 41 states had proposed measures intended to increase uptake of the vaccine, including educational campaigns, public subsidies, and insurance-coverage requirements.[1]

The most contentious proposals were those to make the vaccine mandatory for girls attending school. Bills to make HPV vaccination compulsory were introduced in 24 states, and one state governor imposed a school mandate by executive order (Table 1). Between 2006 and 2008, however, policymakers turned decisively away from the idea that the vaccine should be required for school attendance. As of February 2010, only Virginia and Washington, D.C., had enacted mandates, and Virginia's legislation included an opt-out provision so broad that it may be a misnomer to refer to the law as a mandate.[2]

Immunization requirements, like all compulsory health measures, are politically and ethically sensitive because they intrude on individual autonomy.[3-5] Mandate proposals for HPV vaccination are particularly fraught because they lie at the intersection of two highly charged policy areas: immunization safety and adolescent sexuality. Weighed against these concerns is the success of mandates at achieving high levels of immunization coverage.[6]

The debate over compulsory HPV immunization represents a case study in public health lawmaking amid political and scientific controversy. Given the centrality of compulsory immunization to the control of vaccine-preventable diseases, it is critical to understand the determinants of policy in this area. We analyzed the policymaking process in a sample of states to identify the factors that were most influential in determining how states acted on the issue of mandates.

METHODS

We conducted interviews with 73 key informants in six states that had been actively engaged in legislative and policy deliberations with respect to the HPV vaccine. The states — California, Indiana, New Hampshire, New York, Texas, and Virginia — are diverse geographically and politically and have a wide range of immunization policies (Table 2). Interview respondents were selected to represent a range of stakeholder groups. Interviews were conducted from August 2008 through May 2009 and generally lasted 45 to 60 minutes. Most interviews were with one key informant, but several involved two to four informants. We analyzed interview transcripts, using methods of thematic content analysis as outlined in a detailed coding manual and using the NVivo 8 software package (QSR International). We also reviewed documentary materials, such as legislative testimony, meeting minutes, position papers, and memoranda. A detailed description of the study methods is provided in the Supplementary Appendix, available with the full text of this article at NEJM.org. The study was approved by the institutional review boards of the Harvard School of Public Health and Columbia University's Mailman School of Public Health.

RESULTS

FACTORS FOR PROPONENTS

Proponents of compulsory HPV immunization cited the severity of cervical cancer and the efficacy of the vaccine as primary motivations for wanting to ensure that all girls were vaccinated.

Table 1. HPV Vaccination-Mandate Bills and Orders in the States, 2006–2008.*

State	Bill or Order No.	Date of Introduction	Date of Last Action	Outcome
Arkansas	SB 954	March 5, 2007	March 27, 2007	Withdrawn by author
California	AB 16	December 4, 2006	September 30, 2008	Transformed into mandate for insurance coverage; passed but vetoed by governor
Colorado	SB 80	January 15, 2007	April 5, 2007	Postponed indefinitely in Senate appropriations committee
Connecticut	HB 6977	January 25, 2007	March 2, 2007	No further action after public hearing
Florida	SB 660	January 18, 2007	May 4, 2007	Referred to Senate health policy committee; no further action
Georgia	SB 155	February 14, 2007	January 14, 2008	Referred to Senate committee on health and human services; no further action
Illinois	SB 10	January 31, 2007	December 3, 2007	Referred to Senate committee on rules; no further action
Kansas	HB 2227	January 25, 2007	January 26, 2007	Referred to House health and human services committee; no further action
Kentucky	HB 345	February 7, 2007	March 1, 2007	Referred to Senate appropriations and revenue committee; no further action
Kentucky	HB 396	January 29, 2008	March 24, 2008	Referred to Senate appropriations and revenue committee; no further action
Maryland	SB 54	January 18, 2007	February 7, 2007	Withdrawn by author
Massachusetts	SB 102	January 10, 2007	February 25, 2008	Referred to joint committee on health care financing; no further action
Michigan	SB 1416	September 12, 2006	November 14, 2006	No further action after House reading
Michigan	SB 132	January 31, 2007	January 31, 2007	Referred to Senate health policy committee; no further action
Minnesota	SF 243	January 25, 2007	January 25, 2007	Referred to Senate health, housing and family security committee; no further action
Mississippi	HB 895	January 12, 2007	January 30, 2007	Referred to House appropriations committee; no further action
Missouri	HB 802	February 7, 2007	April 24, 2007	Voted out of House rules committee; no further action
New Mexico	SB 1174	February 15, 2007	April 6, 2007	Passed, but vetoed by governor
New Mexico	SB 244	January 17, 2008	February 8, 2008	Voted out of Senate judiciary committee; no further action
New York	AB 5810	February 23, 2007	February 23, 2007	Referred to assembly health committee; no further action
Ohio	HB 703	December 12, 2006	December 14, 2006	Referred to House health committee; no further action
Ohio	HB 81	February 28, 2007	March 6, 2007	Referred to House health committee; no further action
Oklahoma	SB 487	February 5, 2007	February 8, 2007	Referred to Senate rules committee; no further action
South Carolina	HB 3136	January 9, 2007	April 18, 2007	Died on House floor
Texas	RP 65	February 2, 2007	May 8, 2007	Executive Order 65 issued by governor but overridden by HB 1098
Texas	SB 110	January 29, 2007	April 25, 2007	Referred to House committee on public health; no further action
Vermont	SB 139	February 26, 2007	February 27, 2007	Referred to Senate health and welfare committee; no further action
Virginia	HB 2035	January 10, 2007	April 4, 2007	Passed and signed into law, with liberal opt-out provision recommended by governor added
Washington, DC	DC B30	January 9, 2007	July 12, 2007	Passed and signed into law
West Virginia	HB 2835	February 5, 2007	February 5, 2007	Referred to House health and human resources committee; no further action

* Data are from StateNet Full Text of Bills, All States, 2006, 2007, and 2008. Information on the status of legislation is also available from the National Conference of State Legislatures at www.ncsl.org.

The vaccine was especially important to some female legislators and champions of women's health issues. Some respondents also noted that a mandate fosters the equitable uptake of a vaccine, ensuring that youth whose parents are less motivated or informed about the benefits will receive it.

These arguments were ultimately overshadowed by several countervailing factors. Respondents reported eight factors that impeded the

adoption of school mandates: five relating to characteristics of the HPV vaccine and three relating to the vaccine policymaking process in general. These factors were fairly consistent across states with some variations (Table 3).

Table 2. Sources of 73 Key Informants Interviewed for This Study, According to State and Stakeholder Group.*

Source	No. of Informants (%)
State	
California	11 (15)
Indiana	11 (15)
New Hampshire	10 (14)
New York	10 (14)
Texas	11 (15)
Virginia	10 (14)
None (national)	10 (14)
Stakeholder group	
Legislators	19 (26)
Health officials	18 (25)
Medical professional organizations	15 (21)
Advocacy organizations	13 (18)
Cancer	1 (1)
Women's issues	1 (1)
Youth	1 (1)
Religious or family values	4 (5)
Vaccine safety	1 (1)
Pro-vaccination	4 (5)
Civil liberties	1 (1)
Industry	4 (5)
Pharmaceutical companies	3 (4)
Health insurers	1 (1)
Other	4 (5)
Journalists	1 (1)
Clinical researchers	3 (4)

* Percentages may not total 100 because of rounding.

FACTORS SPECIFIC TO THE HPV VACCINE

Newness of the Vaccine

At the time that mandates were initially proposed, the HPV vaccine had been on the market for only a few months. Many legislators and advocates, along with some public health officials and representatives of medical societies, felt that long-term safety data were needed before mandatory vaccination could be justified. Voicing concern that the vaccine might cause adverse reactions too rare to be detected during premarket clinical trials, respondents asserted that the standard of evidence for mandating a vaccine should be higher than the safety evidence required for approval by the Food and Drug Administration (FDA). In addition to safety concerns, some respondents felt that for a mandate to be acceptable to the public, more time was needed to educate the public about the vaccine and the disease it prevented.

Sexually Transmitted Nature of HPV

A second important factor undermining support for mandates was the sexually transmitted nature of HPV infection. Some social conservatives objected to a compulsory policy because they believed that protecting teenagers against a sexually transmitted disease might undermine prevention messages that emphasize abstinence. Furthermore, respondents indicated that requiring a girl to be vaccinated at the age of 11 or 12 years would force parents to have discussions about sex before they or their children were ready.

These concerns were not limited to organized advocacy groups that identified themselves as conservative. Respondents indicated that a broad range of constituents believed that because parental decision making about children's sexual education and behavior was an especially sensitive area, a compulsory approach was not appropriate for this vaccine.

Nontransmissibility of HPV in the Classroom Setting

The fact that HPV is not contagious through casual contact in the classroom setting emerged as a distinct theme. According to many respondents, the purpose of vaccination mandates is to prevent the spread of contagious disease in schools, not to use school attendance as a lever to achieve other public health goals. These concerns were reportedly a major driver in the decision of the Virginia legislature to include a liberal opt-out provision in its legislation. Respondents reported that making the exemption "broad enough for anybody and everybody to walk through it without a whole bunch of hoops and things that they had to jump through" was crucial to the bill's passage.

Discomfort with the Vaccine Manufacturer's Involvement

A fourth factor that soured many policymakers on mandates was consternation over the involve-

Table 3. Factors Impeding the Adoption of HPV Vaccination Mandates, According to Key Informant Interviews in Six States.*

Factor	Where Factor Was Salient	Illustrative Interview Responses
Specific to the HPV vaccine		
Newness of the vaccine	CA, IN, NH, NY, TX	"One of the issues is, 'Well, it's not a bad idea to have a little more . . . postmarketing safety data.' . . . If we had required this vaccine, that would have created 2 or 3 times the concern and the debates. It would have lent more credence to the safety concerns because it was being required." "This was just approved [8 months previously] and it just felt like it was sort of being forced down our throats a little bit. It was like fast-tracked a little bit. We didn't have time to sort of figure out as a community about whether or not this is something that we felt should be given to every girl. . . . It sort of moved too quickly. That was part of the problem."
Sexually transmitted nature of HPV	CA, IN, NY, TX	"It became a very emotionally charged piece of legislation with regard to the premarital sex. They were saying that I shouldn't be promoting a vaccine. . . . I can remember specific occasions where women would come into my office and would just yell at me saying that's what I should be doing is promoting abstinence instead of a vaccine." "People get very anxious if we start talking about anything below the belly button. So there was this huge backlash . . . about mandating 'families do this,' and 'it promotes sexual promiscuity of our girls.'"
Nontransmissibility of HPV in the classroom setting	CA, IN, NH, NY, VA	"The bigger problem that we found in the beginning . . . is that this would be the first time that we would be imposing a vaccine mandate on children for a disease that was not communicable [in the classroom setting]. So you would essentially be denying entry to school for a disease that, one, they might not have, and two, you couldn't catch. There's no public health epidemic. It's not like measles or mumps or rubella." "I just didn't think that the issue of HPV infection and cervical dysplasia and development of cervical cancer rose in any possible scenario to the point that it was such a public health hazard or risk that it required the intervention of the police power of the state to mandate that kids be vaccinated for this. I can completely support it in certain kinds of infectious diseases that are a threat in terms of morbidity and mortality, and are easily transmitted within a classroom, for example, but HPV is not one of the things."
Discomfort with the vaccine manufacturer's involvement	CA, IN, TX	"My sense is once it came out that Merck had been funding this Women in Government group that had really been working to push this in so many states, that really sort of killed the momentum." "What made people suspicious was how aggressive the campaign was. . . . All of a sudden there's this major crisis. People hadn't even been aware that there was this major crisis before this. . . . It just left people very suspicious that this was really about money. That it was putting kids' health at risk in order to ensure that a pharmaceutical company made a lot of money."
Price of the vaccine	CA, IN, NH, NY, TX	"From the legislators that I talked to, they were concerned about the mandate being an expensive proposition to fill from a state level. Certainly, the doctors were wondering . . . how much they were going to have to pay to stock for their patients, how much that would be." "When a body looks toward a mandate of one procedure or another, obviously there is a financial consideration and the economic impact that would cause. . . . [You ask] is this a good public policy for the general population and then weigh that against the cost."
Related to vaccination policymaking		
Antipathy toward government coercion	IN, NH, VA	"People who are very suspicious of government intrusion into their lives had gotten a little fired up about the idea that this was going to be a mandatory vaccination process." "There were several parts of the policy . . . that made people nervous. One was the mandate on parents. Basically telling parents that . . . the state knows better than the parents do about how to raise their kids. What vaccines to give them."
Antivaccination activism	CA, IN, NH, NY, VA	"Opponents of vaccines saw it as their opportunity to stop another vaccine from becoming a school mandate. So these folks are organized. They saw the time was ripe, and they flooded the airways with it." "We had another foe and that was the autism groups. Obviously, they believed that autism is due to vaccines and the mercury in the vaccines, and so forth, so they put a heavy lobby on that piece of legislation."
Nature of the policymaking process	CA, NY, TX	"Probably in a lot of state legislatures, it's 10 times easier to stop a bill than it is to pass one. . . . It's just the nature of our legislative process. You've got three or four steps in one chamber you have to pass, three or four steps in the other, and then you have a joint conference and that goes to the governor. It's always easier to slow down a bill or to change or stop a bill than it is to pass one." "There are literally thousands of bills introduced. What determines which ones move or not partly depends on the committee chairs and other [procedural] factors."

* States where one or more interview respondents cited the factor as influencing the prospects of an HPV vaccination mandate in the state.

ment of the vaccine's manufacturer, Merck, in the policy process. Merck undertook a multifaceted marketing campaign to promote the passage of mandate legislation. Representatives of the company met with legislators and hired political consultants to promote the vaccine. Merck also provided unrestricted funds to Women in Government, a national organization of female leg-

islators. Many of the bills to require HPV vaccination were introduced by Women in Government members.

Although Merck's lobbying was a key catalyst in the initial push for mandates, many stakeholders came to view the company's efforts as a liability. As media coverage called attention to the company's aggressive tactics, suspicion grew that policy decisions were not being based on the product's merits, and people who were otherwise supportive pulled back. The belief that mandate bills were an effort to make money for the company overshadowed whatever principled arguments might exist for them.

Price of the Vaccine

At $320 for a full course of three doses, Gardasil was considerably more expensive than other required vaccines. Although the federal Vaccines for Children program covers the cost of the vaccine for eligible youth up to the age of 18 years and most private insurers stepped forward quickly to cover it, respondents reported concerns that some families could not afford the vaccine and that it would consume too great a share of states' Medicaid and public health budgets. Some respondents believed that until a financing plan was worked out, a more incremental approach to increasing vaccine uptake was appropriate. Others questioned the cost-effectiveness of the vaccine.

Cost concerns were described as less influential than other factors in the policy debates in most states but loomed large in California, which was having a budget crisis. Although the fiscal implications of a mandate were unclear, the mere possibility that a mandate might impose costs on the state was enough to raise doubts about both the wisdom of mandate legislation and the likelihood that it could escape a gubernatorial veto.

FACTORS RELATED TO VACCINATION POLICYMAKING

Antipathy toward Governmental Coercion

In addition to concerns about the HPV vaccine, decisions about mandates were also strongly influenced by three factors related to the vaccine policymaking process more generally. First, respondents indicated that mandate proposals tapped into generalized antipathy toward governmental coercion among many stakeholders. According to these objections, the bar should be set very high for any governmental intrusion on individual or parental autonomy.

In some states, such as New Hampshire and Texas, resistance to governmental coercion was a strong feature of the state's civic environment in general, regardless of the particular issue involved. In other states, the HPV vaccination issue was dropped into a health-policy environment that was highly fractious because of foregoing debates. Indiana, for example, had recently seen considerable controversy over legislation that mandated mental-health screening for youth. That debate bolstered arguments about excessive governmental coercion to force pharmaceutical products on minors, as well as arguments about drug-company influence. As one respondent said, "Everybody was mad at the pharmaceuticals before Gardasil even got there."

Antivaccination Activism

The debate was also influenced by general antivaccination activism by organizations and individuals who believed that vaccines cause autism and other health problems in children. Although these groups could not plausibly argue that Gardasil, a vaccine given to adolescents, might cause autism, they reportedly were "using HPV as a tool to get the focus on . . . vaccine safety issues," according to one respondent. In some cases, they communicated their concerns by making direct contact with lawmakers or testifying at public hearings. In other instances, lawmakers' awareness of previous activism among these groups with respect to other vaccines was sufficient to make them reluctant to enact a mandate, knowing it would face resistance.

Nature of the Policymaking Process

Finally, aspects of the policymaking process itself contributed to the failure of mandate proposals. All five of the sampled states that considered or adopted mandates did so through an act of the legislature or an executive order, rather than through an administrative decision within the department of health, even though health codes in three of the states provided an administrative mechanism. (The sixth state in the survey, New Hampshire, did not consider a mandate.) The legislative process was perceived as insurmountably onerous in some states, with respondents citing such factors as the power of committee chairs, short legislative sessions, and the sheer number of bills competing for attention.

The executive-order mechanism that was used by the Texas governor circumvented these ob-

stacles but provoked the ire of both liberal and conservative legislators and the public. The order took stakeholders by surprise and angered many legislators, who saw it as an overstepping of authority. Subsequent legislative activities centered less on the merits of the vaccine or various policy approaches and more on the significance of allowing the governor to impose a mandate through this process. The legislature's move to explicitly prohibit a mandate for 4 years was largely a symbolic gesture, since a mandate would have had little chance of passing the state's mostly conservative legislature.

In California, too, deliberations over mandating HPV vaccination became entangled with a broader disagreement about who should have authority to enact vaccine mandates. One respondent reported, "The legislators got very adamant about, 'We want control over this.' Then there were other stakeholders saying, 'Public health [officials] should be able to determine when they want or need a requirement.' So it got into a bigger debate over how requirements should be introduced."

DISCUSSION

Although school vaccination mandates have been effective at achieving high rates of uptake, they raise numerous political and ethical concerns. This study identifies the most salient factors in policy debates about compulsory HPV vaccination in six states and the ways these factors interacted with one another and with each state's broader sociopolitical environment.

Much of the commentary about HPV vaccination, in both the popular media[7,8] and scholarly literature,[9,10] has focused on the ways that policy decisions might be swayed by concerns about adolescent sexuality. Our findings present a more complex and dynamic picture. To be sure, social and religious conservatives were prominent in these debates. Fears that the vaccine might foster sexual activity among teens or force parents into unwanted discussions about sex played a role in impeding the enactment of mandates. However, these concerns were part of a much larger spectrum of interrelated beliefs and attitudes. In none of the states we studied were concerns about teen sexuality either a necessary or a sufficient condition for the failure to enact a mandate. Instead, the prospect of compulsory HPV vaccination provoked opposition from an array of groups and individuals with distinct yet complementary concerns.

Our study has limitations. The sample of states was small and not randomized. Although we selected states that represented a diversity of political environments and policy processes and outcomes, the factors that were influential in the sampled states may not be generalizable to other states. The number of respondents who were interviewed in each state was relatively small, and it is possible that some viewpoints were not captured. However, the sample in each state did include representatives of all the major stakeholder groups identified in our recruitment plan.

Our study revealed several points of both consensus and disagreement among the many stakeholders in vaccination policy decisions. There was wide agreement that it was inappropriate to mandate a vaccine within a few months after its licensure. There were fundamental differences of opinion, however, about many other criteria for mandates, including whether they should be applied to vaccines against diseases that are not casually transmissible, how prevalent and severe a disease should be to mandate vaccination, how long a waiting period is appropriate after a vaccine is licensed, and what costs are acceptable. Respondents suggested that policymakers should use the time after the FDA's approval of a new vaccine to carefully build the case for mandates they feel will eventually be desirable, educating and consulting with stakeholders about these issues.

Second, several of the factors leading to the failure of proposals mandating HPV vaccination were rooted in the fact that states already have extensive lists of required vaccines. As the number of recommended childhood vaccines has doubled over the past two decades, policymakers have become increasingly concerned about maintaining public confidence and minimizing the burdens on parents, health officials, and school administrators.[11] State health officials expressed concerns that a mandate that was enacted without adequate public support might "end up backfiring and hurting . . . mandates for other vaccines by encouraging parents to opt out more." The National Vaccine Advisory Committee, too, has recognized the risk of fueling a "culture of refusal."[12] These questions will grow more pressing with each new vaccine that is brought to market, and a default position of automatically adding newly recommended vaccines to the list

of school-entry requirements in various states will be untenable. As the Association of Immunization Managers noted in a 2006 position paper, "Mandates must be used sparingly, approached cautiously, and considered only after an appropriate vaccine implementation period."[13]

Third, our findings suggest that the legislative process is a suboptimal venue for making immunization policy. Most mandate proposals for HPV vaccination were introduced legislatively, but health codes in two thirds of the states allow health officials to add vaccines to the list of school-entry requirements without legislation.[14] Although the enactment of mandates by means of legislation may increase public accountability and transparency, it also opens the process to input from individuals with limited knowledge or understanding of public health principles. In addition, state legislators, particularly part-time legislators, have few resources for in-depth study of health issues. Regardless of their views on the appropriateness of a mandate for HPV vaccination, many health officials in our sample were worried about the problems that could arise from the making of vaccination policy by legislators, such as enactment of a policy that is not evidence based or is difficult to implement logistically or financially. Many respondents described a lack of communication between state legislators and health departments and believed that more cooperation would be beneficial.

CONCLUSIONS

Ethical and legal principles dictate that public health laws should use the least restrictive means possible to advance health goals.[15] The policymaking dynamics that were illuminated by our study reflect the centrality of this view in politics as well. Robust public health evidence supports the effectiveness of vaccination mandates in achieving high rates of vaccination coverage.[6,16,17] However, proposals for coercive measures may trigger backlash — perhaps for reasons largely unrelated to the merits of the particular proposal. This danger underscores the need for careful, individualized assessment of the risks and benefits of each new expansion of the state's reach into citizens' health decisions.

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