Pharmaceutical Companies' Role in State Vaccination Policymaking: The Case of Human Papillomavirus Vaccination

Michelle M. Mello, JD, PhD, Sara Abiola, JD, PhD, and James Colgrove, PhD

Objectives. We sought to investigate roles that Merck & Co Inc played in state human papillomavirus (HPV) immunization policymaking, to elicit key stakeholders' perceptions of the appropriateness of these activities, and to explore implications for relationships between health policymakers and industry.

Methods. We used a series of state case studies combining data from key informant interviews with analysis of media reports and archival materials. We interviewed 73 key informants in 6 states that were actively engaged in HPV vaccine policy deliberations.

Results. Merck promoted school-entry mandate legislation by serving as an information resource, lobbying legislators, drafting legislation, mobilizing female legislators and physician organizations, conducting consumer marketing campaigns, and filling gaps in access to the vaccine. Legislators relied heavily on Merck for scientific information. Most stakeholders found lobbying by vaccine manufacturers acceptable in principle, but perceived that Merck had acted too aggressively and nontransparently in this case.

Conclusions. Although policymakers acknowledge the utility of manufacturers' involvement in vaccination policymaking, industry lobbying that is overly aggressive, not fully transparent, or not divorced from financial contributions to lawmakers risks undermining the prospects for legislation to foster uptake of new vaccines. (*Am J Public Health.* 2012;102:893–898. doi:10.2105/AJPH.2011.300576)

In June 2006, the Food and Drug Administration approved the first vaccine against human papillomavirus (HPV), the sexually transmitted virus implicated in three quarters of all cases of cervical cancer. Gardasil, produced by Merck & Co Inc, was licensed for vaccination of females aged 9 to 26 years for the prevention of cervical cancer and genital warts.[1] The same month, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention recommended routine vaccination of girls aged 11 to 12 years, with catch-up vaccination of females aged 13 to 26 years.[2] A remarkable burst of legislative activity followed. Within a year, legislation relating to the vaccine was introduced in 41 states and the District of Columbia, including bills in 24 states that would mandate HPV vaccination for 6th-grade girls.[3]

Interest in the political forces behind HPV legislation remains high.[4] Following media reports that Merck was heavily involved in promoting school-entry mandates, questions arose about the extent and appropriateness of industry involvement in vaccine policy. The presidential candidacy of Texas Governor Rick Perry recently prompted a new round of public and media scrutiny of the issue after opponent Representative Michele Bachmann accused the governor of ordering girls to receive the HPV vaccination because of his financial and political ties to Merck.[5] We aimed to investigate these industry roles and elicit key stakeholders' perceptions of their appropriateness and effects on policy outcomes.

METHODS

We conducted a series of case studies combining data from key informant interviews with analysis of media reports and archival materials. We selected 6 states for study; the number was driven by available project resources to conduct in-person interviews. We selected states primarily on the basis of their active engagement in debates about HPV immunization policy (Table 1). We used volume of media coverage as a measure of the intensity of policy engagement in a state. From among the 10 states with the highest volume of media coverage in a LexisNexis search of 2128 newspaper articles from 2006 through early 2008, we selected 4 (Texas, Virginia, New York, and Indiana) that had enacted legislation at the time of the search. We then selected an additional 2 states (New Hampshire and California) on the basis of criteria aimed at ensuring that the sample was diverse geographically, politically, and in terms of immunization policies. In addition to geographic region—New England and the western states were not well represented in the sample—we examined each state's ethnic composition, purchasing policies for vaccines generally, and laws concerning vaccination mandates and exemptions. To measure the political environment, we examined data on political ideology, religiosity, political party control of government, proportion of women legislators, and whether the year in which HPV bills were introduced was an election year in the state. The HPV vaccination policies considered and adopted by the sampled states are described in Table 1.

We used purposive sampling to recruit at least 10 key informants in each state. The within-state sample size represented our estimate of the number of interviews required to reach thematic saturation. First, we composed a list of key categories of stakeholder groups based on interviews with public health experts, representatives from 2 national organizations of health policymakers, analysis of news coverage, and our previous work (Table 2).

TABLE 1—Human Papillomavirus Vaccination Policies in the 6 Study States, 2006–2008

State	Laws Considered	Legislation or Other Policy Adopted
California	School entry mandate Insurance coverage mandate	None (A.B. 1429, requiring any insurance plan that covers cervical cancer screening or surgery to also cover HPV vaccine, passed but was vetoed by the governor).
Indiana	School entry mandate Prohibition on school entry mandate Educational campaign	Legislation requires schools to provide information about the HPV vaccine to parents of 6th-grade girls; requires the Department of Health to develop the informational materials; requires parents to declare whether daughter will be vaccinated; requires schools to report the number of vaccinated and unvaccinated children to the Department of Health; and prohibits school-entry mandates for HPV vaccination (Pub. Law No. 80 [2007]).
New Hampshire	Add HPV vaccine to state immunization program (by administrative decision)	No legislation adopted, but the Department of Health added the HPV vaccine to the state immunization program, making it available free of charge to girls aged 11 to 18 years.
New York	School entry mandate Insurance coverage mandate Educational campaign	Legislature appropriated $5 million to promote the HPV vaccine (N.Y. Chapter No. 54 [2007]).
Texas	School entry mandate (imposed by executive order) Prohibition on school entry mandate Educational campaign	Legislature overrode the governor's 2007 executive order imposing a school-entry mandate for HPV vaccination and prohibited such mandates. Legislation requires schools to distribute unbiased information about HPV vaccine (Tex. Gen. Laws 43 [2007]) and requires Department of Health to develop and distribute educational materials about HPV vaccine, including specified content (H.B. 1379).
Virginia	School entry mandate Insurance coverage mandate	Legislation formally requires vaccination for 6th-grade girls, but allows parents to opt out, even without providing a reason, after receiving informational materials about the vaccine (Va. Chapter Nos. 858, 922 [2007]).

Note. HPV = human papillomavirus.

We then identified representatives of each stakeholder group based on consultation with the national organizations, news coverage, analysis of bill sponsors, and Internet research. We identified additional respondents through snowball sampling. We recruited informants by e-mail and telephone.

Two investigators conducted semistructured interviews face to face or by telephone lasting 45 to 60 minutes, using an interview guide that was vetted with the national policymakers' organizations. Interviews were audiorecorded and transcribed. Respondents were asked to supply relevant archival materials, such as legislative testimony.

We analyzed the transcripts by using methods of thematic content analysis. One investigator coded each transcript by using a detailed coding manual and the NVIVO software package, version 8 (QSR International, Doncaster, Victoria, Australia). We incorporated information from media reports and archival materials as background material.

RESULTS

We interviewed 73 individuals in 51 solo and 9 group interviews. We interviewed at least 10 respondents in each state and 9 individuals who had been involved in multiple states or at the national level (Table 2).

Merck's Role in HPV Vaccination Policymaking

Across all sampled states, the Merck role most consistently mentioned by interview respondents was serving as an informational resource to legislators and health department officials.

Providing information. The company responded to specific requests for scientific information about Gardasil or potential policy strategies. Respondents did not perceive that this role jeopardized independent decision-making by policymakers. Officials at task force and advisory committee meetings that Merck representatives attended universally reported that the representatives contributed to the discussion only when asked. One health official noted, "It was definitely the policymakers who were ultimately making the decision."

Lobbying and presenting policy alternatives to legislators. Merck engaged in direct lobbying to varying degrees in all of the states we studied. Merck proactively contacted legislators to discuss strategies to maximize uptake of Gardasil, either directly through company employees or by using local political consultants, prominent physicians, or public relations firms.

Many respondents reported that company representatives proposed specific legislation, often drafting the bills and searching for a sponsor. In most states, their efforts focused on a school-entry mandate. Respondents pointed out that Merck's activities were not unusual, although the public seemed to have been unaware that private companies played such a role in the legislative process. One commented, "Just about every vaccine mandate that we have lately has been the result, at least partially, of the drug industry's efforts."

The intensity of Merck's lobbying efforts varied across states. No respondents in California recalled Merck representatives directly lobbying legislators. Direct lobbying reportedly took place in New Hampshire, but only briefly, and not aggressively: "It was gentle,"

TABLE 2—Characteristics of Key Informants Participating in Interviews Regarding State Human Papillomavirus Vaccine Policymaking

	No. (%)[a]
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/family values	4 (5)
Vaccine safety	1 (1)
Provaccination	4 (5)
Civil liberties	1 (1)
Industry	4 (5)
Merck employees and consultants	3 (4)
Health insurers	1 (1)
Other	4 (5)
Journalists	1 (1)
Clinical researchers	3 (4)

[a]Total number of respondents = 73. Percentages may not total 100 because of rounding.

a legislator recalled, "I suggested to them that [a school-entry requirement] probably wouldn't have a lot of traction here, and that was it. They dropped it." By contrast, in Indiana respondents consistently noted the high intensity of lobbying for school-entry mandate legislation. One respondent characterized it as a "feeding frenzy" designed "to convince us that this was the best thing since sliced bread."

Merck's lobbying raised special concerns in Texas. Shortly after Governor Perry issued an executive order in 2007 mandating HPV vaccination for girls, a public outcry was sparked by reports that the governor's former chief of staff had worked for years as a lobbyist for Merck (except during his employment in the governor's office) and that Merck had contributed $5000 to the governor's campaign fund.[6,7] In February 2007, Merck announced that it was suspending its efforts to lobby for state mandates.[8,9] Respondents remarked that Merck "backed away" after "it all hit the fan [and] Merck got beat up in the national press."

Ongoing lobbying efforts were more limited in scope and intensity, focusing on legislator education and funding for vaccines.[9] Respondents in New York and Texas opined that Merck's pullback—along with the Texas furor itself—undermined prospects for school-entry mandate legislation. By contrast, a governmental respondent in Virginia perceived that Merck's curtailment of its lobbying contributed to the passage of legislation. Lobbying had created the impression that "they were pushing this, when in fact we were following recommendations that our state wanted to do anyway."

Mobilizing legislators, stakeholders, and the public. Merck mobilized legislators to introduce school-entry mandate and other legislation relating to the HPV vaccine, primarily through Women in Government (WIG), a national, nonprofit group of female state legislators. WIG had identified cervical cancer as a priority issue as early as 2003.[10] Merck contributed unrestricted educational grants to WIG, which, among other things, covered the expenses of dozens of legislators to attend conferences on cervical cancer at appealing destinations convened by WIG and attended by Merck representatives.[11]

In addition to hosting meetings at which legislators were briefed about HPV and Gardasil, WIG prepared reports on cervical cancer prevention efforts in the states, convened a task force to make policy recommendations, prepared a "legislative toolkit" containing model school-entry mandate legislation, and conducted outreach to interest groups and the media to build support for such legislation.[12,13] Members of WIG introduced many of the mandate bills considered across the country.[14]

Respondents were aware of the financial relationship between Merck and WIG. Some saw it as a natural affinity between 2 organizations with intersecting agendas, noting that Merck's grants to WIG were unrestricted and spending decisions were made by WIG's board. Others suspected that Merck had driven WIG's agenda rather than responding to it. One remarked, "WIG bit off hook, line, and sinker the need to have mandated this vaccination across America."

Respondents in every state commented on how effectively Merck prepared the political environment for the introduction of school-entry mandates and other legislation. The company carried out this objective through marketing campaigns to consumers and physicians and direct outreach to political interest groups.[6,15] Public health officials tended to view the direct-to-consumer advertising campaign positively because it motivated patients to seek out the vaccine. Legislators had mixed perceptions of how the media campaign affected legislative action. Several commented that it put the issue on the legislative agenda by creating a public demand for the vaccine, but one perceived that the campaign was so effective in stimulating demand that it had made legislation unnecessary.

There was less enthusiasm among respondents for Merck's marketing efforts to physicians. Merck conducted extensive outreach to the prescriber community, both directly and by training physicians to engage in peer-to-peer education.[6,16] A California governmental respondent related a historical analogy concerning Fosamax, Merck's drug for prevention of osteoporotic fractures:

> They created this paranoia about fracture risk and applied it to a much bigger market. I think that they very successfully did the same thing with Gardasil. . . . They pumped up the level of fear among clinicians about the impact of HPV.

In addition to direct-to-physician marketing, Merck mobilized medical professional organizations and other interest groups.[16] Most respondents from medical and public health organizations described this outreach as fairly routine, although one indicated that the pressure was considerable: "At one point, the CDC rep for the state was being bombarded by pharmaceutical reps, so she asked if she could form an advisory committee around her." Merck also appears to have expanded its efforts to support interest groups financially. One organization that had long worked in the area of cancer prevention reported that both Merck and GlaxoSmithKline, the manufacturer of a competing HPV vaccine, came forward with

unrestricted donations for the first time after Gardasil was introduced.

Filling gaps in access to the vaccine. One final role Merck played was helping to fill gaps in access to Gardasil by donating the vaccine. The company included Gardasil in the Merck Vaccine Patient Assistance Program, which ships vaccines to clinics and licensed prescribers for administration to low-income, uninsured adults. One New Yorker commented that Merck had

> been very good about identifying the financial problems that exist. . . . We can't figure out how to [fill the gap for 19- to 26-year-olds], so they're trying.

Perceptions of Appropriate and Inappropriate Roles

We inquired as to what, if any, role respondents felt that pharmaceutical manufacturers should play in policy processes concerning vaccines. There was broad agreement that providing scientific information about products was vital to a robust policymaking process. This role seemed especially well received in states with "citizen legislatures," where part-time legislators had few resources for researching policy issues. Legislators and health officials acknowledged a risk that information provided by a vaccine manufacturer might be biased, but felt that "it's up to the legislators to sort that out," as one New Hampshire respondent put it.

Respondents also felt that it was appropriate for Merck to donate vaccine and for company representatives to sit in on task force or committee meetings, as long as they only responded to requests for information. Finally, among those who specifically discussed Merck's role in drafting legislation, no one opined that this was inappropriate.

Nearly all respondents thought that, in principle, a lobbying role for vaccine manufacturers was acceptable. A New York respondent noted that, in the past, collaborative efforts between legislators and pharmaceutical manufacturers had been "helpful in advancing access" to products such as Plan B. Many respondents saw Merck's business mission as consonant with a broader, public health mission:

> The industry want[ed] to do a good thing and that was to get a good product out in the market that would help the most people. And, sure, there's a profit motive behind that, but they didn't see any inconsistencies between achieving both goals.

Merck's representative described the company's activities in terms of a partnership to ensure "optimal availability and optimal use of vaccines." He expressed disappointment that Merck's "motives were misinterpreted" and suggested that political interest groups had invoked Merck's financial interest as a red herring to defeat vaccination mandates they opposed on ideological grounds.

Although most respondents saw lobbying as appropriate, many felt that, in this case, Merck executed the role inappropriately. One concern, expressed by several health officials and representatives of groups of health experts, was that Merck's strategy involved an end run around health departments. Although in some states, most notably New Hampshire, there was extensive communication between Merck and the state immunization program, in others, respondents complained that Merck took its message directly to the public or legislature without involving public health officials. A Virginia respondent noted that Merck and other manufacturers had executed, but did not adhere to, an agreement with the Association of Immunization Managers to

> inform the [health department] of their position and . . . seek to reach concurrence prior to undertaking activities in a state concerning legislation, regulation or other immunization policy change (e.g., vaccination requirements).[17(p2)]

She remarked, "Everybody signed off on it and then what happened, I don't know."

A second concern was that the company was too aggressive in pushing for a school-entry mandate so soon after the product's licensure. Moreover, many respondents thought that lobbying for Gardasil mandates presented a conflict of interest not as present in other lobbying efforts. A sizeable group of respondents that cut across states and stakeholder groups did not see Merck's financial mission and the mission of public health as consistent.

Some could not articulate a specific reason for taking this view, but it appeared connected to the fact that Merck focused on mandating immunization, which brought the coercive power of the state to bear on children and parents. Some respondents found it unseemly that Merck stood to profit from a "sweetheart deal" for a mandate or that legislators, in restricting individual liberty, would be influenced by a company with a financial interest in the legislation.

Respondents were divided in their views about whether it was appropriate for Merck to have provided financial support to WIG. One medical expert who had a relationship with Merck saw it as a sensible alliance: "I think it was an honest relationship. They latched onto Women in Government because they were interested in the cervical cancer issue." Some noted that Merck's support of WIG had been relatively restrained—for example, it had not provided large contributions to individual WIG members. Others found it "disconcerting" that "a company who is planning to make some money off a vaccine" would use WIG to try to mandate it.

DISCUSSION

Although it is ethically appealing to conceive of the policy process as insulated from the influence of private industry, the case of HPV immunization suggests that there is a symbiotic relationship between pharmaceutical manufacturers and state health policymakers. Companies depend on policymakers to stimulate demand for their products and provide for the financing and distribution of vaccines. State legislators, in turn, rely heavily on pharmaceutical companies for information, especially in states where legislators work part time with lean staff resources.

Legislators' own practices reinforced this dependence. It was striking that, in most states, even legislators who were leaders on health issues did not have close working relationships with their state's health department. Their failure to seek information from health department officials contributed to their dependence on industry. Many health department officials felt puzzled or disappointed that their ties to legislative health committees were not stronger, and some expressed concern that this lack of communication could lead to legislation that was logistically difficult to implement or scientifically unfounded.

The danger in relying on pharmaceutical companies to evaluate policy options is that they may not present information in the same fashion as a disinterested party, a possibility to which legislators in our sample were highly attuned. However, there was no indication from respondents that scientific information

provided by Merck was inaccurate or biased. Nevertheless, it emerged strongly from our interviews that the terms of the debate were set very early on by Merck's effective communication of its position favoring school-entry mandates. Information gathering from a broader range of sources, including public health experts, might have led to a different policy agenda.

Legislators in our sample acknowledged the utility of the legislator educational programs that Merck underwrote through contributions to WIG. However, respondents also saw political hazards associated with providing such contributions. "I suspect that if they hadn't been quite as involved financially it actually may have played out in their favor a little better," one California respondent observed.

Many respondents were aware that the business practices of pharmaceutical manufacturers were of great public concern at the time legislators took up the issue of school-entry mandates for Gardasil. The legislative debates came on the heels of the Vioxx and Celebrex controversies[18] and several large pharmaceutical fraud settlements. This charged political environment has not abated, so industry-supported legislator education may encounter the same public consternation going forward. The use of intermediary organizations like WIG to sponsor educational programming may do little to dissipate concern.

The concern respondents expressed over financial entanglements between Merck and legislators was centrally a concern about transparency—one that has also been voiced about Merck's relationship with physician professional organizations.[16] Policymakers tended to be most disturbed by Merck's nontransparent roles, such as giving financial contributions to WIG and other interest groups that were not publicly disclosed. Such tactics "gave credence to people's fears that they were trying to do things behind closed doors and push things down people's throats," a Virginia respondent commented.

The number of governmental and nongovernmental respondents who thought it was appropriate for Merck to be involved in the policy deliberations as long as its role was transparent contrasts strikingly with views held by public health experts and the public.[19,20] For example, commentators have urged that

> Since the manufacturer stands to profit from widespread vaccine administration, it is inappropriate for the company to finance efforts to persuade states and public officials to make HPV vaccinations mandatory.[20(p1922)]

Our respondents were more pragmatic, noting beneficial aspects of the company's involvement and denying that there was any conflict between Merck's economic interests and the public health mission.

The question of whether a conflict of interest existed for Merck is an interesting one. Conflicts of interest are defined as

> a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.[21(p46)]

The primary interest of a pharmaceutical company is developing and selling pharmaceutical products. Because Merck's pursuit of its primary interest was not compromised by a secondary interest, "conflict of interest" is the wrong frame for what respondents found troubling about Merck's role (though it captures their concerns about policymakers who accepted contributions from Merck).

Rather, respondents' concern was that an organization whose primary interest was not promotion of the public good might influence policymakers to adopt a law that people found intrusive. Vaccination mandates involve a bodily invasion. There were also worries that a Gardasil mandate would financially burden families and necessitate a conversation about sexuality that many parents were not ready to have with their preteen daughters.[22] What seemed to weigh heavily on respondents' minds is that legislators should impose such burdens only after very careful consideration of what was in the public interest—not Merck's interest.

Lastly, the Gardasil story shows that vaccine manufacturers' political strategies need to be carefully calibrated to the political climate and may backfire if too aggressive. Some respondents felt Merck had underestimated the degree to which conservative groups and the public in some states would object to the idea of a mandate for a sexually transmitted infection. Compounding the political challenge were concerns about Gardasil's safety profile[11] and suspicions that Merck was motivated by a desire to position its product in the market before GlaxoSmithKline's rival vaccine won Food and Drug Administration approval.[23] Some legislators perceived that mandate legislation would have had greater success had the company waited a year or more. As it was, a representative of a national group remarked, it was "a case study of how not to get something passed."

Our methodology had limitations. We reported individuals' perceptions of the policy process, which may be contested. The states we selected for study cannot be considered representative of all states and the number of respondents interviewed in each state was relatively small. However, each state's respondent sample includes the full range of stakeholder groups identified in our recruitment plan.

In conclusion, the case of HPV illustrates the complexities of immunization policymaking in the states. Our nonrandom sample of 6 states is not necessarily representative of all 50 states and their experiences, but does illuminate key lessons emerging from hotbeds of policy activity. Although policymakers acknowledge the utility of vaccine manufacturers' involvement, industry lobbying that is overly aggressive, not fully transparent, or not divorced from financial contributions to lawmakers risks undermining the prospects for legislation to foster uptake of new vaccines. In the future, more restrained industry outreach that is focused on providing scientific and technical information about the vaccine may improve the outlook for legislation that is seen as legitimate by the public it both burdens and benefits.[24] ■

About the Authors

At the time this work was conducted, Michelle M. Mello and Sara Abiola were with the Harvard School of Public Health, Boston, MA. James Colgrove was with the Columbia Mailman School of Public Health, New York, NY.

Correspondence can be sent to Michelle M. Mello, JD, PhD, Department of Health Policy and Management, Harvard School of Public Health, 677 Huntington Ave, Boston, MA 02115 (e-mail: mmello@hsph.harvard.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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Contributors

M. M. Mello and J. Colgrove conceptualized the study, obtained funding, recruited participants, and conducted interviews. S. Abiola designed the sampling plan, recruited participants, and conducted interviews. M. M. Mello analyzed the data and drafted the article. S. Abiola and J. Colgrove revised the draft article for critical intellectual content.

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Human Participant Protection

This study was approved by the institutional review boards of the Harvard School of Public Health and Columbia Mailman School of Public Health.

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