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The Role of Law and Ethics in Recent Preparedness and Response for Vaccine-Preventable Illness

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In 1999, the Centers for Disease Control and Prevention listed vaccination among the leading public health achievements of the 20th century for the United States.[1,2] Critical to this success were effective implementation and enforcement of state and local policies associated with school and day care entry and infectious disease control.[3]

Twenty years later, the World Health Organization listed vaccine hesitancy—"the reluctance or refusal to vaccinate despite the availability of vaccines"[4]—as one of the greatest global health threats. Rising vaccine hesitancy in the United States and abroad has contributed to high-profile outbreaks of vaccine-preventable illnesses. In 2019, the United States reported a 27-year high in measles cases, coming within days of losing its endemic measles–free status.[5] Furthermore, efforts by state and local public health authorities to draw on or strengthen public health laws to address preventable outbreaks of infectious disease have been met by statehouse and courthouse challenges.

Most, but not all, of these challenges to local response efforts have been decided in ways reinforcing and deferring to foundational legal and ethical public health principles. A review of recent vaccine-related agency, legislature, and court activity using these principles can help assess the scope, limits, and vulnerabilities of US public health agencies' authority to protect the public from vaccine-preventable illnesses and to address infectious disease threats such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), for which no vaccines or treatments are available. As discussed further in this article, and as seen in the response efforts to coronavirus disease 2019 (COVID-19) in most states, such a review also can demonstrate the importance of public health agencies' and experts' diligence in efforts to educate and collaborate with their local political leadership.

Police Power, *Parens Patriae*, and Organized Society

Under the US Constitution, the state, through exercise of its police power, holds the primary authority to protect the community's health, welfare, and safety. In its 1905 *Jacobson v Massachusetts* decision,[6] upholding a local health department's requirement that a local pastor subject himself to either receive a smallpox vaccination or pay a fine for refusing it, the Supreme Court offered guidance to states on exercising these powers and identified limits on individuals' constitutionally protected liberty rights when the state needs to protect the common good.

More than a century later, the principles from *Jacobson* continue to guide state and local use of public health power:

1. Deference: states, through their legislatures, possess broad authority to define what constitutes a public health concern, and courts are reticent to second-guess the wisdom of states' decisions about the scope and use of that authority.
2. Delegation: states may choose to endow expert state and/or local bodies (eg, health departments) with the power to identify, track, and respond to public health threats.

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3. Necessity/minimal risk/reasonableness: because infringement on important personal rights (eg, autonomy, parental authority) may be unavoidable during an infectious disease outbreak, states must respond thoughtfully and proportionally to such threats. The means of response must keep individual health and safety risks as low as possible and should restrict constitutionally protected liberties only when and to the extent they absolutely must to achieve the public health goal.[7]

Later Supreme Court decisions built upon *Jacobson*'s principles, finding that states can establish vaccination-related school entry requirements that override a child's right to pursue private or public education[8] or supersede an individual's right to practice his or her religious beliefs.[9] Furthermore, the state may restrict parental control of its children as part of its *parens patriae* responsibility to "guard the general interest in youth's wellbeing," even if parental actions are grounded in religious or deeply held philosophical beliefs.[10] As the Supreme Court stated in *Prince v Massachusetts*, "The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."[11]

The *Jacobson* court states that if we were to hold individual rights and autonomy preeminent, even when facing significant public health threats, "organized society could not exist…. 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 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."[12] Ethicist Dan Beauchamp expands upon this stance, as he describes how application of police power authority "flows from a view of democracy that sees the essential task of government as protecting and promoting *both* private and group interests. . . . [I]t is left to the legislatures to determine which sets of interests predominate when conflicts arise."[10]

Bend-but-Don't-Break Interventions

In using their power, and to maintain trust in public health authorities, states should not merely be reasonable and transparent in their actions but should "adopt the least restrictive alternative that will meet the public health goal."[7,11] At times of low risk (eg, no current infectious disease outbreaks in the area), our system gives preference to freedom. To address public health problems, states should take a stepwise, bend-but-don't-break approach to interventions. They should select first the feasible intervention that minimizes encroachment on important individual freedoms, even if doing so might risk decreasing effectiveness, and then ratchet up to more intrusive interventions only if that approach should prove insufficient. The Nuffield Council on Bioethics' "ladder of intervention"[12] helpfully organizes public health actions from low levels of coercion (eg, providing information) to high levels of coercion (eg, restricting or eliminating choices).

Ethically, the state should not look to the most coercive approaches as a first step in the public health response. With infectious disease control, states must recognize that, to achieve a particular goal (eg, eliminating endemic measles), they may not have to require either compulsion or 100% compliance with an intervention, even if that would more assuredly bring about the improvement. Instead, to build and maintain protective vaccination rates, public health agencies should first focus on maximizing vaccine access; implementing localized, community-engaged health communication and trust-building initiatives; and improving immunization reporting and surveillance systems.

Social Distancing, Scope of Authority, and Declining Deference to Science

Several high-profile examples of use of local health department police power occurred in 2019. A Kentucky Court of Appeals supported a local health department's bend-but-don't-break social-distancing approach to address a chicken pox outbreak at a school where 80% of the students held religious exemptions to vaccination.[13] The department first prohibited unvaccinated students from participating in extracurricular activities during the outbreak and then, when the outbreak continued, prohibited these students from school attendance.[14] By upholding the health department's authority, the court reinforced several core concepts: (1) the state is not obligated to offer any kind of exemption from vaccination as a condition of attending school, and (2) the state acted reasonably both in allowing students to attend school with a religious exemption when risks were low and in retaining the authority to be more restrictive during outbreak response.

In March, a local New York court signaled a troubling turn away from the expert deference described in *Jacobson*. Rockland County, New York, a community with high numbers of religious exemptions, had been facing a months-long active outbreak of measles. When measures that did not infringe on liberty failed to contain the outbreak, the county responded by passing more stringent measures. When the county declared a 30-day public health emergency that barred *all* unvaccinated people from entering *any* place of public assembly, including schools, that action was challenged and thwarted by a local court. The judge noted the county exceeded its authority under local law, which allowed only 5-day emergency orders. The court also raised a worrisome second rationale for its decision. Although the state emergency declaration law allowed such powers to be used when responding to epidemics, neither the statute nor the emergency order offered a scientifically grounded definition

of epidemic. Instead of deferring to the local authority's determination of an epidemic, the court decided that 166 measles cases in a population of more than 300 000 people did not meet the term's "ordinary meaning." This case reminds us that documents, such as emergency orders, are not merely instruments through which governments exert their authority. Through the inclusion of statements such as, "Whereas the Centers for Disease Control and Prevention defines 'epidemic' as 'an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area,'"[15] documents such as emergency orders also can serve as opportunities to improve the public health literacy of the public and potentially reviewing courts. Some governors' COVID-19–related executive orders offer sound examples of documents drafted with an eye toward their role as a means of educating the public about public health concerns.[16]

New York City, during the course of a nearly year-long measles outbreak centered largely in religious communities in Brooklyn, exemplified the stepwise, bend-but-don't-break approach to infectious disease outbreak response. The city health department began with culturally appropriate community education and increasing access to vaccination. The health department then supplemented this action with targeted social-distancing measures, requiring that schools bar unvaccinated children from attendance during the active outbreak. Because some schools allowed unprotected children to continue attending school, and the outbreak endured, the city increased the force of its response: declaring a public health emergency, requiring unvaccinated people within certain Brooklyn zip codes to be inoculated against measles or to be deemed a public nuisance and forced to pay a $1000 fine.

Exemptions Eliminated, Loopholes Closed and Remaining, Deference Grudgingly Given

Arguably the most important legal action taken by states responding to infectious disease outbreaks has been the elimination of exemption grounds from state school and daycare entry rules. After the 2015 Disneyland measles outbreak and a precipitous rise in the number of families filing nonmedical exemptions, California became the third state to limit school and day care vaccination exemptions to medical grounds. New York State and Maine also eliminated nonmedical exemption grounds from their school and day care entry laws in 2019. In contrast, after a sizeable measles outbreak, Washington State eliminated personal/philosophical (but not religious) exemptions for the measles-mumps-rubella vaccine.[17] By adjusting the law for this one specific vaccine, Washington State's approach contrasts with the one-size-fits-all approach of childhood immunization exemption policymaking used by California, New York State, and Maine, and it raises interesting questions about whether there may be more nuanced ways for states to structure their laws to meet the "least restrictive" ethical standards.[18]

Since tightening its vaccination law, California saw a rapid rise in the number of medical exemptions submitted.[19] After a contentious legislative session, the state passed a new law to increase the rigor of medical exemption oversight, empowering state public health authorities, under certain circumstances, to review and reject medical exemptions that do not adhere to expert guidelines. These standards, which will go into effect in 2021, demonstrate an attempt to find an appropriate balance between public health protection and individual rights, which will be triggered when a community has a low rate of vaccine uptake, when schools fail to report vaccination rates to the state, or when a physician submits 5 or more medical exemption reports per year.

Few states have policies like California's that offer public health authorities the power to conduct substantive review and oversight of medical exemption writing, and it is unclear how many state medical licensure boards are willing to mount rigorous oversight campaigns against aberrant medical exemption writers.[20] Unlike California, Washington State will continue to have a considerable loophole in public health protection in its medical exemption submission process. In addition to not empowering the state to review and reject nonconforming medical exemption applications, Washington State law allows an expanded range of health care providers, including naturopathic physicians, to complete the medical exemption qualification examinations and the medical exemption forms.[21]

As the 2019-2020 school year approached, families in upstate New York filed legal challenges against their state's new vaccination requirements. In one decision, the judge expressed concern about the effect of the state's more restrictive law on many families, noting the small percentage of the population that seeks exemption based on religious convictions, especially in comparison to the population that may be unprotected because of poor access to care, vaccine failure, or waning protection as a result of the passage of time.[22] Nevertheless, in denying the family's request to stop the implementation of New York's new law, the judge ultimately felt bound by precedent, in line with *Jacobson*, deferring to the right of the state legislature to determine what equals a public health concern and the appropriate means by which to respond to such threats.

Conclusion

The whirlwind year of vaccine-related legal and political activity of 2019 offers insights into the policies states might establish should a safe and effective SARS-CoV-2 vaccine be developed.

Given the overwhelming disruption caused by COVID-19 to the public's lives and the economy, public interest in and demand for a vaccine are high. Therefore, it is important to ensure that the vaccine is not only safe and effective but also easily and broadly accessible at little or no cost to the public. Robust, multicultural public education campaigns on the benefits, limitations, risks, and availability of the vaccine should precede and accompany the vaccine's distribution. High demand also may minimize the need to impose mandates, although mandates likely will be implemented in certain settings, such as people who work closely with immunocompromised or particularly vulnerable populations. Would states mandate a safe and effective SARS-CoV-2 vaccine for children? That will depend in part on what we learn of children's role in disease transmission, as well as the level and length of immunity granted by the vaccine. In the interim, it is certain we will continue to rely on regular use of social-distancing measures, coupled with improved testing, surveillance, and contact tracing, to control virus spread.

Finally, these infectious disease outbreaks highlight an important reminder to state and local public health officials: legislatures play a critical role in defining what constitutes a public health concern and the state's response to it. People engaged in vaccine promotion efforts must clearly articulate, spread, and reinforce an understanding of public health concepts, norms of solidarity and community connectedness, and public health's central role in supporting human flourishing. Public health authorities and experts need to consider that their mission includes consistent engagement with and education of state and local officials, ensuring legislators understand the public health concerns arising in their communities, and that those charged with protecting the public's health retain the authority and have the resources to put into practice the evidence-based, science-informed interventions necessary to respond.

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