

## Vaccines, Public Health, and the Law

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■ **THE COVID-19 PANDEMIC** has loomed over the world for the better part of a year now; yet, many still cannot shake the disbelief that it is here. Nonetheless, countries around the world continue to be ravaged by death, and the healthcare workers battle on. As vaccine distribution makes its way to the mainstream, I cannot help but wonder, will people even take the vaccine? In an already divided country, where many are refusing to wear masks due to disbelief, violation of liberty, or mere quarantine fatigue, what will become of those that disobey if vaccination orders become mandatory? Public health emergencies may seem novel, but that is not the case. Even with modern technology and the most brilliant minds, certain diseases continue to baffle the scientific community [1, pp. 611–612]. Furthermore, new ones appear and seem to render the world at the same mercy as the diseases of centuries before [1, pp. 618–619]. On the other hand, the evolution of vaccination has been successful on many fronts as well. Vaccines for polio, measles, rubella, mumps, and varicella are just a few of the vaccines that have been used successfully for several decades [2, S5, S6].

Disease prevention due to successful vaccination is a double-edged sword as it can give the illusion that mass vaccination is no longer warranted. Antivaccination movements are not completely absent throughout history, but for example, most recently, parents have been declining childhood vaccines at alarming levels [2, S9]. Safety concerns and misinformation seem to be at the forefront of these movements; however, “...herd immunity will fail if too many refuse to be vaccinated”

[2, S9]. Due to the effects of herd immunity giving the impression that the risk for communicable disease is something we no longer have to actively prevent, the number of people refusing to vaccinate or delaying the vaccine schedule has been on the rise [3, p. e1].

Vaccine hesitancy has been characterized recently by a committee at the World Health Organization as “a behavior, influenced by a number of factors including issues of confidence (do not trust a vaccine or a provider), complacency (do not perceive a need for a vaccine or do not value the vaccine), and convenience (access).” Vaccine-hesitant individuals are a heterogeneous group who hold varying degrees of indecision about specific vaccines or about vaccinations in general [3, p. e2].

Relaxing vaccination requirements, particularly for schools, has allowed parents to waive vaccinations for personal or philosophical beliefs [3, p. e4]. For herd immunity to be effective, it depends on the virus; however, some viruses require up to 95 % herd immunity to provide adequate protection to a population [3, p. e3]. The threat to herd immunity is real, as demonstrated when children in California experienced an outbreak of measles when a number of students had opted out of vaccinations [3, p. e4]. Although the reasons people are opposed to vaccination vary, parents tend to be concerned about adverse effects and the long-term consequences to some of the components common to vaccines, such as mercury and aluminum [3, p. e6]. Parents need to be educated that mercury is no longer contained in the single-dose vials and aluminum is a component necessary to the immunization process; furthermore, a lack of information exists in corroborating any concerns of toxicity [3, p. e6].

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The study [3] seems to suggest that when it comes to adherence with vaccination, outcomes are improved when the pediatrician takes the time to give parents the education that they need to make an informed decision [3, p. e7]. This can be time-consuming; however, in a study that surveyed over 7000 parents, 80% attributed their decision to vaccinate to positive experiences with their primary care provider [3, p. e7]. The key is not so much the information conveyed, but how the information is conveyed. Personalize the experience for parents as best as reasonably possible, discuss the success of the vaccinations, and provide real-life examples of children who were sickened or worse when the disease could have been prevented [3, p. e8].

State and Federal legislative bodies are concerned about the significant number of those declining vaccination. The revival of diseases such as measles has the potential to create not only a public health concern but economic cost as well [4]. Public health goes so much deeper than washing hands and wearing a mask. The policies that drive public health are intertwined with, collective interests, individual freedoms, and free enterprise [5, p. 571]. The resistance to public health reform has been going on for centuries. In 1848, landowners in Great Britain were outraged when the government sought to install infrastructures to manage drainage and waste. “English people would prefer to take the chance of Cholera, rather than be bullied into health” [5, p. 572]. It is at times a slippery slope to determine what is necessary to keep us safe while maintaining what allows us to remain free. In a democratic society, such as the United States, when it comes to public health, the patient is not but one, it is the whole [6, pp. 144–145]. Public health “is what we, as a society, do collectively to assure the conditions for people to be healthy” [6, p. 145]. In a public health crisis, States are empowered by Congress for implementation of the police power authority to protect the overall health of the public [6, p. 146]. Quarantine, contact tracing, and immunization due to an infectious disease are proper under this constitutional authority [6, p. 146].

At the turn of the 20th Century, outbreaks of smallpox were still common, while the city of Cambridge was seeking to protect its citizens from the disease by vaccination [7, at 12]. Under a statute that allowed cities in Massachusetts to enforce vaccination for the good of public health, the city of Cambridge issued a vaccination order. The defendant refused

to comply with the mandatory vaccination and was charged with a criminal complaint [7, at 13]. The defendant pleaded not guilty and requested a jury instruction that would include that the order was an infringement of his rights under the Constitution, particularly, the 14th Amendment that provides that “no state shall make or enforce any law abridging the privileges or immunities of citizens of the United States, nor deprive any person of life, liberty, or property without due process of law,...” [7, at 14 (quoting U.S. Const. amend XIV § 1)]. The Supreme Court held that a State has the authority under the police power to protect the public as a whole. This includes various health laws and quarantine; however, the powers initiated may not conflict with the Constitution [7, at 25 (quoting U.S. Const. amend XIV § 1)]. The defendant in *Jacobson* asserted that mandatory vaccination was a violation upon his body, his liberty, and his personal decisions for health care. The Supreme Court found that when it comes to the greater good for all, personal liberty is not an absolute right [7, at 26 (quoting U.S. Const. amend XIV § 1)]. “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 [this] principle” [7, at 26 (quoting U.S. Const. amend XIV § 1)]. The Court further went on to state, “[e]ven liberty itself, the greatest of all rights, is not unrestricted license to act according to one’s own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others” [7, at 27 (quoting U.S. Const. amend XIV § 1)].

Fast forward to the present day, over a century later, and a pandemic arises with a myriad of executive orders issued by States. It is no surprise that in turn, *Jacobson*, which is still good law in regard to public health emergencies, has been under great scrutiny. The century-old Supreme Court ruling has been battered and bruised through the years and despite a subsequent case, *Bayley’s Campground Inc. v Mills*, *Jacobson* hangs on. In *Bayley’s Campground* several individuals and a business entity sought a preliminary injunction against executive orders initiated by the Governor of Maine at the height of the COVID-19 pandemic [8, at 27]. The executive order issued a mandatory 14-day quarantine to any visitors or residents who had been traveling outside the State of Maine [8, at 25]. The order was issued pursuant to the growing

health concerns of COVID-19 and intended to slow the spread of the virus [8, at 25]. The plaintiffs argued that the mandatory quarantine was unconstitutional, deprivation of their right to travel freely to other states, and a violation of due process [8, at 26]. In response, the Governor cited Jacobson and maintained that per health officials, COVID-19 is easily spread, has no vaccine yet available, and its incubation period is approximately 14 days; hence the 14-day quarantine [8, at 27]. Per the governor, social distancing and quarantine measures are pertinent to slow the spread, keep the citizens of Maine safe, and reduce the burden on the healthcare facilities [8, at 27]. The court in *Bayley's Campground Inc.* found that the police power fortified by Jacobson was not finite. Moreover, the courts have discretion in subsequent matters to police the state mandates [8, at 31]. The court in *Bayley's Campground Inc.* described Jacobson as “a legal standard that is at least the opposite of strict judicial scrutiny” that amounts to “a rubber stamp for all but the most absurd and egregious restrictions on constitutional liberties” [8, at 32]. Ultimately, the preliminary injunction was denied and the court refused to acknowledge Jacobson as controlling [8, at 32, 38]. Distinguished from Jacobson, *Bayley's Campground Inc.* strongly favors the liberties of the Constitution, even at an individual level to the police powers available to the State; however, with little information to go on in regard to COVID-19 and what may be the least restrictive means necessary to protect the public, the executive orders issued by the governor prevailed [8, at 34–35].

A New York court faced a similar preliminary injunction alleging violation of the Constitution; however, this court was more favorable to Jacobson. In *Page v Cuomo*, Governor Cuomo found himself in a similar action where injunctive relief was requested after several months of quarantine orders were issued for the State of New York [9, at 360]. Similar to *Bayley's Campground Inc.*, the plaintiff in *Page* alleges the right to travel freely between states was violated due to the quarantine order. The defendants cited Jacobson as well, stating that the standards of Constitutional analysis are different when facing a public health crisis [9, at 361]. Typically, in normal times, when a Constitutional infringement has been brought into question, the court would evaluate

if the state adhered to a strict scrutiny standard [9, at 361]. Jacobson allows for more leeway when it comes to invasion of Constitution rights, if the state is facing a health crisis of endemic proportions [9, at 361]. The court in *Page* focuses on a showing of irreparable harm as being sufficient to request relief from injunction. The plaintiff in *Page*, however, was unable to prove a sufficient showing of irreparable harm [9, at 362–363].

Under Jacobson, [t]he bottom line is this: when faced with a society-threatening epidemic, a state may implement emergency measures that curtail constitutional rights so long as the measures have at least some ‘real or substantial relation’ to the public health crisis and are not ‘beyond all question, a plain, palpable invasion of rights secured by the fundamental law [9, at 366].

As mentioned by the court in *Page*, Chief Justice Roberts validated Jacobson as good law and particularly relevant to the current pandemic crisis [9, at 366] (Roberts, C.J., concurring, opining that politically accountable officials are deserving of especially broad latitude in areas of medical and scientific uncertainty). The court in *Page* acknowledged that there is an archaic nature to the centurion law, particularly due to the medical advancement that has occurred in the last century [9, at 371]. Are we, as a civilized society, really in a superior position to manage this pandemic? The courts may soon have their chance to create a new precedent or etch Jacobson in stone as the vaccine reaches mainstream. If people felt that their rights were infringed because they were not able to visit their summer homes and sightsee with friends, one could only imagine the outcry if, like Jacobson, vaccination is mandated.

Operation Warp Speed, the collaborative initiative of the government and private companies to research, test, mass-produce, and distribute a vaccine for COVID-19 all in under a year is an unprecedented venture [10, at 692]. As we round the corner to mass distribution, many lie in wait armed with only their masks and hand sanitizer [10, at 692]. Officials associated with the program stated that safety and the ability to mass-produce were the top priorities [10, at 692]. The vaccination concerns are similar to those in the past, such as safety, efficacy, manufacturing, and distribution, particularly due to the ambitious

timeline [10, at 693]. There have already been failed attempts to streamline treatment for COVID-19 as seen with hydroxychloroquine [11, p. 730]. Hydroxychloroquine was approved for off-label use amid reports of its potential to treat COVID-19 infections [11, p. 731]. Subsequent studies would show no evidence of efficacy for treatment [11, p. 731]. Just two months later, Operation Warp Speed was announced promising a vaccine to be made available for every American in under a year [11, p. 731]. Part of Operation Warp Speed's plan is to mass-produce several vaccines prior to the conclusions of the clinical trials in order to streamline distribution [11, p. 731].

Clinical trials are also being streamlined as recruitment for phase III's are being conducted simultaneously to phase I testing [11, p. 732]. The Secretary of Health and Human Services declared COVID-19 a public emergency which allows for reduced restrictions for clinical trials under the Emergency Use Authorizations (EUAs) [11, p. 733]. A budget of ten billion dollars allots for these extreme conditions such as mass production of several vaccines and recruitment for phase III before phase I is complete [11, p. 733]. Having what you need to take it to the next step before it even begins saves massive amounts of time when conducting a clinical trial, but does that mean that corners will be cut for safety? Officials stress that safety and efficacy will remain at the forefront of these operations.

Millions of people all over the world have become infected with COVID-19 and many of those have perished [12, p. 437]. Our efforts to social distance and increase hygiene have not been for naught; "yet it is clear the only way to provide effective herd immunity is with a safe and effective vaccine" [12 p. 437]. As multiple waves hit communities, already struggling healthcare centers brace for impact. It is a year into the pandemic and I continue to hold onto my battered N-95 that I have worn for months. It is stored in a brown paper bag, which at times, we ran out of too. Healthcare workers are emotionally, physically, and mentally drained. How long can we expect the helpers to endure this wrath of not only COVID-19 but of the brokenness that has become of the community? Once hailed as heroes, the impact of the frustrations around us, are as thick in the air as the virus particles. If only our N-95's and our faith were not worn so thin. While many were hunkered down in their homes this past year, medical personnel have worked tirelessly, and

now we need your help. If ever there was a time to step up to save humanity, the time is now. If vaccination from the virus that causes COVID-19 depends on herd immunity, it is only with the showing of trust, will the herd gather. It will take a building of trust and effective communication through building relationships, much like the pediatricians are advised to do with their concerned parents.

**EACH JOURNEY IS** different; no story is the same. I write not to boast or shame, just to share my journey. I received the vaccination in my own time, when I was ready. I did it so that I could hug my grandma again and see family that I haven't seen in over a year. I did it so I could travel and leave my house without fear of this invisible killer. I did it for my co-workers on the front lines who are exhausted and traumatized from what they have seen, yet return day after day. I did it because it is the only route that I could see that offers hope. I chose to become a part of herd immunity to protect those who cannot get vaccinated. Individually, the choice is ours. Collectively, we can beat this. ■

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