

UPDATING VACCINE LAW: RESTRUCTURING *JACOBSON V. MASSACHUSETTS* TO CREATE A SAFE HARBOR FOR STATES

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I. INTRODUCTION AND OVERVIEW

In *Jacobson v. Massachusetts*, a Massachusetts resident challenged the constitutionality of a state statute requiring smallpox vaccinations.¹ The Supreme Court responded, declaring that states have broad power to require vaccinations as long as they are reasonably required for the safety of the public.² Since then, states have imposed vaccines to combat other serious diseases ranging from whooping cough to bacterial meningitis.³ Though state residents sometimes oppose the legality of these programs, such opposition is effectively powerless in the face of *Jacobson's* broad precedent.

However, *Jacobson* was decided in 1905 and focused on the smallpox vaccine—a vaccine that was clearly necessary to protect the public at large.⁴ Future vaccines will not always be as clearly necessary because many other diseases pose less of an immediate threat than smallpox.⁵ The Court in *Jacobson* noted that at some point, a state-mandated vaccine program could exceed the state's power and be deemed unconstitutional.⁶ However, the Court only vaguely discussed the line between constitutional and

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¹ 197 U.S. 11, 12–14, 22–23, 25–26 (1905).

² *Id.* at 27–31.

³ See Elizabeth Hatch, Comment, *To Vaccinate Or Not To Vaccinate?: The Challenges And Benefits of The Implementation Of The Jamie Schanbaum Act*, 15 TEX. TECH. ADMIN. L.J. 187, 188–189 (2013); Linda E. LeFever, Comment, *Religious Exemptions From School Immunization: A Sincere Belief Or A Legal Loophole?*, 110 PENN ST. L. REV. 1047, 1056–57 (2006).

⁴ See Kyra R. Wagoner, Note, *Mandating the Gardasil Vaccine: A Constitutional Analysis*, 5 IND. HEALTH L. REV. 403, 415 (2008).

⁵ See *id.*

⁶ See *Jacobson*, 197 U.S. at 38.

unconstitutional vaccine programs.⁷ Therefore, states have been left to guess, at what point does a vaccine program violate *Jacobson*?⁸ This note proposes a way for states to avoid ever having to find an answer to that question.

This note will recommend a series of procedural steps for the Supreme Court to recommend to states. This procedural guidance would show states how to best ensure that their vaccine programs are constitutional. The Supreme Court would introduce this guidance with a guarantee: as long as a state followed the recommended steps each time it sought to impose a vaccine requirement, then the state's vaccine requirements would be constitutional in the eyes of the Court. This procedural framework would effectively create a safe harbor for state lawmakers—by adhering to the framework, lawmakers could be confident that they were acting within constitutional boundaries. This safe harbor would benefit states by decreasing vaccine-related litigation, thus allowing them to mandate vaccines swiftly and confidently. On the other hand, it would benefit the public by ensuring transparent and well-thought-out vaccine programs.

II. THE CURRENT WEAKNESSES IN VACCINE LAWS AND THE NEED FOR CHANGE

To this day, *Jacobson* has never been overruled and it continues to significantly influence public health law in the United States.⁹ *Jacobson*'s continued prevalence is not due to a lack of litigation; since *Jacobson* was decided in 1905, numerous cases have reinforced and arguably expanded it.¹⁰ The following section will explore some of the most influential cases descending from *Jacobson*, and then briefly focus on the Human Papilloma Virus (HPV) vaccine in order to highlight the modern state of vaccine law.

⁷ See *id.* at 38–39.

⁸ See George J. Annas, *Blinded by Bioterrorism: Public Health and Liberty in the 21st Century*, 13 HEALTH MATRIX 33, 55 (2003); see Ben Horowitz, Comment, *A Shot in the Arm: What a Modern Approach to Jacobson v. Mass. Means for Mandatory Vaccinations During a Public Health Emergency*, 60 AM. U. L. REV. 1715, 1730 (2011).

⁹ See James Lobo, Note, *Vindicating The Vaccine: Injecting Strength Into Mandatory School Vaccination Requirements to Safeguard the Public Health*, 57 B.C. L. Rev. 261, 261 (2016).

¹⁰ See, e.g., *Zucht v. King (Zucht II)*, 260 U.S. 174, 176–77 (1922).

A. *The Legacy of Jacobson v. Massachusetts*

Seventeen years after *Jacobson*, the Supreme Court expanded its stance on state-mandated vaccines in *Zucht v. King*.¹¹ In *Zucht*, a student in San Antonio, Texas challenged a law that made the smallpox vaccine a prerequisite for school enrollment.¹² The Court concluded it was already settled law that states could impose mandatory vaccines; however, the holding in *Zucht* also expanded on *Jacobson*.¹³ While *Jacobson* upheld a vaccine requirement during an ongoing epidemic, *Zucht* upheld a vaccine requirement even though it was purely a preventative measure.¹⁴ By 1934, this expansion of *Jacobson* had already taken root in state courts.¹⁵ In *Booth v. Board of Education of Fort Worth Independent School District*, parents challenged a school district's vaccine requirement as arbitrary because there was no ongoing epidemic.¹⁶ The court in *Booth* concluded that "it is not a question of emergency, but it is only a question of whether the action of the board is arbitrary and without facts upon which minds could have decided rationally that such rules were reasonably necessary"¹⁷

By 1948, some state courts went as far as to interpret *Jacobson* as a *carte blanche* allowing states to mandate any vaccine programs they wished.¹⁸ In *Sadlock v. Board of Education*, the Supreme Court of New Jersey interpreted *Jacobson* to mean that "the question of the desirability or efficacy of compulsory vaccination . . . and whether it is wise or unwise is strictly legislative and not a judicial question."¹⁹ Such holdings seem to interpret *Jacobson* as a justification for any vaccine requirement and disregard *Jacobson*'s prohibition on unreasonable, arbitrary, or oppressive

¹¹ *See id.*

¹² *Zucht v. King (Zucht I)*, 225 S.W. 267, 269–70 (Tex. Civ. App.—San Antonio 1920, writ ref'd).

¹³ *See Zucht II*, 260 U.S. at 176–77.

¹⁴ *See Zucht I*, 225 S.W. at 269; *Jacobson v. Mass.*, 197 U.S. 11, 27–28 (1905).

¹⁵ *See, e.g., Sadlock v. Bd. of Educ. of Borough of Carlstadt*, 58 A.2d 218, 220 (N.J. 1948); *Booth v. Bd. of Educ. of Fort Worth Indep. Sch. Dist.*, 70 S.W.2d 350, 353 (Tex. Civ. App.—Fort Worth 1934, writ disp'd w.o.j.).

¹⁶ 70 S.W.2d at 353.

¹⁷ *Id.* at 352.

¹⁸ *Sadlock*, 58 A.2d at 220.

¹⁹ *Id.*

2017]

UPDATING VACCINE LAW

465

state actions.²⁰ By the mid-1950s, it was arguably settled law that vaccination mandates were presumptively valid.²¹

B. The HPV Vaccine as an Example of Controversies to Come

Currently, the World Health Organization lists twenty-four diseases that are being targeted by vaccines in development.²² These diseases range from Malaria to Tuberculosis to HIV.²³ With new vaccines soon to be available, states will need to decide whether some vaccines should be mandatory or optional. That decision might be easy at times; a locale experiencing an outbreak of Malaria would surely be a reasonable candidate for a mandatory Malaria vaccine. However, the propriety of imposing other vaccines will not be as apparent. For example, vaccines for sexually-transmitted diseases would only directly benefit sexually active persons; therefore, state-wide vaccine requirements for such diseases might be overbroad and even unconstitutional.²⁴ Unfortunately, these hypothetical controversies have become a reality as new diseases emerge and vaccines are developed to combat them.²⁵ In recent years, state legislatures have repeatedly grappled with the decision of whether to mandate newly developed vaccines.²⁶ These legislative controversies have highlighted the necessity of updating the nation's vaccine laws.

One such controversy involved Gardasil, a vaccine developed by Merck, Inc. in the early 2000s to prevent the HPV.²⁷ HPV is a sexually transmitted virus, and even a decade after the development of a preventative vaccine, the Center for Disease Control estimates that 79 million Americans are

²⁰Mary Holland, *Compulsory Vaccination, The Constitution, And The Hepatitis B Mandate For Infants And Young Children*, 12 YALE J. HEALTH POL'Y, L. & ETHICS 39, 52 (2012).

²¹*Id.*

²²*Immunization, Vaccines, and Biologicals*, WORLD HEALTH ORG. (2016).

²³*Id.*

²⁴Allison Lucas, *Mandated Human Papillomavirus Vaccination: An Overextension of Jacobson v. Mass.*, 10 T.M. COOLEY J. PRAC. & CLINICAL L. 253, 275–76 (2008).

²⁵*See, e.g.*, H. Research Organization, Bill Analysis, Tex. H.B. 1816, 82nd Leg., R.S. (2011); Horowitz, *supra* note 8, at 1716–17 (discussing the 2009 outbreak of the H1N1 influenza virus and describing how state legislatures were forced to quickly explore the possibilities of state-wide H1N1 vaccines).

²⁶*See, e.g.*, H. Research Organization, Bill Analysis, Tex. H.B. 1816, 82nd Leg., R.S. (2011); Wagoner, *supra* note 4, at 426.

²⁷Rachel Reynolds, Comment, *Dispatch from the Culture War: Virginia's Failed HPV Vaccination Mandate*, 16 RICH. J.L. & PUB. INT. 59, 61, 63 (2012).

currently infected with HPV.²⁸ Well after Gardasil received FDA approval in 2006, perceptions of the vaccine varied dramatically.²⁹ On the one hand, some quickly embraced the vaccine.³⁰ A number of states raced to combat the spread of HPV by implementing mandatory vaccine programs.³¹ For example, within the same year that the drug received FDA approval, Virginia required HPV vaccinations for all school-age girls.³² In 2007, Texas' governor, Rick Perry, also imposed a law forcing all school-age girls to receive the vaccine.³³ Numerous other states took similar approaches, such as requiring Medicaid to pay for the vaccine or appropriating funds so the vaccine could be offered free of charge.³⁴ On the other hand, Gardasil was met with staunch opposition by some state officials and residents.³⁵ Some opposed the idea of a Gardasil requirement because close ties between Merck's lobbyists and lawmakers blurred the lines between politics and epidemiology.³⁶ Some questioned the safety of the HPV vaccine, claiming that vaccine was linked to mental retardation and even death.³⁷ Others feared that vaccinating children against a sexually transmitted disease would encourage promiscuity.³⁸ This variety of concerns, at least in part, prompted the Texas Legislature to overrule Governor Perry's executive order before Texas' HPV vaccination program was ever active.³⁹

²⁸ Human Papillomavirus (HPV), CENTER FOR DISEASE CONTROL AND PREVENTION (2016), <http://www.cdc.gov/std/hpv/stdfact-hpv.htm>.

²⁹ See Lucas, *supra* note 24, at 274.

³⁰ Reynolds, *supra* note 27, at 63.

³¹ *Id.*

³² *Id.*

³³ *Id.* at 59.

³⁴ *Id.*

³⁵ Carrie A. Roll, *The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?*, 10 J. HEALTH CARE L. & POL'Y 421, 437, 438 (2007).

³⁶ Wade Goodwyn, *In Texas, Perry's Vaccine Mandate Provoked Anger*, NPR (Sep. 16, 2011, 3:22 PM), <http://www.npr.org/2011/09/16/140530716/in-texas-perrys-vaccine-mandate-provoked-anger>.

³⁷ See Sarah Anne Hughes, *Michele Bachmann's HPV Claims Just Latest in Gardasil Debate*, THE WASHINGTON POST (Sep. 14, 2011), https://www.washingtonpost.com/blogs/blogpost/post/michele-bachmanns-hpv-claims-just-latest-in-gardasil-debate/2011/09/14/gIQA9FjESK_blog.html.

³⁸ Roll, *supra* note 35, at 427.

³⁹ Goodwyn, *supra* note 36.

C. *The Weaknesses of Vaccine Law Today*

As in Texas, many states that contemplated mandatory HPV vaccines were ultimately dissuaded by public fears and internal political tensions.⁴⁰ The public outcry surrounding Gardasil demonstrates that vaccines can provoke heated discourse and polarize communities. The Gardasil controversy highlights the need to update vaccine laws by offering concrete examples of the two main problems with existing laws: (1) they foster public distrust of state governments and (2) they expose states to frequent litigation that risks local resources.

1. Existing Vaccine Laws Foster Public Distrust of State Governments

Today's vaccine laws empower public officials but simultaneously foster a social environment that is hostile towards them.⁴¹ Because states can mandate vaccine programs without having to engage in any public discourse, unanswered questions about the programs' safety and necessity often fester into fears.⁴² However, because states have nearly unbridled power to impose vaccines, there is generally little need for states to reassure fearful communities.

As previously discussed, Texas Governor Rick Perry disregarded overwhelming concerns about the HPV vaccine when he signed an executive order that initiated a mandatory HPV vaccine program in 2007.⁴³ The order was signed so swiftly and with so little discussion that many of the state's senators only heard about it after the fact.⁴⁴ Similarly, in 2009 during the H1N1 outbreak, New York's Health Commissioner promulgated an emergency regulation requiring hospital workers to be vaccinated against H1N1 even though the vaccine had yet to be licensed.⁴⁵ Healthcare workers subjected to the H1N1 vaccine responded with anger and fear.⁴⁶

⁴⁰ See Wagoner, *supra* note 4, at 426.

⁴¹ See Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS U. J. HEALTH L. & POL'Y 113, 143 (2010).

⁴² See Dan Eggen, *Rick Perry and HPV Vaccine-Maker Have Deep Financial Ties*, THE WASHINGTON POST (Sep. 13, 2011), https://www.washingtonpost.com/politics/perry-has-deep-financial-ties-to-maker-of-hpv-vaccine/2011/09/13/gIQAVKKqPK_story.html.

⁴³ *Id.*; see also Parmet, *supra* note 41, at 147–48.

⁴⁴ See Goodwyn, *supra* note 36.

⁴⁵ Parmet, *supra* note 41, at 141–42.

⁴⁶ *Id.*

Regardless of whether these states made well-informed decisions, because the public was left out of the discussion altogether, the decisions were met with criticism and anxiety.⁴⁷ The American public's skepticism surrounding state-mandated vaccines stems from two main sources. First, there is widespread distrust of pharmaceutical companies; second, the public often questions the safety of newly developed vaccines.⁴⁸

Americans' distrust of pharmaceutical companies arises from many of the companies' close relationships with the government.⁴⁹ For example, during the international H1N1 outbreak, despite international panic, the U.S. government appeared to favor vaccine manufacturers over the American public.⁵⁰ Congress effectively shielded vaccine makers from almost all liability by preventing the public from suing manufacturers over vaccine-related injuries.⁵¹ Again, looking back to the Gardasil controversy in Texas, Governor Perry's connections to the pharmaceutical industry raised eyebrows across the state.⁵² Merck, Inc., the manufacturer of Gardasil, had contributed to Perry's campaign in the past and Perry's former Chief of Staff was a lobbyist for Merck.⁵³ Because Americans often view such relationships between the government and pharmaceutical companies as evidence of corruption, they are hesitant to accept the vaccines provided by those same parties. When government officials then ignore public concerns over the safety and necessity of vaccines, the public's fears fan into outrage.⁵⁴

⁴⁷ *Id.*

⁴⁸ See Lauren Haertlein, *Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases*, 75 LAW & CONTEMP. PROBS., no. 2, 2012, at 218. \

⁴⁹ See Parmet, *supra* note 41, at 146.

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² Goodwyn, *supra* note 36.

⁵³ *Id.*; see also Parmet, *supra* note 41, at 148.

⁵⁴ Haertlein, *supra* note 48, at 218 (stating in 2005, Rolling Stone magazine published an article by Robert Kennedy Jr. in which he discussed vaccines' links to autism: "If as the evidence suggests, our public-health authorities knowingly allowed the pharmaceutical industry to poison an entire generation of American children, their actions arguably constitute one of the biggest scandals in the annals of American medicine.").

2. Existing Laws Expose States to Frequent Litigation and Risk States' Resources

Commentators often only discuss *Jacobson* because of the broad powers that the Court granted to states.⁵⁵ However, these commentators fail to recognize that *Jacobson* also placed a significant burden on states because the Court failed to lay down any rigid guidelines for mandating vaccines.⁵⁶ In *Jacobson*, the Court simply stated that while a local government can mandate vaccines in order to protect the community at large, it cannot exercise its power in an arbitrary or unreasonable manner, or go beyond what is reasonably required for the public's safety.⁵⁷ While seemingly putting states in a position of power, these broad guidelines exposed states to constant litigation.⁵⁸ Individuals test *Jacobson*'s vague boundaries, drawing states into vaccine-related litigation on a regular basis. The fact that such litigation is commonplace proves that *Jacobson* was not the final word on vaccine law in the U.S.

The continuity of vaccine-related litigation puts states on uncertain footing—particularly in situations when the vaccine in question is highly controversial.⁵⁹ For example, a state legislature might impose a vaccine program that is widely unpopular. Although litigation might be imminent, the state would understandably want to move forward with the program in an attempt to combat the targeted disease. If a court were to eventually hold that the state's vaccine program is unconstitutional, then the state would lose credibility with its residents and future vaccine programs would be met with heightened public scrutiny.⁶⁰ Furthermore, the state would have effectively wasted all of the resources used to fund and supply the program.

⁵⁵ See, e.g., Ariel Pizzitola, *The Constitutionality of Opting Out of Adolescent Sex: HPV Vaccine-Mandate Legislation Raises Constitutional Questions*, 24 J. CONTEMP. HEALTH L. & POL'Y 399, 404–05 (2008); Warren Kaplan, *Massachusetts Disease Control Law in the 21st Century: Running in Place?*, 87 MASS. L. REV. 84, 89 (2002).

⁵⁶ See Pizzitola, *supra* note 55, at 404–05; Kaplan, *supra* note 55, at 89.

⁵⁷ *Jacobson v. Mass.*, 197 U.S. 11, 362 (1905).

⁵⁸ See, e.g., *Workman v. Mingo Cty. Bd. of Educ.*, 419 Fed. Appx. 348 (4th Cir. 2011); *Sherr v. Northport-E. Northport Union Free Sch. Dist.*, 672 F. Supp. 81 (E.D.N.Y. 1987); *Hanzel v. Arter*, 625 F. Supp. 1259 (S.D. Ohio 1985); *Dalli v. Bd. of Educ.*, 267 N.E.2d 219 (Mass. 1971); *Itz v. Penick*, 493 S.W.2d 506 (Tex. 1973); *Abney v. Fox*, 250 S.W. 210 (Tex. Civ. App.—Austin 1923, writ ref'd).

⁵⁹ Haertlein, *supra* note 48, at 224.

⁶⁰ See *id.*

Vaccinating even a small fraction of the population is a costly endeavor.⁶¹ Vaccine prices have gone from single digits to sometimes triple digits in the last two decades.⁶² Current vaccine prices already strain some public health programs.⁶³ These same programs could not afford to waste precious resources by purchasing large quantities of a vaccine, only to find that their supplies will go unused. It is these economic and legal uncertainties that cause wide variations in how state legislatures impose vaccine requirements.⁶⁴ In an attempt to insulate themselves from risk, some states are hesitant to impose vaccines at all.⁶⁵ While mitigating legal risks, these states then risk the general health of their communities by leaving them exposed to preventable diseases.⁶⁶

D. Supreme Court Precedent Casts Uncertainty on Jacobson's Relevance

Aside from the societal impacts of existing vaccine laws, there are legal issues too. It is unclear how states' powers under *Jacobson* stand up to the Supreme Court's modern stance on fundamental rights.⁶⁷ In *Cruzan v. Director, Missouri Department of Health*, the Court strongly indicated that it views the right to refuse medical treatment as a fundamental right.⁶⁸ This rhetoric seemingly contradicts *Jacobson*, which permitted states to force vaccines onto unwilling citizens. The Court decided *Jacobson* in 1905 and *Cruzan* in 1990.⁶⁹ Because the Court has yet to hear a case that pits the states' powers under *Jacobson* against the Court's rhetoric in *Cruzan*, states cannot be sure how the Court would react in such a situation. If the Court were to decide that the right to refuse medical treatment is a fundamental right that overrides *Jacobson*, then state-imposed vaccine programs would

⁶¹ See Elisabeth Rosenthal, *The Price of Prevention: Vaccine Costs Are Soaring*, THE NEW YORK TIMES (July 2, 2014), http://www.nytimes.com/2014/07/03/health/Vaccine-Costs-Soaring-Paying-Till-It-Hurts.html?_r=0.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Horowitz, *supra* note 8, at 1729–30.

⁶⁵ *Id.* at 1729.

⁶⁶ See *id.* at 1729–30.

⁶⁷ See *id.* at 1733.

⁶⁸ *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990); *id.* at 289 (O'Connor, J., concurring); *id.* at 305 (Brennan, J., dissenting); Horowitz, *supra* note 8, at 1726–27.

⁶⁹ *Cruzan*, 497 U.S. at 297; *Jacobson v. Mass.*, 197 U.S. 11, 29–31 (1905).

have to undergo a strict-scrutiny review when challenged.⁷⁰ For a vaccine program to survive strict-scrutiny review and be deemed constitutional, it would need to support a compelling state interest and be narrowly tailored to effectuate only that interest.⁷¹

III. THE PROPOSED FRAMEWORK

The framework put forth in this note would focus on enhancing vaccination laws at their weakest points. First, the framework would improve the public's perceptions of state-mandated vaccine programs. Second, it would offer states protection from vaccine-related litigation. Finally, it would offer states a degree of certainty even in the face of a strict-scrutiny standard of review. The following sections will outline the proposed framework and explain each component.

A. *Implementation of the Framework*

Jacobson states the broad power to mandate vaccines, but warned that this power had limitations—states cannot mandate vaccines in an arbitrary, unreasonable, or oppressive manner.⁷² However, the Court has never explicitly explained these limitations.⁷³ Therefore, currently states are left to hope that their vaccine programs are not considered arbitrary, unreasonable, or oppressive. The Court should elaborate on *Jacobson* to precisely define states' powers—the framework proposed in this note would do exactly that.

The framework would consist of steps that the Court would encourage states to take when they are considering whether to implement a mandatory vaccine program. The Court would declare these recommended steps to be a safe harbor for states, meaning that as long as a state took each of the recommended steps, then its vaccine program would be deemed constitutional.⁷⁴ This safe-harbor framework would effectively instruct states how to create a constitutionally sound vaccine program. However,

⁷⁰Horowitz, *supra* note 8, at 1718.

⁷¹*See Zablocki v. Redhail*, 434 U.S. 374, 388 (1978).

⁷²*See Jacobson*, 197 U.S. at 37–38.

⁷³Michael Sanzo, *Vaccines and the Law*, 19 PEPP. L. REV. 29, 32 (1991).

⁷⁴The Supreme Court has the authority to delineate safe harbors for state action and it has done so in the past. *See, e.g., Zablocki*, 434 U.S. at 388 (holding that when a state action interferes with a fundamental right, that action will be upheld as long as the state's interest is sufficiently important and the action is narrowly tailored to effectuate its interest).

before providing a step-by-step guide to constitutionality, it is first necessary to determine what constitutes a constitutional vaccine program.

In *Jacobson*, the Court explained that any state-imposed vaccine requirement must be within the scope of its police powers and it must be reasonable.⁷⁵ A law is within the scope of the state's police powers when it is designed to protect the public's health or safety.⁷⁶ Even if a law is within the scope of the state's police power, it cannot be arbitrary, unreasonable, or go beyond what is reasonably required for the public's safety.⁷⁷ The basic rule stemming from *Jacobson* is that a vaccine mandate cannot be judicially overturned unless it clearly has no substantial relationship to the protection of the public's health and safety.⁷⁸

Fast forwarding to present times, any post-*Cruzan* vaccine program should be tailored to survive a strict scrutiny standard of review.⁷⁹ To survive the strict-scrutiny standard of review, a vaccine program would need to support a compelling state interest and be narrowly tailored to effectuate only that interest.⁸⁰ Accordingly, considering *Jacobson* and the Court's modern application of the strict scrutiny standard of review, a vaccine program should comply with the following requirements in order to ensure constitutionality: The program must be (1) related to the protection of the public's health or safety, (2) be reasonable in light of what is required to protect the public, (3) fulfill a compelling state interest, and (4) be narrowly tailored in light of the state's objective.⁸¹ These requirements for constitutionality shape each step of the proposed framework; the following discussion explores those steps.

B. *The Framework's Steps*

Generally, when a state's legislature explores the possibility of imposing a vaccine program, the program is proposed as a bill.⁸² After a period of research and debates, the legislature makes an informed decision regarding

⁷⁵ See *Jacobson*, 197 U.S. at 25.

⁷⁶ See *id.* at 25, 31.

⁷⁷ See *id.* at 30–31.

⁷⁸ See *id.*

⁷⁹ See *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 279, 289, 305 (1990) (including dicta suggesting that the right to refuse a vaccine might be a fundamental right).

⁸⁰ See *Zablocki v. Redhail*, 434 U.S. 374, 388 (1978).

⁸¹ See *Cruzan*, 497 U.S. at 279, 289, 305; *Jacobson*, 197 U.S. at 30–31.

⁸² See, e.g., H. Research Organization, Bill Analysis, Tex. H.B. 1816, 82nd Leg., R.S. (2011).

the imposition of the vaccine.⁸³ However, the process is not always that calculated and sometimes a vaccine program may be imposed without any real discussion in the legislature.⁸⁴ Specifically identifying concrete steps for states to follow when considering a vaccine program would have two major benefits. First, it would establish a predictable process for states to follow. This would benefit the public by allowing for transparency in states' decision-making processes, thus alleviating some of the public's fears surrounding state-mandated vaccines. Second, it would benefit states by offering them protection from vaccine-related litigation. Currently, states are forced to defend themselves from vaccine-related litigation, but this framework would create a safe harbor so that states can be confident that their vaccine programs are constitutional.⁸⁵

The framework's "steps" are key considerations relating to public health. In order to fall within the proposed safe harbor, states would have to thoroughly weigh each of the following considerations when deciding whether to impose a vaccine program: (1) the communicability of the disease at issue; (2) the severity of the disease at issue; (3) the effectiveness of the vaccine in question; (4) the side-effects of the vaccine; and (5) the necessary scope of the vaccine (e.g. all persons over 40, all infants, all women between the ages of 12 and 22). While seemingly a commonsense approach to imposing a vaccine, these guidelines would illuminate a clear path to constitutionality.

1. Disease Communicability

Communicability is a consideration included in the framework because it would help to satisfy three of the four requirements for constitutionality. First, by considering communicability, a state's legislature would be able to show that its proposed vaccine program is related to the protection of the public's health and safety. Even if a disease is not rapidly communicable

⁸³ See, e.g., *id.* (proposing a mandatory bacterial meningitis vaccine for certain students and discussing the side effects of the vaccine, the contagiousness of meningitis, its mortality rate, and other considerations).

⁸⁴ See, e.g., Goodwyn, *supra* note 36 (discussing Rick Perry's decision to bypass the legislature and require the HPV vaccine for school-age girls).

⁸⁵ See, e.g., *Workman v. Mingo Cty. Bd. of Educ.*, 419 Fed. Appx. 348, 350 (4th Cir. 2011); *Sherr v. Northport-E. Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 86 (E.D.N.Y. 1987); *Hanzel v. Arter*, 625 F. Supp. 1259 (S.D. Ohio 1985); *Dali v. Bd. of Ed.*, 267 N.E.2d 219 (Mass. 1971); *Itz v. Penick*, 493 S.W.2d 506, 507 (Tex. 1973); *Abney v. Fox*, 250 S.W. 210 (Tex. Civ. App.—Austin 1923, writ ref'd).

(e.g. an airborne illness), by simply showing that the disease may spread among a community, the state can prove that the vaccine program is valid because it is designed to protect at least some members of the community.⁸⁶ Second, considering communicability will help to show that the mandate is a reasonable way to protect the public. Implementing a vaccine program to prevent a communicable disease has repeatedly been deemed a reasonable act.⁸⁷ Finally, ensuring that states consider the communicability of the targeted disease would show that the vaccine program was needed to fulfill a compelling state interest. The Supreme Court has held that protecting citizens' health is a compelling state interest.⁸⁸ Therefore, showing that a proposed vaccine program would work to contain a communicable disease would show that the program served a compelling state interest.⁸⁹ When considering communicability, a state should gather information on how the disease is transmitted, estimates on the probable speed of transmission, and any other data that could speak to the necessity of a vaccine mandate.

2. Disease Severity

The severity of the targeted disease is a consideration included in the framework because it would help to satisfy three of the four requirements for constitutionality. First, by considering the severity of the disease, the state could show that its proposed mandate would benefit the public by stopping the spread of a harmful illness. Again, it is not necessary to show that the targeted disease is an apocalyptic pandemic; the state simply needs to show that preventing the disease would have at least some benefit on the public's health and safety.⁹⁰ Second, gathering information on the severity of a given disease would help to explain why a mandatory vaccine program is a reasonable measure. For a vaccine mandate to be constitutional, the state cannot go too far beyond what is reasonably required to protect the public.⁹¹ Therefore, by showing that the program's targeted disease could

⁸⁶ See *Jacobson v. Mass.*, 197 U.S. 11, 30 (1905) (indicating that as long as the challenged vaccine mandate has some connection to the public's health and safety, the mandate will not be overturned).

⁸⁷ See, e.g., *Boone v. Boozman*, 217 F.Supp.2d 938, 954 (E.D. Ark. 2002); *Wright v. DeWitt Sch. Dist.*, 385 S.W.2d 644, 648 (Ark. 1965).

⁸⁸ See *Simopoulos v. Virginia*, 462 U.S. 506, 519 (1983) (stating that states do have a compelling interest to protect mothers' health and safety).

⁸⁹ *Id.*

⁹⁰ See *Jacobson*, 197 U.S. at 31.

⁹¹ See *id.*

have dire consequences on the public, a community-wide vaccine requirement seems increasingly reasonable.⁹² Finally, illustrating the severity of the disease would show that the state's mandate serves a compelling state interest. As previously mentioned, protecting human health is a compelling state interest.⁹³ When considering the severity of a targeted disease, the state should gather data on mortality, pain and suffering, long-term effects, and any other information that illustrates the human cost of the disease.

3. Vaccine Effectiveness

The proposed vaccine's effectiveness is a consideration included in the framework because it would help to show that the vaccine program in question is related to the protection of the public's health and safety. When considering the vaccine's effectiveness, a state would ask: how successfully can the vaccine prevent the targeted disease, and how quickly can individuals be vaccinated? Even if a vaccine has limited effectiveness, as long as the state can show that it benefits at least some individuals, then the vaccine mandate would be reasonably related to the public's health and safety. As the Court in *Jacobson* said, the judiciary can only review state laws purporting to protect the general welfare when those laws have "no real or substantial relation to . . . [the public's health, morals, or safety], or is, beyond all question, a plain, palpable invasion of rights secured . . ."⁹⁴ By exploring the effectiveness of a vaccine during the decision-making process, a state would have the opportunity to show that the vaccine is related to the public's health and safety. As long as a state could show that the vaccine was in some way related to the public's health or safety, then the proposed vaccine program would be within *Jacobson*'s boundaries.⁹⁵

4. Vaccine Side Effects

The proposed vaccine's side effects are a consideration included in the framework because it would help satisfy the requirement that the vaccine

⁹² See, e.g., *Boone*, 217 F.Supp.2d at 943, 954 (explaining that a Hepatitis B vaccine requirement for school children was reasonable because, even though no evidence suggested that children were at grave risk of contracting it, the disease had severe consequences on the human body).

⁹³ See *Simopoulos*, 462 U.S. at 519.

⁹⁴ See *Jacobson*, 197 U.S. at 31.

⁹⁵ See *id.*

program be reasonable.⁹⁶ The Court in *Jacobson* warned that a vaccine mandate could be considered unreasonable, and thus unconstitutional, if the mandate went far beyond what was necessary to protect the public.⁹⁷ The Court specifically indicated that a state could overstep its police powers by knowingly forcing dangerous vaccines upon individuals.⁹⁸ Showing that a vaccine does not have severe or commonly-occurring side effects would help to show that the vaccine is not overzealous or irrational.

Furthermore, the inclusion of opt-out provisions would likely help to establish the reasonableness of a vaccine program. Because *Jacobson* indicated that states need to consider individual health concerns in special circumstances when mandating vaccines, opt-out provisions are an attractive option for states.⁹⁹ Opt-out provisions differ, but generally they allow for individuals to decline an otherwise mandatory vaccination if they have a specific reason (e.g., religious opposition or a special medical condition).¹⁰⁰

5. Vaccine Program Scope

The necessary scope of the proposed vaccine program is a consideration included in the framework because it would help to satisfy two of the four requirements for constitutionality. First, considering the scope of the program would help show that the state's action was narrowly tailored. As previously discussed, under a strict-scrutiny standard of review, if a state's actions infringe on an individual's fundamental rights, the state must be able to show that its actions are narrowly tailored to achieve the state's objective.¹⁰¹ Second, considering the scope of the program would help to show that the proposed vaccine program was reasonable as required in *Jacobson*.¹⁰²

Encouraging a state to explain the scope of its proposed program would help fulfill these requirements because it would allow the state to show that the vaccine program was designed to fulfill one narrow objective—to protect the health of the community by immunizing a deliberately chosen segment of the population. By explaining the rationale behind the vaccine

⁹⁶ See *id.* at 23.

⁹⁷ See *id.* at 28.

⁹⁸ See *id.* at 39.

⁹⁹ See *id.*

¹⁰⁰ Wagoner, *supra* note 4, at 428–30.

¹⁰¹ See *Zablocki v. Redhail*, 434 U.S. 374, 388 (1978).

¹⁰² See *Jacobson*, 197 U.S. at 25, 31.

program's scope, a state could show that the program only encompasses the smallest possible segment of the population.¹⁰³ As long as a state has a reasonable basis for its program's target population, the program is likely to be well within *Jacobson's* reasonableness boundaries and survive a strict-scrutiny standard of review.¹⁰⁴

IV. CONCLUSION

The current state of vaccine law is chaotic. New vaccines are arising to combat a variety of diseases, yet states sometimes struggle to deploy these vaccines efficiently. While *Jacobson* empowered states, it left states to wonder how far their power extended.¹⁰⁵ In light of an increasingly skeptical public and the Court's modern strict-scrutiny standard of review, states need guidance.

The framework proposed in this note would not extend states' powers by any means; rather, the framework would show states how to stay within the boundaries of their power. Explicitly delineating the requirements of a constitutional vaccine program would have two main benefits. First, states could more quickly decide on the propriety of a proposed vaccine program and reduce the risk of subsequent related litigation. Second, at least some of the public's concerns over vaccine mandates would be alleviated. The public would be assured that state officials were thoroughly considering the most relevant questions relating to any proposed vaccine mandate (e.g., the vaccine's effectiveness and side effects). There would also be greater transparency in the decision-making process. Currently, states sometimes impose vaccine requirements quickly and carelessly, but the framework would encourage them to thoroughly consider a variety of issues or risk having their program overturned.¹⁰⁶ Because the framework would only serve to fully delineate existing vaccine law, it would not cause a radical

¹⁰³ A vaccine program generally only needs to achieve "herd immunity" to be effective. Herd immunity is achieved when a significant portion of the at-risk population is vaccinated against a certain communicable disease. Because the disease is passed between people, when a large part of the at-risk population is vaccinated, there is a low likelihood that unvaccinated individuals will come into contact with the disease. Therefore, herd immunity protects even unvaccinated individuals. Hatch, *supra* note 3, at 201; Arthur Allen, *Bucking the Herd*, THE ATLANTIC (Sept. 2002), <http://www.theatlantic.com/magazine/archive/2002/09/bucking-the-herd/302556/>.

¹⁰⁴ See *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 279, 289, 305 (1990); *Jacobson*, 197 U.S. at 31.

¹⁰⁵ See Sanzo, *supra* note 73, at 32.

¹⁰⁶ See Wagoner, *supra* note 4, at 415.

change to the current regime; however, it would offer structure in a largely undefined area of the law.